	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING _		02/1	7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Υ	28454 L	ESS, CITY, STIVINGSTO CIA, CA 91			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES OF BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	DBE	(X5) COMPLETION DATE
D3000	must meet the applic §§493.1101 through approves a procedur quality testing as spestate Operations Ma (a) Reporting of SAR the Public Health Em 400.200 of this chapt performs a test that is SARS-CoV-2 or to di COVID-19 (hereinafte "SARS-CoV-2 test") I test results to the Semanner, and at such the Secretary may promissed on the number deficiencies cited here the Condition for FAC was not met as mand Title 42 of the Code of Findings included:  1. The laboratory faile contamination of patienstruments, reagents for the laboratory's Contamination of patienstruments, reagents for the laboratory faile contamination of patienstruments, reagents for the laboratory faile procedures to ensure chemical, biochemical materials (See D301.2).  3. The laboratory faile procedures to ensure chemical, biochemical materials (See D301.2).	performs nonwaived to able requirements und 493.1105, unless HHS e that provides equival cified in Appendix C of mual (CMS Pub. 7). IS-CoV-2 test results Diergency, as defined in ter, each laboratory that intended to detect agnose a possible caster referred to as a must report SARS-CoV cretary in such form an timing and frequency, rescribe.  met as evidenced by: If an an an evidence of the rein, it was determined citality ADMINISTRATI lated by CLIA in Subpator Federal Regulation.  The determinant of the respective of the respective of the respective of the rein, it was determined citality ADMINISTRATI lated by CLIA in Subpator Federal Regulation.  The determinant of the respective of the	er ent f the uring § t e of /-2 d as that ON rt J of	D3000	(1 - D3003) The laboratory has an Amplico Contamination Prevention Plan (CA-SAFE 1.0, approved by Lab Director, in effect at tinspection. This plan describes the measure place to prevent contamination that include design and construction of air lock doors, environmental controls with separate HVA unidirectional sample flow, secure PCR plat use of PPE with defined gowning/degownin procedures, dedicated equipment and consteach room, aerosol-resistant pipette tips, derefrigerators/freezers to separate reagents and asceptic cleaning techniques all of worlequipment. The observation made at time of stated that the lab use of 70% ethanol did not EUA and our procedure. Based on CDC guitheletter from our corporate quality organisminimum percent ethanol required for decontamination is 60. See section D3003 for details.  (2 - D3011) The finding was the observation inspectors, of two individuals working in the time. Based on information from the BSC me are permitted to have two individuals uthood at a time due to the type of work they performing, sample tube decapping. Proced SAFE-POL-002, version 1 that was approved irector with an effective date of 22Oct2020 (v6, approved by the director on 26Feb2021 the number of individuals permitted in a BStime, as established by the manufacturer. Se D3011 for more details.  (3 - D3027) As stipulated in the contractual with the State of California, all requisition form stored at Color Genomics (CLIA #05D2081 Requisition data are retained by Color Genomer at Color Genomics (CDPH Branch L receives the confirmation of a test requisition sample by way of electronically requesting the components during the accessioning proces completed by a system-to-system communichannel between the Color Genomics IT sof system indicates that the sample is not approveded. See section D3027 for more detail	POL-019 v me of s put in d laboratory C systems, e transport, g umables in dicated in d samples, c areas and of inspection of match the delines and zation the or more in, by e BSC at one canufacturer dilizing the are ure CA-d by the lab was update in to specify C at one e section agreement ata is that is 492). Omics for 20 section agreement ata is that is 492). Section is enomics for 20 section is enomics for section is enomics oved for are s.	8Mar2021  X6) DATE
				Aloseny		11Marc	

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID ID PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D3000 | Continued from page 1 D3000 Continued From page 1 SARS-CoV-2, for at least two years (See D3027). (4 - D3041) CA-DC-SOP-003 v1 effective at the time of inspection states that patient results are retained for a 4. The laboratory failed to retain records of minimum of 3 years. As stipulated in the contractual original test reports of all patients tested for agreement with State of California, all reports are generated electronically through Color Genomics. Per their policies SARS-CoV-2, for at least two years (See D3041). and procedures. (CLIA #05D2081492), reports are retained D3003 FACILITIES D3003 for 20 years and are accessible to CDPH Branch Laboratory 8Mar2021 CFR(s): 493.1101(a)(2) for auditing purposes. In the event that a report must be amended, both the original The laboratory must be constructed, arranged, and the amended reports are retained. Original and amended and maintained to ensure contamination of versions of the reports affected by the error on 04Dec2020 have been retained. See section D3041 for more details. patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. D3003 This Standard is not met as evidenced by: Finding 1: Based on interview with the laboratory staff on The laboratory has an Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan December 8, 2020, review of policies and procedures (P/P) for Quality Management Plan describes the measures put in place to prevent and FDA EUA IFU for Perkin Elmer New contamination that included laboratory design and Coronavirus Nucleic Acid Detection Kit, random construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample review of test records covering the period from flow, secure PCR plate transport, use of PPE with 11/22/2020 to 12/08/2020, for 60 out of 60 patient defined gowning/degowning procedures, dedicated test records reviewed, it was determined that the equipment and consumables in each room, aerosolresistant pipette tips, dedicated refrigerators/freezers to laboratory failed to ensure that contamination of separate reagents and samples, and asceptic cleaning patient specimens, equipment, instruments, techniques all of work areas and equipment. The observation made at time of inspection stated that the reagents, materials, and supplies for the lab use of 70% ethanol did not match the EUA and our laboratory's COVID-19 Reverse procedure (See Section 5.7.2). Additionally, a default Transcriptase-Polymerase Chain Reaction Safety statement was included in the technical SOPS (listed in the findings) that contradicted the current (RT-PCR) was minimized. approved practice and the Laboratory Quality Management Plan (approved by the director and in effect at time of inspection (CA-QM-SOP-001 va Findings included: effective 12OCT 2020) did not provide the robust environmental prevention and decontamination 1. Decontamination Protocol initiatives outlined in the Amplicon Contamination a. During the laboratory tour at approximately The FDA EUA instructions for use of the PKI nucelic 10:00 a.m., the laboratory staff stated the use of Acid detection kit provided possible actions for preventing contamination; The decontamination 70% Ethanol to decontaminate the working area prevention instructions do not impact the performance at least twice a day for accessioning, heat characteristics of the test and it is the Laboratory inactivation, decapping of swab transport tubes Director who determines the contamination prevention

contamination prevention plan.

and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work

surface area and the instruments is not approved by the Laboratory Director and therefore not included in the

Jena).

(Festo Decapper), extraction (Chemagic 360), PCR set-up (Janus G3), and PCR (Analytik

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED IDENTIFICATION NUMBER: A. BUILDING \_ AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D3003 D3003 Continued From page 2 Continued from page 2 Based on CDC guidelines and the letter from our b. Review of the laboratory's policies and corporate quality organization the minimum percent ethanol required for decontamination is 60. procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date (1) Immediate Corrective Action: Updated all technical protocols to reflect the current disinfectant in use, 70% Ethanol and 11/01/2020) stated only the temperature and humidity monitoring for environmental and safety remove the (See Attachment X for list of documents, approval date). AS 70% was already monitoring. The laboratory failed to have written the disinfectant used in the lab, re-training was protocols to ensure the performance, frequency, not required. and documentation of environmental Updated the Quality Management Plan (CA-OM SOP-001, Sections 6.3.4.7, 6.5.1, 6.8.1, decontamination. approved by Lab Director and effective 01Mar2021) to reflect contamination prevention c. Review of the laboratory's policies and and monitoring that is in place, following current Amplicon Contamination Prevention Plan procedures for accessioning, heat inactivation, (SAFE-POL-019., v1.1, approved by Lab Director and effective 14Dec202). Staff were decapping, sample transfer, extraction, and PCR ( Policy # CA-ACC-SOP-001, Title: Accessioning assigned to read and acknowledge the changes to this document. for SARS-CoV-2 Samples, Effective Date 12/05/2020; CA-EXT-SOP-001, Title: Heat (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or Inactivation of Viral Swab Samples, Effective recommended patient action (retesting), and there would not be patient harm. Appropriate quality control reactions are helpful in determining Date 11/18/2020; CA-EXT-SOP-002, Title: Decapping and Batch Preparation for Janus G3. whether contamination has occurred. A patient Effective Date 12/03/2020; CA-EXT-SOP-003, lookback (from 28OCT2020 to 08DEC2020) and a Title: Sample Transfer Using the Janus G3, patient lookforward (09DEC2020 to 28FEB2021) was conducted to review all positive and negative Effective Date 12/06/2020; CA-EXT-SOP-004, controls to look for the presence of viral targets that could indicate contamination. There was no Title: Viral RNA DNA Extraction Using the Chemagic 360-D, Effective Date 11/03/2020) evidence of contamination as values were well below 2% threshold. (See Attachment 1) The trend stated under Section 6.0 Occupational Health and downward noted is due to a software change Safety that, "while little is known about this novel allowing for color compensation and better virus, the comparable genetic characteristic with resolution and not attributable to EtOH or % of EtOH used. Per Dr. Rosendorff, the current Lab SARS-CoV and MERS-CoV suggest that Director, there is no contamination of patient 2019-nCoV may likely be susceptible to samples or test results. disinfectants including Sodium Hypochlorite for (3)Preventative measure: Not applicable as no general surface disinfection, 75% ethanol, 0.5% evidence of contamination has been found Hydrogen Peroxide, Quarternary Ammonium, and (4)Monitoring mechanism: The sign out manager is Phenolic compounds, if used according to actively monitoring positive and negative controls and manufacturer's recommendations. VTM the laboratory supervisors are conduct weekly Contamination Wipe Tests. There has been no containing Guanidine may produce cyanide with evidence of contamination on the instruments, work bleach, therefore not recommended as cleaning areas, lab instrumentation, equipment, and computers (See Attachment 1 for examples of last 4 Wipe tests). agents in CDPH Branch Lab." (1) The laboratory's procedure failed to specify

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/\$UPPLIER/\$LIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE **VALENCIA, CA 91355** SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION PRÉFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D3003 D3003 Continued From page 3 Appendix A: The Quality Management Plan has been which disinfectant is being used at the CDPH revised and reorganized to consolidated information about existing laboratory processes (CA-QM-SOP-001 ver 2.0 effective 01Mar2021). Branch Lab. (2) At the time of the on-site survey on See Attachment 1. December 8, and 9, 2020, the laboratory was Summary: The laboratory has a plan for Amplicon using Molecular Transport Media (MTM), not Contamination Prevention Plan (see CA-SAFE-POL-019). The use of 70% EtOH meets the standard set Viral Transport Media (VTM). The laboratory was by CDC. Heat inactivation is an effective method to also using 70% ethanol as a disinfectant, and not inactivate SARS-CoV-2. Disposal of MTM sample collection tubes that have been subjected to heat any of the disinfectants (75% ethanol, 0.5% inactivation in bleach is not necessary. Therefore, the area in which the samples were handled was adequately Hydrogen Peroxide, Quaternary ammonium, and Phenolic compounds) specified in its procedure. decontaminated. (3) The laboratory failed to provide documentation and written protocol to ensure that 70% ethanol was sufficient to minimize environmental contamination. d. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021 for version 7.0) stated under Warnings and Precautions #10 that, "Sterile centrifuge tubes and filter-tips should be disposed into a waste bin containing a 10% Sodium Hypochlorite solution. After the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared 10% Sodium Hypochlorite solution, and then cleaned with 75% Ethanol or pure water. Finally, turn on UV light to disinfect working surfaces for 30 minutes." (1) The laboratory failed to utilize waste bin containing a 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. The laboratory failed to specify what was being used if it was not using 10% Sodium Hypochlorite.

STATEMENT OF DEFICIENCIES		(X1) PROVIDER/SUPPLIER/O		1	PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
AND PLAN	D PLAN OF CORRECTION IDENTIFICATIONNUMBER:		CK.	A. Bulchino		COMPLETED	
		05D21974	16	B. WING	02/17/2021		
	ROVIDER OR SUPPLIER				ATE, ZIP CODE		
CDPH BI	RANCH LABORATOR	Y		VINGSTO			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE COMPLETION	
D3003	(2) The laboratory fai protocol for work area disinfectants, and the 2. Decontamination Testing Process  a. During the labora 2020 at approximately was observed to have Solution in dispensing expiration date. (1) Lot # 267015, Exp dispensing bottles) (2) Lot # A100120021 12/07/2020 (2 dispensing bottles) b. Review of the lat procedures (Policy # Quality Management 11/01/2020) stated the should be used in testindicated expiration of 3. The following are the 60 randomly reviecovering the period fr 12/08/2020, wherein SARS-CoV-2 tests at failed to ensure contains.	led to provide written a, and instrument surface use of UV light.  I Solution in the story tour on December 10: 30 a.m., the laborate bottles beyond its biration Date: 12/03/20/3, Expiration Date: sing bottles)  Doratory's policies and CA-QM-SOP-001, Title Plan, Effective Date at reagents and chemicating process within the ate.  In the accession number ate.  In the accession number ate at the accession number ate.  In the the accession number ate at reagents and chemicate at the accession number ate.  In the accession number ate at the accession number ate at the accession number ate, and reported results, but amination of patient at, instruments, reagents.	er 8, atory aning 20 (2 ec. cals ein ers of ds ed t	D3003	Finding 2,3,4,5:  We acknowledge the failure to discard some thanol reagent bottles that were in use pass expiration; 2 bottles 5 days past expiration; at 1 day past expiration date.  (1) Immediate Corrective Action:  • The bottles were discarded and fresh made available. Walkthrough conduct supervisory teams ensuring that all of were labelled appropriately and in dat the policies and procedures outlined Management Plan (CA-QM-SOP-00).  • A new SOP, Labeling of Reagents and (CA-LABGEN-SOP-002) was approven Lab Director with an effective date of 09DEC2021 and assigned to all techns.  (2) Patient Impact: A lookback review of all performed on specimens received from 01D 12DEC 2020 was conducted and there was not contamination of patient samples as a resexpired 70% ethanol. See QC report in Attact The power point shows the negative control data with the specified time frame and indice percentage of possible negative contamination to patient results reporting during this time.  (3) Preventative measure:  • An audit, specific to compliance with logs and reagent labeling and expiration (2021AUDIT-005) carried out 26Feb been reported to Managers and Super Response is expected by15Mar2021 fc corrective actions and future preventactions.  • Supervisor daily checklists (implement first week of March 2021) utilized in shandoff communications include a dreagents in their respective areas to incompliance with labeling and expiration An example of several completed cheincluded in Attachment 2.  (4) Monitoring mechanism: In addition to supervisor review of reagents, a monthly wa audit conducted by Quality Dept has been a 2021 Audit Schedule.	ethanol was ted by the her reagents te to reflect the Quality  Solutions ed by the ologists.  I QC EC2020 to to evidence ult of the thment 2. analyzed ates on (but not boratory ion impact period.  equipment on 2021 has visors. or any attive  thed the shift to shift tily check of sure on dates. cklists are  the daily lkthrough	

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING \_ AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING \_ 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) 1D SUMMARY STATEMENT OF DEFICIENCIES PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D3003 Continued From page 5 D3003 Continued from page 5 Supporting Documentation: a.Read notification of CA-LABGEN-SOP-002 approved by Lab Director and in effect 09Dec2020. b.Supervisor Daily Checklists (example of in use) - See CAP response document of completed checklists. c.2021 Audit Schedule d.2021Audit-005 Report (first page) e.CA-LABGEN-SOP-002 Labeling of Reagent and Solutions See Attachment 2 and Attachment 1. Summary Statement for Deficiency D3003, D5415, D5417, D5433 and D6093: In summary, expired reagents, such as the 70% EtOH, were only expired by a few days. Since the main concern of aging EtOH is evaporation and CDC states over 60% EtOH is effective, the risk posed is low, and negative controls on testing during this time did not indicated contamination. 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized. D3011 8Mar2021 D3011 FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WNG		02/17/2021		
NAME OF PE	OVIDER OR SUPPLIER		STREET ADDRE	DRESS, CITY, STATE, ZIP CODE				
CDPH BE	ANCH LABORATOR	γ	28454 LI	VINGSTO	NAVE			
	VAL		VALENC	IA, CA 913	355			
(X4) ID	SUMMARY ST	TATEMENT OF DEFICIENCIES	5	ID	PROVIDER'S PLAN OF CORRECTION	ON (X	5)	
PRÉFIX TAG		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)			
D3011	. 0			D3011	Findings 1-6:			
	from physical, chemical, biochemical, and							
	electrical hazards, and biohazardous materials.				The Biosafety hoods provide secondary con	tainment		
	This Standard is not i	met as evidenced by:	1		controls and ventilation controls that only			
		ith laboratory staff on			operation and improve the safety of the dec			
	December 8, 2020, re				operation. The laboratory contacted NuAir manufacturer of the BSL2 hoods used onsit			
		General Facilities Safe	•		confirmed there should be no operational p			
		of test records covering			having 2 personnel working in one cabinet	at any given		
		/2020 to 12/08/2020, for			time.			
		records reviewed, it wa aboratory failed to obse			To all alterior monet de diter als e case els ed de como	4.4:		
		ensure protection from			In the link provided in the attached docum- will see that if the two cabinet operators are			
	physical, chemical, b				with different types of work (dirty and clear			
	biohazardous materia				would be an issue. However, in this situation	n, the two		
			-		personnel would be performing the exact sa	me process		
	Findings included:		1		with the same reagents and materials.			
					(1) Immediate Corrective Action: The CA			
		atory tour on Decembe			POL-002 document was updated to reflect current version is 6 which was approved by			
		y 11.00 a.m., the labor	atory		Director on 26Feb2021.			
		ID-19 sample transfer			(2) Patient Impact: Per Lab Director Dr. R	osendorff.		
		by one testing person			there is no change in diagnosis, treatment,			
		Biosafety Cabinet (BSC naterials contaminated			recommended patient action (retesting), an			
		inated with infectious o			would not be patient harm. The BSC manu confirmed that safety specifications to allow			
		als and for maintaining			individuals to decap in BSC for this assay.	two		
	sterility of the materia				(3) Preventative Measures: None			
	2. During the labora	atory tour on December	g		(4) Monitoring Mechanism: None			
		was observed with two	-,		See Attachment 3			
	- · · · · · · · · · · · · · · · · · · ·	working in one Biosafe	etv					
	Cabinet.	•						
		boratory's policies and	itla					
		CA-SAFE-POL-002, To fety Plan, Effective Dat						
		indicate the number of						
		who can utilize one BS						
		nimize contamination.	•					
	S. Out o Salvey and III							
	4. The following are	the accession number	s of					
		ewed patient test record						

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING \_ IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING \_ 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION (X4) ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D3011 Continued From page7 D3011 covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. Accession Number 5. Based on the laboratory's annual testing

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		1	(X2) MULTIPLE CONSTRUCTION  A. BUILDING COMPL			
ANDIBUN	SI GORREOTION	DENTI ICATIONNOMBI	LIN.	A. GGEDING		COMPLET	EU	
		05D21974	16	B. WNG	B. WING		7/2021	
	ROVIDER OR SUPPLIER				ATE, ZIP CODE			
CDPH BI	RANCH LABORATOR	Υ		LIVINGSTO ICIA, CA 91				
						NA .	(X5)	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL!	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		
D3011	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 until 6. The Laboratory I 12, 2021 at approxim	the laboratory director ratory reported 00 SARS-CoV-2 test re 12/16/2020. Director affirmed (Februately 2:00 pm) the serve safety procedure m physical, chemical,	uary	D3011				
D3027	RETENTION REQUICER(s): 493.1105(a)d Test requisitions and records of test requisauthorizations, included medical record if use authorization, for at lest the standard is not a Based on interviews with director on December test requisitions, and records covering the 12/08/2020, for 10 our eviewed, it was deterfailed to retain record SARS-CoV-2 patient Findings included:  1. The laboratory properties of the samples under the laboratory of direct detection of SA patient samples under the laboratory of the laborato	authorizations. Retain itions and test ing the patient's chart of as the test requisition east 2 years. The staff and the laborar is a 2020, the absence random review of test period from 11/22/2020 at of 10 patient test recommend that the laborat is of test requisitions for testing.  The staff and the staff and the laborar is a 2020, the absence random review of test period from 11/22/2020 at of 10 patient test recommend that the laboration is of test requisitions for testing.  The staff and the staff and the staff are the order of the Staff are the order of the Staff are the order of the Staff are the order patients with the staff and the staff are the order of the order of the Staff are the order of the order o	tory of  toto ords ory r  the	D3027	Per contractual agreement between CHHS a Branch Laboratory, all information is collect electronic requisition form that is stored at Genomics (CLIA #05D2081492) at established collection sites D5311). Data needed for testing is transferre Branch Laboratory. Requisition data are reta Color Genomics for 20 years per their polici procedures. These documents are accessible Branch Laboratory for auditing purposes.  (1) Immediate Corrective Action: None  (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient h  (3) Preventative Measures: None  (4) Monitoring Mechanism: Monthly aud 2021 to determine availability and complian required elements are performed by the qua organization. The availability of the requisiti report was confirmed for 10 samples via a retracer audit performed 26Feb2021.  See attachment 4 and attachment 5	ed on the Color  (see do to CDPH sined by es and to CDPH  arm.  lits for FY ce with all lity on and	8Mar2021	

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPP IDENTIFICATION			(X2) MULTIPLE CONSTRUCTION  A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING	02/17/2021		
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		ESS, CITY, ST.	N AVE		
(X4) ID PREFIX TAG	SUMMARY S (EACH DEFICIENCY MUS OR LSC ID:		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE COMPLETION DATE		
D3027	generate a test requi  3. During the initial California clinical laboratest requisition that wis only one of the sexprior to receiving a late 10/20/2020, the laborated ditled, "The Sample Requisition that will be not been generating patient.  4. There was no matest requisition was There was also no matest requisitions were retained to read the sample for the sampl	stages of its application oratory license, we tory to submit an example used. A test requirements to be boratory license. On ratory submitted a rest Order Requisition—on- Example Only v.3." It is submitted an example used, the laboratory is a test requisition for each echanism in place to each guernalism to ensure the ained by the laboratory. It is the accession numbers were patient test recordered.	Covid Even e nad nch ensure attest ers of ds ed failed	D3027	The CDPH Branch Laboratory reconfirmation of a test requisition for ea way of electronically requesting the data conduring the accessioning process. This is consystem-to-system communication channel Color Genomics IT software system and the Branch Laboratory's LIMS software system that a test requisition is not available the rest the Color Genomics system indicates that the not approved for processing and no collecting are provided. The Color API for Exter [External] document outlines the process for transmission and the data fields exchanged.  (1) Immediate Corrective Action: Non.  (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient I.  (3) Preventative Measures: None.  (4) Monitoring Mechanism: Monthly a FY 2021 to determine availability and compatity organization. The availability of the requisition and report was confirmed for 10 via a routine tracer audit performed 26Feb2 audit (2021Audit-008) of an additional 25 s was initiated 11MAR2021 to verify that require are available and include all necessary requirelements.  See attachment 4 and attachment 5	ch sample by mponents mpleted by a between the e CDPH. In the event sponse from the sample is on date and nal Labs or data.  e   the control of the cont	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(XI) PROVIDER/SUPPLIENCLIA		1 ' '	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17/	2021	
NAME OF PR	ROVIDER OR SUPPLIER		STREET ADDR	ADDRESS, CITY, STATE, ZIP CODE				
CDPH BF	RANCH LABORATOR	Y		VINGSTO				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROPRIEM DEFICIENCY)	(X5) COMPLETION DATE		
D3027	6. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 7. The laboratory diaffirmed December 8 11:00 a.m. that the la records of test reques RETENTION REQUI CFR(s): 493.1105(a)	poratory's annual testing the laboratory director ratory reported 00 SARS-CoV-2 test resector and testing person, 2020 at approximately boratory failed to retain sts.  REMENTS (6)	onnel	D3027	Findings 1-7  CA-DC-SOP-003 v1 effective at the time of in states that patient results are retained for a min 3 years. As stipulated in the contractual agrees that of California all reports are generated all reports.	nimum of ment with	8Mar2021	
	of the original report and corrected reports date of reporting.  (i) In addition, retain in as specified in 21 CF  (ii) and pathology test after the date of reporthis Standard is not a Based on email complete after the date of reports acovering the period for 12/04/2020, for 10 or reviewed, it was deter failed to retain record SARS-CoV-2 patient.  Findings included:  1. The laboratory process and generated through Comparison of SA patient samples, and generated through Comparison.	treports for at least 10 yrting. met as evidenced by: munication with the 12/24/2020, the absen- and review of test recor- from 12/02/2020 to ut of 10 patient test recor- mined that the laborate as of original test report testing.  erformed SARS-CoV-2 eveloped test (LDT) for uRS-CoV-2 virus RNA for	nary, the orts years  ce of rds ords ords orry s for		State of California, all reports are generated el through Color Genomics. Per their policies ar procedures. (CLIA #05D2081492), reports are for 20 years and are accessible to CDPH Bran Laboratory for auditing purposes.  In the event that a report must be amended, be original and the amended reports are retained and amended versions of the reports affected on 04Dec2020 have been retained.  Confirmed through 3 external audits that ALI that have been amended have an accessible or amended report.  (1) Immediate Corrective Action: None  (2) Patient Impact: Per Lab Director Dr. Rost there is no change in diagnosis, treatment, or recommended patient action (retesting), and not be patient harm as the amended reports a reports are retained.  (3) Preventative Measures: None  (4) Monitoring Mechanism: Audit of ALL A Reports to ensure compliance with SOP (avaioriginal report, original results included on the Report, and confirmation of Amended Repornotification to client and/or patient is incorporthe 2021 Audit Schedule as a monthly audit a performed by the quality organization.  See attachment 5.	oth the l. Original by the error  L results iginal and  sendorff, there would nd original  amended lability of the Amended torated into		

	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CL IDENTIFICATIONNUMBER			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416		16	B. WING		02/1	7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		SS, CITY, ST.	N AVE		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D3041	SARS-CoV-2 but shot laboratory process end.  3. CDPH Branch la Laboratory about the which amended report 12/07/2020.  4. CDPH Branch Latthe test results for SA provide the original to 12/04/2020 and amended the 10 reviewed patient the period from 12/02 wherein the laborator tests and reported resident in the second content of the second content in th	build have been invalid of the ror on 12/04/2020.  boratory informed Color test results reported in the rts were issued on aboratory has access with ARS-CoV-2 but failed to est results reported on anded on 12/07/2020.  The the accession number of the results records covering the results records covering the results records covering the records and the records covering the records and the records covering the records and the records are records are records and the records are records are records and the records are records are records are records are records and the records are records.	error ith or ers of	D3041			
	declaration signed by 12/16/2020, the labor	00 SARS-CoV-2 test res	ron				
	2021 at approximatel	irector affirmed (Februa y 2:00 pm) that the tain records of original			d.		

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/C			1	PLE CONSTRUCTION  G	(X3) DATE SUP COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		ESS, CITY, ST. IVINGSTOI CIA, CA 91:	N AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D3041	Continued From pag	je 12		D3041	<u>D5300</u>		
D5300	reports.			D5300	CDPH Branch Laboratory receives all samp Testing Task Force collection sites. These sit registered with Color Genomics and operate standing order from Dr. Erica Pan, Acting S Officer, State Epidemiologist, Deputy Direct for Infectious Disease, CDPH.	es are under a tate Health	8Mar2021
					(5301/5305/5313) All data, including collect collection time, are collected on the electron form that is stored at Color Genomics (CLIz #05D2081492). All CLIA required requisitionare included in the electronic requisition. Redata are retained by Color Genomics for 20 their policies and procedures. These documaccessible to CDPH Branch Laboratory for a purposes. Manual paper requisition forms a for use in extreme emergent priority as requived CHHS and documented as deviation from suprocedure.  See section 5301, 5305, 5313 for more detail.		
8					(5311) During the initial planning and exect Valencia Branch Laboratory (VBL) project team provided feedback to the state of Calific collection process and media. Specifically, the outlined the process for administering the n sample, the contents of the collection kit, pa infectious agents' identification (UN3373) lat room temperature, and shipping timeline information was then collated into the Testi Playbook and the processes at the collection laboratory procedure CA-CLSRV-SOP-002.	ution of the he laboratory ornia on the he team asal swab ckaging, abel, storage . This ng Taskforce site and	
					Color Genomics provides COVID-19 testing own laboratory. References to their corporal collection materials is specific to their laborate Genomics is contracted by CDPH Branch Laprovide kits that are comprised of a sample tube prefilled with MTM and barcoded with identifiers, one collection card for the patier matching barcode, and an absorbent pad. A tested to date were collected in Color collect containing MTM.  Procedure CA-CLSRV-SOP-002 specifies us Procedure CA-ACC-ACC-001 incorrectly used.	te site atory. Color aboratory to collection at two at the with a all samples ion kits	
	the date and time of	ed to ensure it docume	69		(viral transport media) as a generic term. The corrected to MTM; however, the rejection of procedure are sufficient since samples sent of Color system are "Not Approved".  See section 5311 for more details.	riteria in the	

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:				PLE CONSTRUCTION  G	(X3) DATE SUI COMPLET	
		05D21974	16	B. WING 02/1			7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Υ		ESS, CITY, ST VINGSTOI IIA, CA 91:	N AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	.DBE	(X5) COMPLETION DATE
D5301	5. The laboratory fail written policies and prechanism to monitor indicated, correct propreanalytic system (STEST REQUEST CFR(s): 493.1241(a)  The laboratory must request for patient temperson.  This Standard is not Based on interviews the laboratory direct absence of written profor retaining test requirequisitions for each review of test records 11/02/2020 to 12/08/2 test records reviewed laboratory failed to refor SARS-CoV-2 patients amples under the state from the State that the state are test required.  3. During the initial	ed to ensure it establis procedures for an ongo or, assess, and when oblems identified in the See D5391).  have a written or electricating from an authorized met as evidenced by: with testing personnel or on December 8, 202 olicies and procedures uisitions, the absence of patient tested, and range covering the period from 2020, for 10 out of 10 pad, it was determined the etain records of test records.	and 0, the (P/P) of test dom on atient at the juests	D5301	Continued from page 13 (5391) The lab acknowledges that its written procedure to monitor, assess, and when indica correct problems identified were not clearly doverall plan and were scattered throughout m In acknowledgement of this observation, the I completed a major revision of its Quality Mar Plan (CA-QM-SOP-001, v2), approved by the and effective as of 01MAR2021. Refer to the Section 5.5.1 for specific preanalytical measur assessed at CDPH Branch Laboratory. Refer to Inspecific preanalytical measur assessed at CDPH Branch Laboratory. Refer to Improvement and Occurrence Management 6.5 for Process Management of all 3 of the phatesting (preanalytical, analytical and post analydication, a new SOP, PreAnalytical QA Proces SOP-003 v1, approved by Lab Director on 24 created to define the procedural guidelines for sample tracking for quality assurance purpose for specific details.  D5301 Findings 1-3, 5-7 Per contractual agreement with CHHS and CBranch Laboratory, all information is collecte electronic requisition form at established colleoperating under the standing order from Dr. Requisition form information is stored at Col (CLIA #05D2081492; see D5311). Deata neede is transferred to CDPH Branch Laboratory. Radata are retained by Color Genomics for 20 yepolicies and procedures. These documents are to CDPH Branch Laboratory for auditing pur (1) Immediate Corrective Action: CA-C SOP-002 was updated on 11Mar2021 to refl acceptance of Dr. Pan's standing order. Also QMP (CA-QMP-SOP-001 v2, approved by on 01MAR2021), Section 5.5.1.1 outlining test order management and the use of a stan from Dr. Pan, as stipulated by CHHS. Refer A.  (2) Patient Impact: Per Lab Director Dr. there is no change in diagnosis, treatment, or recommended patient action (retesting), and would not be patient harm.  (3) Preventative Measures: None (4) Monitoring Mechanism: Monthly au 2021 to determine availability and complian required elements are performed by the quaiorganization. The available and include all neorgenisations are available and	efined in an ultiple SOPs. aboratory taggement to Lab Director Appendix A, e that are to Sections 6.1 Continuous and Section asses of lab yitical). In ss (CA-ACC-FEB2021 was internal to section sites Pan. To Genomics of or Genomics of or Genomics of for testing equisition ears per their e accessible poses. CLSRV-lect the tupdated Lab Director he process of ding order to Appendix Rosendorff, or their edits for FY ce with all lity on was raudit -008) of an that	8Mar2021

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI			PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED		
	05D2197416		16	B. WING		02/1	7/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE			
CDPH BF	RANCH LABORATOR	Y		IVINGSTOI CIA, CA 91:				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY  OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL	PROVIDER'S PLAN OF CORRECTION ACH CORRECTIVE ACTION SHOULD BE. SS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		
D5301	laboratory to submit a that will be used. A to the several requirement receiving a laboratory the laboratory submit "Test Order Requisiting Requisition- Example laboratory submitted will be used, the laboratory submitted will be used, the laboratory fapolicy on the use of some mechanism in place requisition was generated.  The following are the 10 randomly review to remain the period from 12/08/2020, wherein SARS-CoV-2 tests as	an example test requisitest requisition is only or ents to be met, prior to be license. On 10/20/2020 ted a documented titler on Covid 19 Sample of Only v.3." Even though an example requisition ratory had not been uisition for each patient alled to provide a writtent tanding orders. There are to ensure a test rated for each patient.	ne of 20, d, h the that t. n was	D5301	The CDPH Branch Laboratory receives the confirmation of a test requisition from regicollection sites operating under Dr. Pan's significant or each sample by electronically requive data components during the accessioning pris completed by a system-to-system communicational between the Color Genomics IT so system and the CDPH Branch Laboratory's software system. In the event that a test requot available the response from the Color Cosystem indicates that the sample is not approprocessing and no collection date and time provided. The Color API for External Labs document outlines the process for data transand the data fields exchanged.  (1) Immediate Corrective Action:  (2) Patient Impact: Per Lab Director Rosendorff, there is no change in diagnosis or recommended patient action (retesting), and there would not be patient  (3) Preventative Measures: None  (4) Monitoring Mechanism: Monthly FY 2021 to determine availability and cowith all required elements are performed borganization. The availability of the requisition confirmed for 10 samples via a routine trace performed 26Feb2021. An audit of an addit samples was initiated on 11Mar2021. (see 2021AuditPlan-008)  Reference attachment 4 and attachment 5	stered tanding desting the process. This inication of the process. This inication of the process		
	declaration signed by 12/16/2020, the labor	0 SARS-CoV-2 test res	on					

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING \_\_ COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION DATE (X4) ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACHCORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5301 D5301 Continued From page 15 7. The laboratory director and testing personnel affirmed (December 8, 2020 at approximately 11:00 a.m.) that the laboratory did not have test requisitions for each patient or policies to address standing orders. D5305 TEST REQUEST D5305 8Mar2021 Findings 1-6 CFR(s): 493.1241(c) All information, including Dr. Pan's information as the The laboratory must ensure the test requisition ordering provider, is collected on the electronic solicits the following information: requisition form that is stored at Color Genomics (CLIA #05D2081492) at established collection sites (see (1) The name and address or other suitable D5311). Manual paper requisition forms are available identifiers of the authorized person requesting the for use in extreme emergent priority as requested by test and, if appropriate, the individual responsible CHHS and documented as deviation from standard for using the test results, or the name and procedure. Data needed for testing is transferred to address of the laboratory submitting the CDPH Branch Laboratory. Requisition data are retained by Color Genomics for 20 years per their policies and specimen, including, as applicable, a contact procedures. These documents are accessible to CDPH person to enable the reporting of imminently life Branch Laboratory for auditing purposes. threatening laboratory results or panic or alert values. The inspectors observed paper manifests (finding 2) (2) The patient's name or unique patient identifier. accompanying the specimens. These are the shipping (3) The sex and age or date of birth of the patient. manifests from the collection sites and are date/time (4) The test(s) to be performed. stamped at receipt and are recorded into the electronic Specimen Delivery Logs (CA-ACC-SOP-004 Day Shift (5) The source of the specimen, and CA-ACC-SOP-005 Night Shift) from the computers when appropriate. located near the receiving area. Specimen count, time (6) The date and, if appropriate, time of specimen received, sending facility, verification of manifest, collection. courier company, name of the Driver and any (7) For Pap smears, the patient's last menstrual discrepancies are noted (cancelled specimens, period, and indication of whether the patient had unacceptable specimens). The shipping manifests are a previous abnormal report, treatment, or biopsy. scanned electronically, emailed to the Operations Manager who stores the reports. All manifests are (8) Any additional information relevant and available for audit. The SOPS mentioned above are listed necessary for a specific test to ensure accurate in Attachment 5. and timely testing and reporting of results, including interpretation, if applicable. This Standard is not met as evidenced by: Based on interviews with laboratory staff and the laboratory director on December 8, 2020, the absence of written policies and procedures (P/P) for ensuring test requisitions solicited required

information, the absence of test requisitions for

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/O IDENTIFICATION NUMBER		LIA .		PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WNG		02/17/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST IVINGSTO CIA, CA 91:		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	DBE COMPLETION
D5305	each patient tested, a records covering the 12/08/2020, for 10 or reviewed, it was dete failed to ensure test in necessary informatio test results for COVII Transcriptase-Polyme (RT-PCR).  Findings included:  1. The laboratory undiagnostic laboratory undiagnostic laboratory undiagnostic laboratory direct detection of SA patient samples. It untisolation of the viral in RT-PCR assay on Arrow 2. During the laborate approximately 10:00 stated that CDPH Brawith another CLIA ce healthcare providers patients diagnosed winfections. It was obspatient sample was of indicating the total nureceived, site point of company number, concollected, site name as 3. The laboratory farequisitions for each which included informand address of the authe test, patient's namage, date of birth, test of specimen, date and address of specimen, date and approximately specimen approxima	and random review of to period from 11/22/2020 at of 10 patient test recommined that the laborate requisitions included in for accurate reporting 0-19 Reverse erase Chain Reaction at lilized SARS-CoV-2 RT developed test (LDT) for accurate reporting 0-19 Reverse erase Chain Reaction at lilizes Chemagic 360 for accurate rolling accurate reporting 0-19 reveal that laboratory states the laboratory to help in ordering the test for a lilizes chemagic 360 for accurate reporting the test for a lilizes chemagic 360 for accurate reporting the test for a lilizes chemagic 360 for accurate reporting the test for a lilizes chemagic 360 for accurate reporting the test for a lilizes chemagic 360 for accurate reporting the test for a lilizes chemagic 360 for accurate reporting the test for a lilizes and a lilizes accurate reporting the test for accurate reporting the reporting t	o to ords orly of ords orly of ords orly of ords orly of ords orly ords orly ords or the ords ords ords ords ords ords ords ords	D5305	Continued from page 16 (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dr. Ros there is no change in diagnosis, treatment, or recommended patient action (retesting), and not be patient harm. (3) Preventative Measures: None (4) Monitoring Mechanism: Monthly audits to determine availability and compliance with elements are performed by the quality organisms. See attachment 5	there would for FY 2021 all required

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5) (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRÉCEDED BY FULL REGULATORY PREFIX (EACHCORRECTIVEACTION SHOULD BE PREFIX OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) Continued From page 17 D5305 to ensure accurate and timely testing and reporting of results. 4. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, but failed to provide test requisitions which included information necessary for accurate test result reporting. Accession Number Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. The laboratory director and testing personnel affirmed December 8, 2020 at approximately 11:00 am, that the laboratory did not have test requisitions which included necessary information for accurate test results reporting. D5311 D5311 SPECIMEN SUBMISSION, HANDLING, AND 8Mar2021 REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written

	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/O			PLE CONSTRUCTION	(X3) DATE SU	
AND PLAN C	F CORRECTION	IDENTIFICATION NUMBI	ER:	A. BUILDIN	G	COMPLET	ED
		05D21974	16	B. WING		02/1	7/2021
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Y	28454 L	IVINGSTO	N AVE		
			VALENC	CIA, CA 91	355		
(X4) ID		TATEMENT OF DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTION		(X5)
PREFIX TAG		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)		COMPLETION DATE
D5311	Continued From pag	e 18		D5311	Findings 1-6		
	policies and procedur	res for each of the follo	wing,				
	if applicable:				Instruction for collection:		
	(1) Patient preparatio				During the initial planning and execution of t	he Valencia	
	(2) Specimen collection				Branch Laboratory (VBL) project the laborator		
		, including patient nam			provided feedback to the state of California or collection process and media. Specifically, the		
		ier and, when appropr	iate,		outlined the process for administering the nas		
	specimen source.				sample, the contents of the collection kit, pack		
	(4) Specimen storage	-			infectious agents identification		
	(5) Conditions for spe	*			(UN3373) label, storage at room temperature		
	(6) Specimen process				shipping timeline. This information was then the Testing Taskforce Playbook and the proce	collated into	
	<ul><li>(7) Specimen accepta</li><li>(8) Specimen referral</li></ul>				collection site and laboratory procedure CA-0		
	This Standard is not				SOP-002.		
		with laboratory staff on					
	December 8, 2020, re				Instructions for obtaining sample kits (via Co		
	procedures (P/P) for				for CDPH Branch Laboratory), collection an		
		, and random review o	ftest		samples is provided to collection sites set up b Task Force. See attached and website below.	by the Testing	
		period from 11/02/2020			Task Porce. See attached and website below.		
		it of 10 patient test rec			Specimen collection (D5311 and D5403 parts	c. e. and f).	
		rmined that the laborat			operation consector (20011 and 20100 parts	0, 0, 4114 1/1	
	failed to ensure that v		-		Please note, Color Genomics provides COVII	D-19 testing	
	procedures for specin				through its own laboratory. Color assembles a	and	
	handling were followed	ed.			distributes collection kits on the processes and		
					developed in their laboratory. These activities		
	Findings included:				completely separate from the CDPH Branch I activities and have no bearing on the CDPH I		
					Therefore, it is inappropriate to compare info		
		ilized SARS-CoV-2RT			the Color website with procedures at the CDI		
		developed test (LDT) f			Laboratory.		
		RS-CoV-2 virus RNA 1			As it relates to testing that occurs at the Valen	ojo Dromah	
		lizes Chemagic 360 fo			Laboratory (VBL) the state of California has c		
	isolation of the viral n	ucleic acids followed b	y the		for two purposes: sample kit distribution and		
	KI-PUK assay on An	alytik Jena Thermal C	voler.		operations.	Ü	
	2 Pavious of the lab	oraton/e policice and			Color Genomics is contracted by CDPH Bran		
		coratory's policies and CA-CLSRV-SOP-002,	Title:		Laboratory to provide kits that are comprised collection tube prefilled with MTM and barco		
		Storage, and Shipping			two identifiers, one collection card for the pat		
	Effective Date 12/07/2		,		matching barcode, and an absorbent pad.		
		estructions for collection	1				
		ng are provided to the	,		See attachment 6		
		th a third-party vendor.	Α				
	specimen that is	,					

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATIONNUMBER: 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID COMPLETION (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PRÉFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5311 D5311 Continued From page 19 Continued from page 19 not collected correctly will lead to inaccurate Sample kits not intended for the CDPH Branch results." Laboratory are not tested. All samples tested to date were collected in Color The laboratory failed to provide the instructions collection kits containing MTM (see MTM Attestation provided to all staff in the collection sites for their Letter from Color; Purchase order from PrimeStore procurement process. Procedure CA-CLSRV-SOP-002 specifies use of MTM. a. Correct specimen collection using Procedure CA-ACC-ACC-001 incorrectly used VTM the appropriate technique and (viral transport media) as a generic term. This has been containers corrected to MTM (molecular transport media); however, the rejection criteria in the procedure are sufficient since samples sent outside of the Color b. Specimen labeling, including patient name or system are "Not Approved" and section 8.3.3 would be unique identifier, and specimen source followed. Finding 5 c. Proper storage and preservation The lab acknowledges that its written policies and d. Proper transportation procedure to monitor, assess, and when indicated, to correct problems identified were not clearly defined in an overall plan and were scattered throughout multiple e. Specimen acceptability, rejection SOPs. In acknowledgement of this observation, the and disposition laboratory completed a major revision of its Quality Management Plan (CA-QM-SOP-001, v2), approved 3. During the laboratory tour on 12/08/2020 at by the Lab Director and effective as of 01MAR2021. approximately 11:00 a.m., the laboratory staff Refer to the Appendix A, Section 5.5.1 for specific stated that they only process samples collected preanalytical measure that are assessed at CDPH Branch Laboratory. Refer to Sections 6.1 for in Molecular Transport Media (MTM), transported Leadership Oversight and Section 6.4 for Continuous at room temperature, and stable for seven days. Improvement and Occurrence Management and The laboratory coordinates with COLOR Section 6.5 for Process Management of all 3 of the Laboratory for specimen collection and phases of lab testing (preanalytical, analytical and post submission to CDPH Branch Lab. analytical). In addition, a new SOP, PreAnalytical QA Process (CA-ACC-SOP-003 v1, approved by Lab Review of COLOR website for specimen Director on 24FEB2021 was created to define the requirements only indicated VTM or UTM media procedural guidelines for internal sample tracking for quality assurance purposes). See D5391 for specific transported at 2-8 Degrees Celsius within 24 details. hours, or -20 Degrees Celsius on dry ice if the specimen is to be submitted >24 hours. b. The laboratory failed to provide the client service manual that contains the reference laboratory's requirements for swab specimens transported in MTM.

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WING _	;(		7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Υ	28454	DRESS, CITY, ST LIVINGSTO ICIA, CA 91	N AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL REENTIFYING INFORMATION)		ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL	PROVIDER'S PLAN OF CORRECTION EACH CORRECTIVE ACTION SHOULD BE OSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	
D5311	4. The following are the 10 randomly review covering the period from 12/08/2020, wherein reported SARS-Coversults, but failed to eprocedures for special	e the accession number ewed patient test recor rom 11/02/2020 to the laboratory tested a 2 RT-PCR patient test ensure written policies	ds and	D5311	(1) Immediate Corrective Action: Created internal Preanalytical QA Process (CA-AC SOP-003) that defined current practice for internal samples and clearly specifying tha are received only through Color Genomics Section 5.1.  (2) Patient Impact: Per Lab Director Dr. Fethere is no change in diagnosis, treatment, recommended patient action (retesting), and there would not be patient (3) Preventative Measures:  Daily compilation and review of una specimens as tracked in the Day and Specimen Delivery Logs.  Monthly Specimen Acceptability Rato Quality and included in the Quality Management Review.  (4) Monitoring Mechanism: Monthly endaudit are be performed by the quality organisms.	tracking tra	
D5313	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 6. The laboratory di 12, 2021 at approximately approximately 430,00 from 11/02/2020 to 12	20 SARS-CoV-2 test rest 2/16/2020. rector affirmed (Februal ately 2:00 pm) that the asure written policies a men submission and	r on sults ary and	D5313	See attachment 6		8Mar2021
	The laboratory must of it receives a specime This Standard is not it.		I time				

NAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATORY  SIMMAPLY SYSTAMANT OF DEPTIGUATION  (SACH DEFINITIONS TO THAT IT OF DEPTIGUATION YOUR CONTROL OF THAT IT OF THE APPROPRIATE OF TH		COMPLETE CONTRACTOR OF THE CON		(X3) DATE SUR				
NAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATORY  SUMMARY STATEMENT OF DEFICIENCIES  (FACH DEFICIENCY MUST SE PRECISED OF YOUL RESOLUTION)  DESTINATION  COLLEGE DESTITATION OF DEFICIENCIES  SUMMARY STATEMENT OF DEFICIENCIES  (FACH DEFICIENCY MUST SE PRECISED OF YOUL RESOLUTION)  DESTINATION  COLLEGE DESTITATION OF DEFICIENCIES  SUMMARY STATEMENT OF DEFICIENCY  DEFICIENCY  DEFICIENCY  DEFICIENCY  SUMMARY STATEMENT OF DEFICIENCIES  CONDSTRETE ADD CORRECTION  SUMMARY STATEMENT OF DEFICIENCY  DEFICIENCY  DEFICIENCY  SUMMARY STATEMENT OF DEFICIENCY  DEFICIENCY  DEFICIENCY  DEFICIENCY  All information is collected, inclining data and time of collection, and is to related to clerction from the state of the DEFICIENCY  All information is collected, inclining data and situate of the second collection, and is to relate the decidency of the and in the state is to collection. And so the decidency of the deciden	AND PLAN O	PCORRECTION						
CDPH BRANCH LABORATORY  28454 LIVINGSTON AVE VALENCIA, CA 91355  DOCUMENT OF THE CONTROL OF CONTROL			05D21974	16	B. WING		02/17	//2021
DAIL PROPERTY   SUMMARY STATEMENT OF DEFICIENCIS	NAME OF PR	OVIDER OR SUPPLIER		STREET ADDR	ESS, CITY, STA	ATE, ZIP CODE		
SUMMARY STATEMENT OF DEFICIENCY STATEMENT OF DEFICIENCIES   10 PREPAY   CRCAFF CHICAGN CONSECTIVE ACTION SPORTABLE   COMMERCING CONSECTIVE ACTION SPORTABLE   COMMERCING COMME	CDPH BR	ANCH LABORATOR	Υ					
PRETY TAG  D5313 Continued From page 21 Based on interviews with laboratory staff on December 8, 2020, review of available policies and procedures (P/P), and random review of patient test records covering the period from 11/02/2020 to 12/08/2020, for 10 aut of 10 patient test records reviewed, it was determined that the laboratory failed to ensure the date and time of specimen receipt in the laboratory for each specimen roceipt in the laboratory for each taboratory of each specimen roceipt in the laboratory for each specimen roceipt in the laboratory of each specimen roceipt in the laboratory of each specimen roceipt in the laboratory developed test (LDT) for the direct detection of SARS-COV-2 virus RNA from patient samples, It utilizes Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler.  2. During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory staff stated that CDPH Branch Lab has been working with another CLIA coefficial each and time of collection for individual patient samples as of the collection of continuation secondary and the received date and time of collection for individual patient samples.  3. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002 Title: Specimen Collection, Storage, and				VALENC	IA, CA 913	355		
Based on interviews with laboratory staff on December 8, 2020, review of available policies and procedures (P/P), and random review of patient test records covering the period from 11/02/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to ensure the date and time of specimen receipt in the laboratory for each specimen for SARS-CoV-2 patient testing was documented.  Findings included:  1. The laboratory utilized SARS-CoV-2RT-PCR based diagnostic laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples. It utilizes Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler.  2. During the laboratory tour on 12/08/2020 at approximately 10.00 a.m., the laboratory staff stated that CDPH Branch Lab has been working with another CLIA certified laboratory to help healthcare providers in ordering the test for patients possible with Covid-19 infections. It was observed that along with the patient sample was only a "paper manifest" indicate the date and time of collection for individual patient samples.  3. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002 Title: Specimen Collection, Storage, and	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			PREFIX	(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE		COMPLETION	
December 8, 2020, review of available policies and procedures (P/P), and random review of patient test records covering the period from 11/02/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to ensure the date and time of specimen receipt in the laboratory for each specimen for SARS-CoV-2 patient testing was documented.  Findings included:  1. The laboratory utilized SARS-CoV-2RT-PCR based diagnostic laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples. It utilizes Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler.  2. During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory staff stated that CDPH Branch Laboratory for commended patient samples with delayed receipt were canceled are performed 27 the availability of the requisition was confirmed for 10 sensitions and reports from the certonic requisition from that some ded for testing is transferred to CDPH Branch Laboratory additional to CDPH Branch Laboratory additional to CDPH Branch Laboratory additional transferred to CDPH Branch Laboratory additionally at the time of accessible to CDPH Branch Laboratory additionally, and the received date and time of additionally, and the received date and time of accessible to CDPH Branch Laboratory additionally, and the received date and time of additionally, and the received date and time of accessible to CDPH Branch Laboratory additionally, at the time of accessible to CDPH Branch Laboratory additionally, at the time of accessible to CDPH Branch Laboratory additionally, at the time of accessible to CDPH Branch Laboratory additionally, at the time of accessible to CDPH Branch Laboratory additionally, at the time of accessible to CDPH Branch Laboratory additionally, at the time of accessible to CDPH Branch Laboratory additionally, at the time of additionally, at the time of additionally, and the time of additionall	D5313	Continued From pag	je 21		D5313	Findings 1-6		
Shipping, Effective Date 12/07/2020) did not include the requirement to document the date and time of collection for SARS-CoV-2	D5313	Based on interviews December 8, 2020, rand procedures (P/P patient test records of 11/02/2020 to 12/08/ test records reviewed laboratory failed to e specimen receipt in t specimen for SARS- documented.  Findings included:  1. The laboratory of based diagnostic I (LDT) for the direct virus RNA from pa Chemagic 360 for nucleic acids follor on Analytik Jena 1  2. During the labor approximately 10: stated that CDPH working with anoth to help healthcare test for patients poinfections. It was of patient sample was indicating only the collected at the col indicate the date a individual patient s  3. Review of the la procedures (Polic) Title: Specimen C Shipping, Effective include the require	with laboratory staff on eview of available police), and random review of available police, and random review of available police. A severing the period from 2020, for 10 out of 10 pd., it was determined the nature the date and time the laboratory for each CoV-2 patient testing with the individual of the viral aboratory developed the state of the viral wed by the RT-PCR as Thermal Cycler.  The atory tour on 12/08/2020 a.m., the laboratory Branch Lab has been the CLIA certified laboratory be a certified laboratory are cut along with a sonly a "paper manife to date for all the samples and time of collection for samples.  The aboratory's policies and the collection, Storage, and the Date 12/07/2020 didement to document the	cies of notices of notices of notices of notices of notices of contices of notices of no	D5313	All information is collected, including date collection, and is on the electronic requisition is stored at Color Genomics (CLIA #05D20 needed for testing is transferred to CDPH E Laboratory. Requisition data are retained by Genomics for 20 years per their policies and These documents are accessible to CDPH B Laboratory for auditing purposes.  Additionally, at the time of accessioning the date and time are logged. In the requisitions file located in attachment 4 the "Accession are presents the received date and time.  For additional information see D3027.  (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dr. there is no change in diagnosis, treatment, recommended patient action (retesting), as would not be patient harm.  (3) Preventative Measures: None  (4) Monitoring Mechanism: Monthly au 2021 to confirm that samples with delayed canceled are performed by the accessioning supervisors. The availability of the requisit confirmed for 10 samples via a routine trac performed 26Feb2021. An audit of an addit samples was initiated on 11Mar2021. (see 2021AuditPlan-008)	on form that 81492). Data Branch y Color of procedures. Franch e received s and reports at field e. Rosendorff, or and there e. dits for FY receipt were g ion was zer audit tional 25	

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING \_\_\_ COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION (X4) ID PROVIDER'S PLAN OF CORRECTION ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5313 Continued From page22 D5313 4. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, but failed to ensure the date and time of specimen receipt was documented. Accession Number 5. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 6. The laboratory director affirmed (February 12, 2021 at approximately 2:00 pm) that the laboratory failed to ensure the laboratory documented the date and time of specimen receipt. D5391 Findings 1-5 PREANALYTIC SYSTEMS QUALITY D5391 8Mar2021 **ASSESSMENT** Appendix A: The Quality Management Plan has been CFR(s): 493.1249(a) revised and reorganized to consolidated information about existing laboratory processes (CA-QM-The laboratory must establish and follow written SOP-001). policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §493.1241

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES A. BUILDING \_ COMPLETED IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION B. WING 05D2197416 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5391 D5391 Continued From page 23 Continued from page 23 through 493.1242. To determine if any delayed samples (> 7 days) had been This Standard is not met as evidenced by: received, a retrospective search of all samples received by the Laboratory (~1.6 million) was conducted, 129 Based on interview with the laboratory staff on samples received more than 168 hours (7 days) were December 8, 2020, review and the lack of identified. To determine potential impact on these documentation of policies and procedures (P/P) samples, the manufacturer of the MTM sample for Test Requisition, it was determined that the collection tubes, Longhorn Vaccines and Diagnostics, laboratory failed to establish written policies and LLC provided data from multiple studies that procedures for an ongoing mechanism to demonstrated extended stability of RNA in MTM up to monitor, assess, and when indicated, correct 30 days after collection. problems identified in the preanalytic systems specified at CFR 493.1241 through 493.1242. See Attachment 7. See Attachment 4 and D3027. See Attachment 6 and D5311. Findings included: (1) Immediate Corrective Action: None Review of the laboratory's policies and (2) Patient Impact: Per Lab Director Dr. Rosendorff, procedures (Policy # CA-QM-SOP-001, Title: there is no change in diagnosis, treatment, or Quality Management Plan, Effective Date recommended patient action (retesting), and there would 11/01/2020) did not include an ongoing not be patient harm since the manufacturer has mechanism to perform and document quality demonstrated stability of samples in MTM 30 days after issues regarding the lack of test requisition with collection. complete information necessary to ensure (3) Preventative Action: On 15Feb2021, Color accurate test results reporting (See D5301 and Genomics instituted a > 96-hour cancellation policy for D5305); as well as specimen submission and CDPH Branch Laboratory samples, therefore, any sample handling (See D5311 and D5313). accessioned at the Laboratory after 96 hours will register as canceled. In addition, a LIMC update (in progress, estimated release date 15Mar2021) will not allow The laboratory uses off-site collection accessioning of samples > 72 hours. facilities. The laboratory failed to establish policies and procedures to ensure proper (4) Monitoring Mechanism: Monthly audits for FY accountability or tracking of specimens from time 2021 to confirm that samples with delayed receipt were canceled are performed by the accessioning supervisors. of collection to receipt in the laboratory. a. At the time of the on-site survey on December 8, 2020, the laboratory was only using Molecular Transport Media (MTM) to transport swab specimens, with a stated stability of seven days at room temperature. In the absence of documented specimen

receipt

collection date and time, and specimen

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION			(X3) DATE SURVEY				
AND PLAN C	OF CORRECTION	IDENTIFICATION NUMB	EK:	A. BUILDIN	G	COMPLETED	
		05D21974	16	B. WING _		02/17	7/2021
NAME OF PR	ROVIDER OR SUPPLIER		STREET ADDRE	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BE	RANCH LABORATOR	Y		VINGSTO			
			VALENC	IA, CA 91	355		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
D5391	Continued From page date and time into the will not be able to def acceptability based or days at room tempers.  3. The following are the 10 randomly review covering the period from 12/08/2020, wherein reported SARS-CoV-results, wherein the lattere was an ongoing document quality issues systems.  Accession Number  4. Based on the lab declaration signed by 12/16/2020, the laboration of th	e laboratory, laboratory termine specimen in sample stability of seature.  e the accession number ewed patient test recommend of 1/02/2020 to the laboratory tested at 2 RT-PCR patient test aboratory failed to ensume than is much an is in the preanalytic error of the laboratory directory tested at the laboratory directory tested a	even  rs of ds  nd  ure and		(5401/5403/5407) During the initial planning execution of the Valencia Branch Laboratory the laboratory team provided feedback to the california on the collection process and medic Specifically, the team outlined the process for administering the nasal swab sample, the cont collection kit, packaging, infectious agents' ide (UN3373) label, storage at room temperature, shipping timeline. This information was then the Testing Taskforce Playbook and the proce collection site and laboratory procedure CA-CSOP-002.  Color Genomics provides COVID-19 testing town laboratory. References to their corporate collection materials is specific to their laborate Genomics is contracted by CDPH Branch Lab provide kits that are comprised of a sample coprefilled with MTM and barcoded with two id collection card for the patient with a matching and an absorbent pad. All samples tested to decollected in Color collection kits containing M Procedure CA-CLSRV-SOP-002 specifies use Procedure CA-ACC-ACC-001 incorrectly use (viral transport media) as a generic term. This corrected to MTM; however, the rejection crit procedure are sufficient since samples sent ou Color system are "Not Approved".  To determine if any delayed samples (> 7 days received, a retrospective search of all samples the Laboratory (~1.6 million) was conducted. received more than 168 hours (7 days) were id determine potential impact on these samples, manufacturer of the MTM sample collection to Longhorn Vaccines and Diagnostics, LLC proform multiple studies that demonstrated exter of RNA in MTM up to 30 days after collection.	ents of the entification and collated into ssees at the CLSRV-through its site bory. Color coratory to ellection tube lentifiers, one grand barcode, and the were entifiers of MTM. The seen eria in the tside of the solution the lentifiers. The wided data and ded stability the mbers use a	
	12, 2021 at approximate laboratory failed to en mechanism to perform issues in the preanaly	-	oing		(1) secure data repository and (2) a PerkinElm based application. Both of these are hosted with PerkinElmer network and are secured behind. The only method to access the systems remote a secured VPN tunnel using a PerkinElmer issuredentials on a PerkinElmer issued laptop. Defented the session the data and system being access the system being access to the system being access to the data and system being access the system being access to the data and system being access to the data and system being access the system being access to the data and system being access to the data and system being access to the system being access to the data and system being access to the system being access	thin the a firewall. ely is through sued set of uring any essed are	
D5400	ANALYTIC SYSTEMS	S		D5400	located on the prior mentioned internal IT syshardware. See sections 5401, 5403, 5407 for more details.		8Mar2021

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: в. ₩1 з\_ 05D2197416 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D540 Continued from page 25 D540 Continued From page 25 (5401/5407) There is scientific and clinical debate regarding CFR(s): 493.1250 the best interpretation of high Ct values. All reports issues Each laboratory that performs nonwaived testing did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, onmust meet the applicable analytic systems site Laboratory Director, who is directly involved in day-torequirements in §§493.1251 through 493.1283, day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area unless HHS approves a procedure, specified in now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as Appendix C of the State Operations Manual appropriate. (CMS Pub.7), that provides equivalent quality Contrary to Laboratory Director affirmation, LIMC User testing. The laboratory must monitor and Specification and Acceptance Testing forms were signed. Both the User Specification and the User Acceptance forms evaluate the overall quality of the analytic systems and correct identified problems as signed by both Laboratory Directors is provided. The effective date 29Oct2020 is the date the blank form specified in §493.1289 for each specialty and (template) was effective Delayed procedure approval: This subspecialty of testing performed. timeline reflects the difficulty in coming to a scientific and clinical consensus on how low viral load (high Ct value specifically > 37 - < 42) results should be interpreted. The VBL Playbook has been in use by the Task Force since This Condition is not met as evidenced by: the beginning of testing and was approved by the Lab Based on the number and severity of the Director. deficiencies cited herein, the Condition: Test results are transmitted to from the LIMS API thorough ANALYTIC SYSTEM was not met. the Color Platform to both CalREDIE and CalOES. CalREDIE transmits results to California county public health authorities and federal public health authorities as Findings included: required by law. See section 5401 and 5407 for more details. The laboratory failed to ensure procedure (5401/5411/5417/5423/5791) The laboratory has an manuals were established, available to, and Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of followed by laboratory personnel (See D5401). inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with 2. The laboratory failed to ensure the procedure separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/ manuals met the requirements specified in 42 degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, CFR 493. 1251 (b)(1)-(b)(14) (See D5403). dedicated refrigerators/freezers to separate reagents and samples, and asceptic cleaning techniques all of work areas The laboratory failed to ensure procedure and equipment. The observation made at time of inspection manuals were updated, approved, signed and stated that the lab use of 70% ethanol did not match the EUA and our procedure (see section 5.7.2). Based on CDC dated by the current Laboratory Director (See guidelines and the letter from our corporate quality organization the minimum percent ethanol required for D5407). The laboratory failed to ensure it followed the Heat inactivation is a desirable method for ensuring that the infection risk associated with of SARS-CoV-2 clinical samples is as low as possible. Validation studies carried out prior the beginning of testing included LoD studies with both heat inactivated and non-heat inactivated samples (see adopted FDA EUA IFU, the subsequent revisions to the EUA, and changes made in the laboratory's policies and procedures (See D5411). validation report sent to LFS at 1:55pm PST on October the 24th). There was no performance impact on heat 5. The laboratory failed to ensure reagents were inactivation.

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5)SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX DATE PREFIX CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5400 | Continued from page 26 D5400 Continued From page 26 labeled as required (SeeD5415). Clinical performance in asymptomatic people: Per version 7 (06Jan2021) of The PerkinElmer\* New Coronavirus Nucleic Acid Detection Kit IFU, the intended use for the kit is 6. The laboratory failed to ensure the intended for: ...the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare decontamination solution used for SARS-CoV-2 RT-PCR were not used past the labeled provider (HCP), and anterior nasal swab specimens expiration dates (See D5417). collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 7. The laboratory failed to ensure it established and verified performance specifications prior to The CDPH Branch Laboratory is using this kit within the reporting patient test results using its modified parameters of intended use FDA EUA IFU SARS-CoV-2 RT-PCR (See Thermocycler Parameters: The correct collection temperature is 65oC. A universal .trf file containing the PCR D5423). thermocycling conditions is generated by the PCR Janus program at the time a 384-well plate is set-up. The .trf file is imported to the AJ thermocycler. This file is correct. Records 8. The laboratory failed to the ensure the from the PCR output files for the 60 randomly chosen established maintenance protocol for samples demonstrate that the correct temperature is being used (LFS Response Cycling Parameters). Appendix A of CA-PCR-SOP-002v1 contained a typographical error. This centrifuges were performed and documented (SeeD5433). error was corrected in v2 (approved 26Jan2021). See sections 5401, 5411, 5417, 5423, 5791 for more details. The laboratory failed to establish and follow (5401/5415/5433/5791) We acknowledge that labeling of some reagents was incomplete and are working to improve written policies and procedures for an ongoing compliance. Non-compliance in reagent labeling and mechanism to monitor, assess, and when completion of instrument logs has been noted (QER-20-014, indicated, correct problems identified in the QER-20-015, QER-20-017, QER-20-036 and CAPA-20-007) and corrective action has been initiated. Supervisors and analytic systems (D5791). D5401 managers were instructed to review good documentation 8Mar2021 D5401 practices Instrument forms have been updated to make clear PROCEDURE MANUAL appropriate documentation for a shift when instrument is CFR(s): 493.1251(a) See sections 5401, 5415, 5433, 5479 for more details. A written procedures manual for all tests, assays, and examinations performed by the laboratory D5401 must be available to, and followed by, laboratory personnel. Textbooks may supplement but not Please see responses to findings for D5403, D5407, replace the laboratory's written procedures for D5411, D5415, D5417, D5423, and D5433 below. testing or examining specimens. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60

out of 60 patient test records reviewed, it was

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) (X4) ID ſΒ PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5401 Continued From page 27 D5401 determined that the laboratory failed to ensure the procedure manuals for the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test were established and followed by the laboratory staff. Findings included: 1. The laboratory failed to establish and follow written P/P in all phases of clinical testing for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit RT-PCR in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler, when it started testing patient samples on 11/02/2020. 2. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory started performing SARS-CoV-2 tests and reported results, but failed to ensure policies and procedures were established and followed by laboratory staff. Accession Number

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) (X4) ID COMPLETION PRETIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5401 Continued From page 28 D5401 Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to ensure policies and procedures were established and followed by laboratory staff. 5. Details of the required elements for policies and procedures are enumerated in D5403, (See D5403). D5403 D5403 PROCEDURE MANUAL 8Mar2021 CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation;

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WING \_ 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE **VALENCIA, CA 91355** (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued From page 29 D5403 Finding 1 specimen collection, labeling, storage, preservation, transportation, processing, and Instruction for collection: referral; and criteria for specimen acceptability During the initial planning and execution of the Valencia and rejection as described in §493.1242. Branch Laboratory (VBL) project the laboratory team provided feedback to the state of California on the (2) Microscopic examination, including collection process and media. Specifically, the team the detection of inadequately prepared outlined the process for administering the nasal swab sample, the contents of the collection kit, packaging, (3) Step-by-step performance of the procedure, infectious agents identification (UN3373) label, storage at including test calculations and interpretation of room temperature, and shipping timeline. This results. information was then collated into the Testing Taskforce (4) Preparation of slides, solutions, calibrators, Playbook and the processes at the collection site and laboratory procedure CA-CLSRV-SOP-002. controls, reagents, stains, and other materials used in testing. Instructions for obtaining sample kits (via Color Genomic (5) Calibration and calibration for CDPH Branch Laboratory), collection and shipping of verification procedures. samples is provided to collection sites set up by the Testing (6) The reportable range for test results for Task Force the test system as established or verified in §493.1253. Specimen collection (D5311 and D5403 parts a- f): (7) Control procedures. Please note, Color Genomics provides COVID-19 testing (8) Corrective action to take when calibration or through its own laboratory. Color assembles and control results fail to meet the laboratory's distributes collection kits on the processes and methods developed in their laboratory. These activities are criteria for acceptability. completely separate from the CDPH Branch Laboratory (9) Limitations in the test methodology, including activities and have no bearing on the CDPH laboratory. interfering substances. Therefore, it is inappropriate to compare information on (10) Reference intervals (normal values). the Color website with procedures at the CDPH Branch (11) Imminently life-threatening test results, Laboratory and described in laboratory procedure CAor panic or alert values. CLSRV-SOP-002. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This Standard is not met as evidenced by: 1. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records,

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O IDENTIFICATION NUMBI					(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING	B. WING		02/17/2021	
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		ESS, CITY, STAIVINGSTON	N AVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D5403	random review of part the period from 11/22 out of 60 patient test determined that the I to include the following accurate and reliable.  Specimen of appropriate technique.  Specimen Is name or unique iden.  Proper stora transportation.  Specimen a disposition.  Findings included:  a. The laboratory farmanual that met all the for Perkin Elmer New Detection Kit Real Till Reaction (RT-PCR) in utilizing Chemagic 30 nucleic acids followed Analytik Jena Therm.  b. During the on-site and 9, 2020, we note three sources, and a below:  (1) Staff interviews (2) Perkin Elmer Emer (EUA) Instructions for the source of the properties of the propert	tient test records cover 2/2020 to 12/08/2020, for records reviewed, it was aboratory's procedure in grequirements to ensist test results:  collection using the ele and containers abeling, including patie tifier, and specimen so age, preservation, and acceptability, rejection acceptabil	ior 60 as failed ure  nt urce  and  edure ents Acid  he viral y on  ber 8 these gh "f"	D5403	As it relates to testing that occurs at the Va Branch Laboratory (VBL) the state of Calif contracted for two purposes: sample kit dis and testing site operations.  Color Genomics is contracted by CDPH B Laboratory to provide kits that are comprisample collection tube prefilled with MTM barcoded with two identifiers, one collection the patient with a matching barcode, and a pad.  Sample kits not intended for the CDPH Br Laboratory are not tested.  All samples tested to date were collected in collection kits containing MTM (see MTM Letter from Color; Purchase order from Pr MTM)  Procedure CA-CLSRV-SOP-002 specifies Procedure CA-ACC-4CC-001 incorrectly (viral transport media) as a generic term. Torrected to MTM (molecular transport m however, the rejection criteria in the proce sufficient since samples sent outside of the system are "Not Approved" and section 8.3 followed.  Procedure and process are designed to matelectronic order to the sample tube receive See Attachment 4, 6, and 8 for additional in	ranch sed of a land on absorbent anch and land on absorbent anch according to the sed of a land on absorbent anch according to the sed of a land on absorbent anch according to the sed of a land or according to the sed of accordi		

STATEMENT OF DEFICIENCIES TIXT) PROVIDER/SUPPLIER/CLIA I '		IPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED					
,		05D21974	16	B. WING	02/17/2		7/2021
NAME OF PROVIDER OR SUPPL CDPH BRANCH LABOR		Y		I SS, CITY, STA VINGSTON IA, CA 913	N AVE		
(X4) ID SUMMARY STATEMENT OF DEFICIENCIES PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE	
the appropria containers  (1) Based on on 12/08/2020 samples colled Media (MTM).  (2) Review of Coronavirus Nuse of Viral Tripate 03/20/20 01/12/2021). Tregarding the  (3) Review of CA-CLSRV-Sistorage and Sistemates with a specimen colled to the college of the	interviol, the lacted in  of FDA I lucleicoranspor  of the lacted of the	en collection using hnique and ew with the laboratory suboratory only process Molecular Transport  EUA IFU for PE New Acid Detection Kit stated the Media (VTM) (Effective vised 09/16/2020 and was no information proving MTM in the IFU.  boratory's P/P (Policy#2, Title Specimen College, Effective Dated that CDPH Branch Label COR laboratory for and submission.  DR website for nots indicated VTM or	d the ve vided ction, ab	D5403	Color Genomics provides COVID-19 testir its own laboratory. Color assembles and discollection kits on the processes and method in their laboratory. These activities are comseparate from the CDPH Branch Laborator and have no bearing on the CDPH laborator. Therefore, it is inappropriate to compare in on the Color website with procedures at the Branch Laboratory.  As it relates to testing that occurs at the Val Branch Laboratory (VBL) the state of Califo contracted for two purposes: sample kit dis and testing site operations.  Color Genomics is contracted by CDPH Branch Laboratory to provide kits that are compriss sample collection tube prefilled with MTM barcoded with two identifiers, one collection the patient with a matching barcode, and an pad.  Sample kits not intended for the CDPH Branch Laboratory are not tested.  (1) Immediate Corrective Action: None  (2) Patient Impact: Per Lab Director Dr. R. there is no change in diagnosis, treatment, are commended patient action (retesting), and would not be patient harm.  (3) Preventative Action: None  (4) Monitoring Mechanism: Monthly audic confirmation of lot numbers of materials proposed and used in sample collection kits are performed the quality organization.	stributes sta developed upletely y activities by activitie	

	STATEMENT OF DEFICIENCIES (XT) PROVIDER/SUPPLIER/CLIA		1 - 2	(X2) MULTIPLE CONSTRUCTION (X3 A. BUILDING		(3) DATE SURVEY COMPLETED		
		05D21974	16	B. WING		02/17	02/17/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST.	ATE, ZIP CODE			
CDPH BF	RANCH LABORATOR	Y		IVINGSTOI CIA, CA 91:				
(X4) ID	SUMMARY S	TATEMENT OF DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTI	ON	(X5)	
PREFIX TAG	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	COMPLETION DATE	
D5403	Continued From pag	e 32		D5403				
	only a "paper manife:	st" indicating the follow	ring:					
	ii. Site poi	mber of samples receivent of contact	ved		Specimen collection (D5403 part e):		5	
	iii. Tracking iv. collectiv	g company number			To determine if any delayed samples (> 7 d been received, a retrospective search of all s			
		collected			received by the Laboratory (~1.6 million) w	as		
	v. Site nar				conducted. 129 samples received more than (7 days) were identified. To determine pote			
	vi. Site add	dress			on these samples, the manufacturer of the M	MTM sample		
	(2) Review of the lal	boratory's P/P (Policy#	E		collection tubes, Longhorn Vaccines and D LLC provided data from multiple studies th			
		2, Title Specimen Colle			demonstrated extended stability of RNA in			
		g, Effective Date 12/07	/2020)		30 days after collection.			
	indicated the elemen electronic manifest, s				(1) Immediate Corrective Action: None			
	electroffic marifest, s	sucii as.						
		g company and numbe	r		(2) Patient Impact: Per Lab Director Dr. R there is no change in diagnosis, treatment,			
		st number			recommended patient action (retesting), ar	nd there		
	iv.Site na	f sample collection	10		would not be patient harm since the manuf demonstrated stability of samples in MTM			
	v. Site ad				collection.	30 days arter		
		oint of contact						
-	(name, phone number				(3) Preventative Action: On 15Feb2021, C Genomics instituted a > 96-hour cancellation			
	VII. TOLALT	number of samples			CDPH Branch Laboratory samples, therefo	re, any		
7	(3) The laboratory fai	led to ensure the polic	y		sample accessioned at the Laboratory after register as canceled. In addition, a LIMC up			
		formation for individual			progress, estimated release date 15Mar2021			
	patients, such as pat		7		allow accessioning of samples > 72 hours.			
	e. Proper storage, preservation, and transportation				(4) Monitoring Mechanism: Monthly audi	ts for FY		
					2021 to confirm that samples with delayed canceled are performed by the accessioning	receipt were		
			stoff		See attachment 6			
	(1) Based on interview with the laboratory staff on 12/08/2020, the laboratory would receive MTM							
		perature, and good for						
	seven days.							
	(2) Review of FDA I	EUA IFU for PE New						
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Acid Detection Kit state	d the					

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WNG	302/17/20		17/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST LIVINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		1D PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D5403	use of VTM, stored at to 72 hours after coll shipping is expected stored at -70 degrees 03/20/2020, Revised 01/12/2021).  (3) Review of the late CA-CLSRV-SOP-002 Storage and Shipping indicated that CDPH with COLOR laborate and submission.  (4) Review of COLO requirements indicate transport should be should be should be requirements indicate transport should be should be requirements indicated transport should be requirements.  (5) Review of the late CA-CLSRV-SOP-002 Storage and Shipping stated under storage specimens collected degrees Celsius (roo "Manufacturer's instructemperature storage followed."	at 2-8 degrees Celsius of ection. If a delay in test of ections. If a delay in test of ections (Effective Data 19/16/2020 and	ing or  ie  ction, 2020) ates tion  n  ees 24 4 then  ction, (2020) that -25 ays.	D5403			

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBER			(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WNG 02		02/1	02/17/2021	
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 L	ESS, CITY, STA IVINGSTON CIA, CA 913				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOWN CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
D5403	09/16/2020 and 01/1  (7) The laboratory faits policies and proces of the laboratory faits policies and proces of the laboratory faits policies and proces of the laboratory faits policies and disposition  (1) Review of the laboratory faits and disposition  (1) Review of the laboratory faits and submit of the laboratory faits and s	iled to specify and includedures, the use of MTM sptability, rejection soratory's P/P (Policy #2, Title Specimen and Shipping, Effective dithat CDPH Branch Laboratory for special spe	Date ab ecimen art bes es (i.e.	D5403				

			(X3) DATE SURVEY COMPLETED			
		05D21974	16	B. WING 02/17		02/17/2021
NAME OF PR	ROVIDER OR SUPPLIER		STREET ADDRE	SS, CITY, ST	ATE, ZIP CODE	
CDPH BR	ANCH LABORATOR	Y	28454 LIV	/INGSTO	NAVE	
			VALENC	IA, CA 913	355	
(X4) ID	SUMMARY ST	ATEMENT OF DEFICIENCIES	3	ID	PROVIDER'S PLAN OF CORRECTION	ON (X5) COMPLETION
PREFIX TAG		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	
D5403	Continued From pag	e 35		D5403	Finding 2	
	2. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory's procedure failed to include the step-by-step performance of the procedure, including test calculations, and interpretation of results.  Findings included:		nontrol  ing  or 60  as  failed  the		1. For the purposes of data analysis, the stafuse a (1) secure data repository and (2) a Pe LIMS web based application.  2. Both of these are hosted within the Perkinetwork and are secured behind a firewall.  3. The only method to access the systems rethrough a secured VPN tunnel using a Perkissued set of credentials on a PerkinElmer is laptop. During any remote session the data being accessed are located on the prior meninternal IT systems hardware.  4. The two data analysts who performed renanlysis were trained and qualified to do so a. EV – Trained in data analysis and delegaresponsibilities of a General Supervisor b. MN – CLS trained in data analysis  5. CMS has made an exception to allow pat	erkinElmer nElmer emotely is sinElmer ssued and system titioned mote : ted the
	laboratory failed to pr and procedure for test interpretation of test	esults utilized by the iewed performing onsi	icy		other healthcare professionals to work remethe pandemic. CAP concurred with this exception of high Ct values. All reports match the analysis rules in place at the time processing. To manage this evolving field, a	ding the best issues did of sample a full-time,
	<ul> <li>b. The laboratory also requested approval that the quality metrics (including raw data) and curves generated from the PCR test be analyzed at remote locations by CLIA qualified testing personnel for test results of positive, negative, invalid, or inconclusive in order to shorten the turn- around-time from specimen collection to reporting of the test on 12/21/2020 without an approved policy and procedure on how to proceed with accurate remote reporting of patient test results.</li> <li>c. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results, but failed to include the step-by-step performance of the</li> </ul>		lyzed g ve, ne to		on-site Laboratory Director, who is directly day-to-day laboratory operations and result has been hired so that decisions regarding contemperation area now made in a timely mean consultation of CDPH Leadership, the Test Taskforce and other professionals as appropriate of the consultation of CDPH Leadership and CDPH Leadership.	t reporting data anner, with ing
			ers of ds ed		Immediate Corrective Action: Analysts we instructed that they may not analyze data re Patient Impact: Per Lab Director Dr. Rosenthere is no change in diagnosis, treatment, or recommended patient action (retesting), an would not be patient harm.  Preventative Action: A request to remove software from analyst computers has been pure to the properties of records made on 26Feb20 not be completed due to complexity. Removaccess will remove need to monitor.	emotely.  Indorff,  or  Ind there  VPN access placed.  Ty for  21 could

	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C			PLE CONSTRUCTION	(X3) DATE SU		
AND PLAN C	OF CORRECTION	IDENTIFICATIONNUMB	ER:	A. BUILDIN	G	COMPLE	TED	
		05D21974	16	B. WNG _		02/1	17/2021	
	ROVIDER OR SUPPLIER			DDRESS, CITY, STATE, ZIP CODE				
CDPH BF	RANCH LABORATOR'	Y		VINGSTO IA, CA 91				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D5403	d. Based on the lab	oratory's annual testing the laboratory director		D5403				
	from 11/02/2020 to 12	0 SARS-CoV-2 test res /16/2020.	und					

	MENT OF DEFICIENCIES LAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION  A. BUILDING		(X3) DATE SURVEY COMPLETED			
			05D2197416			B. WING	400-	02/17	//2021
NAME OF PR	ROVIDER OR SUP	PLIER			STREET ADDRI	ESS, CITY, ST.	ATE, ZIP CODE		
	RANCH LABO		Y		28454 LI	VINGSTO	NAVE		
					VALENC	IA, CA 913	355		
(X4) ID	St	JMMARY S	CATEMENT OF	DEFICIENCIES	3	1D	PROVIDER'S PLAN OF CORRECTION	ON	(X5)
PREFIX TAG	,			DED BY FULL REFORMATION)	EGULATORY	PREHX (EACH CORRECTIVE ACTION SHOULD BE TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		COMPLETION DATE	
D5403	Continued F	rom pag	e 37			D5403	Finding 3		
D5403	e. The Lak (February 12 pm) the labor the step-by-procedure, including tes results.  3. Based of laboratory streview of po (QC) and querandom reviethe period frout of 60 particles determined to include correference in Findings inc.  a. Review Coronavirus Date 03/20/201/112/2021) kit with valid i. SARS-Coviii SARS-Coviii Invalid	poratory in 2, 2021 a pratory far a pratory far a step perfect taff on Defect taf	Director aff t approxim iled to ensi- ormance o tions, and i observatio ecember 8 d procedure urance (QA- ient test re t/2020 to 12 records re aboratory's nd consiste ormal valu  DA EUA IF Acid Detect vised 09/10 d the expect ontrol as: Detected  CELEBROX) Section 12 Section 13 Section 14 Section 15 Section 16 Section 16 Section 17 Section	ately 2:00 ure include interpretation in, interviews and 9, 2020 es, quality co in records, incords cover 2/08/2020, fo viewed, it was is procedure if ent information es).	ewith ing or 60 as failed on on  ew ective or the	D5403	There is scientific and clinical debate regard interpretation of high Ct values. Due to disk among Laboratory Directors, the procedure analysis was not approved, a consistent method interpretation was used (see Analysis Timel All reports issues did match the analysis rul at the time of sample processing. To manage evolving field, a full-time, on-site Laborator who is directly involved in day-to-day labor operations and result reporting has been his decisions regarding data interpretation area in a timely manner, with consultation of CI Leadership, the Testing Taskforce and othe professionals as appropriate.  Please refer to the Analysis Timeline.  • 28Oct2020 – 11Nov2020 – results we as per the IFU (cutoff < 42 as positive * 11Nov2020 – 11Dec2020 – a lower C (<37) was set for positive results base value observed during validation, refichange in interpreted as inconclusive 25Jan2021 – present were interpreted as inconclusive 25Jan2021 – present were interpreted presumptive positive – high Ct value 42)  (1) Immediate Corrective Action: The squestion were resulted as per SOP (see D58)  (2) Patient Impact: See D5800  (3) Preventive Action: No revision to SO is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. checklist is being completed at shift change Data Analyst staff and verified by the Sign of Manager.  (4) Monitoring Mechanism: Monthly au integrity are performed as stipulated in the	cussion e used in her. d of ine below). es sin place e this ry Director, ratory red so that a now made DPH r  tree reported e) t cutoff d on Ct lecting a U lues (> 37 - e l as s (> 37 - < becimens in hoo).  P or process r. A daily by the Out  dits for data 2021 audit	
	>40 or Both targets Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.			schedule by the Quality organization. The I audit (see attachment 4) confirmed that the matched the current SOP and process 1009 time.  See Attachment 9 and Attachment 10	results				
	/: No requireme	nt on the CI	valut.	<b>,</b>			and recueinment 10		

	TATEMENT OF DEFICIENCIES ND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:				PLE CONSTRUCTION  G	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	17/2021
	OVIDER OR SUPPLIER	Y	28454 LI	ESS, CITY, ST VINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	IOULD BE	(X5) COMPLETION DATE
D5403	if the result for a spe value of the internal contributions of the internal contribution of the internal contribution of the internal contribution of the internal contribution of the interpretation of test laboratory staff intervidate analysis and interpretation, and revalues).  c. The following are the 60 randomly reviewed the period for 12/08/2020, wherein	cimen is SARS-CoV-2 RNA not do of must be ≤ 40, otherwise the recimen is SARS-CoV-2 RNA not do of must be ≤ 40, otherwise the recipion on 12/08/2020, rovide an approved polist calculations, and results utilized by the riewed performing onsit ference intervals (normally 19/20/2020) to the laboratory performent reported results but plete and consistent	etected, the Ct essult of that the Cy e	D5403			

					u di govierni (arici:		
	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/O			PLE CONSTRUCTION	(X3) DATE SU COMPLE	
AND PLAN O	F CORRECTION	IDENTIFICATIONNUMB	EK:	A. BUILDING		COMPLE	IED
		05D21974	16	B. WING		02/	17/2021
NAME OF PR	OVIDER OR SUPPLIER		STREET ADD	DRESS, CITY, STA	ATE, ZIP CODE		
	ANCH LABORATOR	Y		LIVINGSTON			
				ICIA, CA 913			
(X4) ID	SUMMARY S	TATEMENT OF DEFICIENCIES	3	1D	PROVIDER'S PLAN OF	CORRECTION	(X5)
PREFIX TAG	(EACH DEFICIENCY MUS	BT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		PREFIX TAG	(EACH CORRECTIVE ACT CROSS-REFERENCED TO T DEFICIENCE	ION SHOULD BE THE APPROPRIATE	COMPLETION DATE
D5403	Continued From pag	ge 39		D5403			
			6 =				
		a					
	d. Based on the lal	boratory's annual testin	a				
		y the laboratory directo					
	12/16/2020, the labo						
		00 SARS-CoV-2 test res	sults				
	from 11/02/2020 to 12	2/16/2020.					
		Director affirmed (Febr	uary				
	12, 2021 at approxim	nately 2:10 pm) the nsure include complete					
		nation on reference inter					
	(normal values).	iadon on releiende inter	ruio .				
	4. Based on dir	ect observation, intervi	ews				
		on December 8 and 9,					
	review of policies and	d procedures, quality of					
	(QC) and quality ass	urance (QA) records,					
		tient test records cover					
		2/2020 to 12/08/2020, f					
		records reviewed, itwa					

AND PLAN OF CORRECTION IDENTIFICATION		(X1) PROVIDER/SUPPLIER/C			PLE CONSTRUCTION	(X3) DATE SURVE COMPLETED	Y
		05D21974	16	B. WING		02/17/2	021
AND PLAN OF	CORRECTION  OVIDER OR SUPPLIER  ANCH LABORATOR  SUMMARY S' (EACH DEFICIENCY MUS OR LSC IDI  Continued From pag policies and procedu Reporting.  Findings included:  a. At the time of ins 9, 2020, and until Fel laboratory failed to pri and procedure for Inf Reporting.  b. The following are the 60 randomly revie covering the period fr 12/08/2020, wherein SARS-CoV-2 tests af failed to provide policies	ratement of deficiencies the preceded by Full resolution on December 8 bruary 12, 2021, the rovide an approved policetious Diseases the accession number ewed patient test recorrom 11/22/2020 to the laboratory perform nd reported results, but ises to ensure it complies se Reporting required	STREET ADDR 28454 L VALENCE SEGULATORY  asses  and licy ers of eds ed t ed	A. BUILDING	ATE, ZIP CODE	ON OS API EDIE OS And I by law.	
						,	
					79Q211 If o	continuation sheet Pag	ge 41 of 123

State 2567

Z9Q211

(FACH DESICIENCY MUST BE DESCREED BY SUIT DECLU ATORY (FACH CORRECTIVE ACTION SHOULD BE	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
CDPH BRANCH LABORATORY  28454 LIVINGSTON AVE VALENCIA, CA 91355   (X4) ID PREFIX TAG  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG  OR LSC IDENTIFYING INFORMATION)  28454 LIVINGSTON AVE VALENCIA, CA 91355  DPROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		05D2197416	B. WING		02/17	7/2021
(X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION GARDY PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)						
PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACHCORRECTIVE ACTION SHOULD BE COM CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		V	ENCIA, CA 9135	55		
D5403 Continued From page 41 D5403	PREFIX (EACH DEFICIENCY MU	JST BE PRECEDED BY FULL REGULATO	PREFIX	(EACHCORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	DBE	(X5) COMPLETION DATE
	D5403 Continued From pa	age 41	D5403			
c. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.  d. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to provide policies to ensure it complied with Infectious Disease Reporting required by local, state, and federal authorities.  D5407  PROCEDURE MANUAL CFR(s): 493.1251(d)  Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.  This Standard is not met as evidenced by:  1. Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality	declaration signed by 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1 d. The Laboratory 12, 2021 at approximated to put the complied with Infect required by local, st.  PROCEDURE MAN CFR(s): 493.1251(d.)  Procedures and chas approved, signed, a laboratory director by 1. Based on direct laboratory staff on D.	by the laboratory director on poratory reported 1000 SARS-CoV-2 test results 12/16/2020.  The provide policies to ensure it sticus Disease Reporting tate, and federal authorities.  NUAL d)  anges in procedures must be and dated by the current before use.  The provide policies to ensure it sticus before use.  The provide policies to ensure it sticus before use.  The provide policies to ensure it sticus before use the provide policies to ensure it sticus before use.  The provide policies to ensure it sticus before use the provide policies to ensure it sticus before use.	D5407			8Mar2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CL IDENTIFICATIONNUMBER			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED				
				05D21974	16	B. WING		02/17	7/2021
NAME OF PE	ROVIDER OR SUPF	PLIER			STREET ADDR	SS, CITY, ST	ATE, ZIP CODE	•	
CDPH BE	RANCH LABO	RATOR	Y		28454 LI	8454 LIVINGSTON AVE			
						IA, CA 91			
0(4) ID	CII	MANAGOV CO	FATCMENT	C DEFICIENCIE				211	(75)
(X4) ID PREFIX TAG	(EACH DEFICIE	ENCY MUS	T BE PRECEI	OF DEFICIENCIES  DED BY FULL RE  NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVEACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5407	Continued F	rom pag	e 42			D5407	Finding 1		
	control (QC)			ance (QA) red	cords.		Thiding I		
	random revie		•	• •			Findings a-f		
	the period fro						There is scientific and clinical debate regard		
	out of 32 pati						interpretation of high Ct values. Due to disc among Laboratory Directors, the procedure	cussion	
	determined th						analysis was not approved in a timely mann	ier.	
	the procedure						Although not approved, a consistent metho	od of	
							interpretation was used (see Analysis Timel		
	using the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic was approved, signed, and dated by the laboratory director.					All reports issues did match the analysis rul at the time of sample processing. To manag			
						evolving field, a full-time, on-site Laborator			
				orv		who is directly involved in day-to-day labor	ratory		
						operations and result reporting has been his decisions regarding data interpretation area	red so that		
							in a timely manner, with consultation of CI		
	Findings inclu	uded:					Leadership, the Testing Taskforce and other	r	
							professionals as appropriate.		
	a. During th	ne first d	ay of the c	on-site inspe	ction		Please refer to the Analysis Timeline.		
	on 12/08/202	0, we in	terviewed	laboratory			• 28Oct2020 – 11Nov2020 – results we	ere reported	
	directors and	senior	perations	personnel, a	ind		as per the IFU (cutoff < 42 as positive		
	requested for	r the labo	oratory's d	ocumented			• 11Nov2020 – 11Dec2020 – a lower C		
	investigation	and corr	ective act	ion regarding	the		(<37) was set for positive results base value observed during validation, ref	lecting a	
	increased nur	mber of i	nconclusiv	e patient res	ults.		change in interpretation from the IF	U	
					_		• 11Dec2020 – 25Jan2021 – high Ct va		
				ns for Use (I	FU)		<ul> <li>&lt; 42) were interpreted as inconclusive</li> <li>25Jan2021 – present were interpreted</li> </ul>		
	of the Emerg						- 25jan2021 present were interpreted	u uo	
	laboratory's a	-					presumptive positive – high Ct value	00 (> 27	
	New Coronav				. The		12)	,	
	"Examination						(1) Immediate Corrective Action: The	specimens	
	Specimen Re				-		in question were resulted as per SOP (see D	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	the expected		or the kit v	with valid pos	sitive		(2) Patient Impact: See D5800.		
	and negative	control.					(3) <b>Preventive Action</b> : No revision to SC		
							process is placed into use until the Lab Dire Rosendorff, has provided written approval.		
	a consecutation of the case of	de threshol		Result Interpre	tation		checklist is being completed at shift change		
	IC (VIC/HEX)	7	RF1ab ROX)	ļ			Analyst staff and verified by the Sign Out M		
	≤ 40	Both targe		SARS-COV-2 Not	Detected		(4) Monitoring Mechanism: Monthly a	udits for	
	1	Both targe	ined or > 42 ts < 42	SARS-CoV-2 Det	ected		data integrity are performed as stipulated ir	n the 2021	
	1		targets < 42	SARS-CoV-2 Det			audit schedule by the Quality organization.		
		1		Invalid result,			26Feb2021 Tracer audit of 10 samples confi the results matched the current SOP 100% of		
	>40 or	Both targe	ts	needs to be re-			An audit of an additional 25 samples will be		
	Undetermined	1	ned or > 42	re-extraction of	18		beginning 11Mar2021.	1	
				from patient fo	r test.		See Attachment 9 and Attachment		
		<u></u>					10		

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIEF IDENTIFICATION NUM			1	PLE CONSTRUCTION	(X3) DATE SUI COMPLET	
	×	05D21974 <sup>-</sup>	16	B. WNG_		02/1	7/2021
NAME OF P	ROVIDER OR SUPPLIER		STREET ADDRE	SS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR'	Y		VINGSTOI IA, CA 91:			,
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULI CROSS-REFERENCED TO THE APPROF DEFICIENCY)	DBE	(X5) COMPLETION DATE
D5407	c. In order to compacalculating and interpalso asked the laborato provide the LIMC L System (LIS) and its interpretation of patie (i) A policy and propagatory was not aw 2020.  (ii) Neither an unsign was available on Decoder 12/08/2020, indicated patient test result a result of incorrect dinterpretation.  e. The following day conducted random sapatient test records we during the first week E.  f. On December 15 on-site at the laborato patient test records.	are how the laboratory watering patient results, votory on December 8, 20 aboratory Information policy and procedure for the specimen results.  Decedure signed by the valiable on December 8 and procedure signed by the valiable on December 8 and procedure signed by the valiable on December 8 and procedure was a possible to the valiable of the valiab	re rector sility or as	D5407			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X 1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			1 '	E CONSTRUCTION	(X 3) DATE SUR\ COMPLETE			
			05D219741	6	B. WING	<u>,                                    </u>	02/17	/2021
	OVIDER OR SU			1	SS, CITY, STAT /INGSTON A. CA 9135	AVE		
(X4) ID PREFIX TAG		CIENCY MUST	TEMENT OF DEFICIENCIES BE PRECEDED BY FULL REG NTIFYING INFORMATION)	GULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D5407	g. The pope Dec. 16, 20 (i) An ardocument in 10/29/2020 (ii) It was an effective (iii) The Soversion 1.2 h. The Dispecification showed the patient speciment speciment in Compalaboratory's speciment result category.	From page  plicy and pro 20 showed  anotation or indicated, "I "the docum  an Initial do date of De oftware Nan  detailed Use ons section e following procimen resu  Update analysis rule "Not Detected" "Not Detected "Not Detected" "Not Detected" "Not Detected" "Not Detected" "Not Detected" "Not Detected "Not Detected" "Not Detected" "Not Detected "Not Detected" "Not Detected "Not Det	cedure sent via e-mail I the following: In the top portion of Effective Starting Inent version history: Incument, Version 1.0, via Incember 13, 2020. Incember 14, 2020. Incember 15, 2020. Incember 16, 2020. Incember 16, 2020. Incember 17, 2020. Incember 17, 2020. Incember 18, 2020. Incember 19, 20	vith AC, of as "Inconclusive" as "Invalid".	D5407	Finding 1  Findings g-k  Contrary to Laboratory Director affirmation Specification and Acceptance Testing forms signed.  LIMC documentation: Provided. Please not following:  -Both the User Specification and the User Aforms signed by both Laboratory Directors. The effective date 29Oct2020 is the date the form (template) was effective  Delayed procedure approval: This timeline difficulty in coming to a scientific and clinic consensus on how low viral load (high Ct v specifically > 37 - < 42) results should be in Please refer to the Analysis Timeline.  • 28Oct2020 – 11Nov2020 – results were reper the IFU (cutoff < 42 as positive)  • 11Nov2020 – 11Dec2020 – a lower Ct cut was set for positive results based on Ct valuduring validation, reflecting a change in infrom the IFU  • 11Dec2020 – 25Jan2021 – high Ct values were interpreted as inconclusive  • 25Jan2021 – present were interpreted as positive – high Ct values (> 37 - < 42)  See Attachment 9, Attachment 10, and Attachment 11	te the  Acceptance is provided. he blank  reflects the ical ralue – heterpreted.  eported as coff (<37) he observed terpretation  (> 37 -< 42)	
	identified as User Requirement Specifications							

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED A. BUILDING \_ IDENTIFICATION NUMBER: AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY **VALENCIA, CA 91355** (X5) PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES ID (X4) ID COMPLETION (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX DATE PREFIX CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC (DENTIFYING INFORMATION) TAG DEFICIENCY) D5407 D5407 Continued From page 45 (1) Immediate Corrective Action: The specimens in question were resulted as per SOP CA-COMP-FM-001 Version 1.0, was approved, (see D5800). signed, and dated by the Laboratory Director. (2) Patient Impact: This policy and procedure did not include the See D5800. laboratory's signature. There was also no (3) Preventative Action: No revision to SOP or indication or verification that the laboratory process is placed into use until the Lab Director, Dr. director affixed a digital signature approving, Rosendorff, has provided written approval. A daily signing and dating the document checklist is being completed at shift change by the Data Analyst staff and verified by the Sign Out Manager. Based on direct observation, interviews with (4) Monitoring Mechanism: Monthly audits for data laboratory staff on December 8 and 9, 2020, integrity are performed as stipulated in the 2021 audit review of policies and procedures, quality control schedule by the Quality organization. A 10Feb2021 (QC) and quality assurance (QA) records, Tracer audit of 10 samples confirmed that the results random review of patient test records covering matched the current SOP 100% of the time. An audit the period from 11/22/2020 to 12/08/2020, for 60 of an additional 25 samples will be performed out of 60 patient test records reviewed, it was beginning 11Mar2021. determined that the laboratory failed to provide the updated and approved procedure manuals signed by the current laboratory director for the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. Findings included: a. At the time of inspection on 12/08/2020 and 12/09/2020, there was no updated P/P, approved, signed and dated by the laboratory director for the following: Client procedure manual provided to all staff in the collection sites for patient preparation, specimen collection, labeling, storage, preservation, transportation, processing, referral, and criteria for specimen acceptability.

	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIP A. BUILDING	JEY D		
		05D21974	16	B. WING		02/17	/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		ESS, CITY, STA VINGSTON CIA, CA 913	I AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	_D BE	COMPLETION DATE
D5407	ii. Step-by-step pe including test calcular results.  (1). Onsite Data Ana (2). Remote Data Ariii. Reference Interiv. Infectious Disease b. The following at the 60 randomly rev covering the period 12/08/2020, whereir SARS-CoV-2 tests a	ations, and interpretationallysis halysis vals (normal values) ases Reporting are the accession number iewed patient test record from 11/22/2020 to a the laboratory perform and reported results, but dated P/P, approved, signations.	ers of rds	D5407	Finding 2  The VBL Playbook has been in use by the since the laboratory opened and ward document control and approved for the Laboratory Director on 07Dec2021. CA-CLSRV-SOP-002 was used in draft prior to Laboratory Director approval on Please see D5407 finding 1 regarding delay of procedures.  Test results are transmitted to from the LI thorough the Color Platform to both CalR CalOES. CalREDIE transmits results to Ca county public health authorities and feder health authorities as required by law.  Remote analysis: For the purposes of data staff members use a (1) secure data reposit PerkinElmer LIMS web based application. are hosted within the PerkinElmer networ secured behind a firewall. This infrastruct configuration eliminates the ability for indiaccess the site and file repository from an elocation on a general internet connection. transferred to the location of the remote (operson. The only method to access the systis through a secured VPN tunnel using a Fissued set of credentials on a PerkinElmer During any remote session the data and sy accessed are located on the prior mentione systems hardware. Therefore, the experient analyst is the same and no separate trainin procedure is used. Remote analysis is no lose also D6082.  (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dithere is no change in diagnosis, treatment recommended patient action (retesting), and there would not be patien (3) Preventative Action: None (4) Monitoring Mechanism: Monthly in are performed are performed by the LIMC Color Genomics.  See Attachment 16.	as moved to use by In addition, version 07Dec2020.  In addition, version 07Dec2020.  In approval  MS API EDIE and allifornia all public  In analysis, the cory and (2) a Both of these k and are ure lividuals to external Data is never offsite) tems remotely terkinElmer issued laptop. It is the good of the g	

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY IDENTIFICATION NUMBER: A. BUILDING AND PLAN OF CORRECTION COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION PRETIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACHCORRECTIVEACTIONSHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5407 Continued From page 47 D5407 c. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. d. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to provide policies to ensure proper instructions to clients, accurate step-by-step test calculations, reference intervals, interpretation of results, and it complied with Infectious Disease Reporting required by local, state, and federal authorities. D5411 TEST SYSTEMS, EQUIPMENT, D5411 8Mar2021 INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIAND PLAN OF CORRECTION IDENTIFICATIONN		(X1) PROVIDER/SUPPLIER/C		(X2) MULTIPLE CONSTRUCTION  A. BUILDING		(X3) DATE SURVEY COMPLETED	
AND PLAN C	F CORRECTION	IDENTIFICATIONNUMBE	EK:	A. BUILDING		COMPLETED	
		05D21974	16	B. WING	T	02/17/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	RANCH LABORATOR'	Y	28454 LIVINGSTON AVE				
			VALENC				
(X4) ID		CATEMENT OF DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTION	COMPLETION	
PREFIX TAG		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTIONSHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	DATE	
D5411	Continued From page	0.48	-	D5411	Finding La		
D3411				D3411	Finding 1a: The laboratory has an Amplicon Contamin	ation	
	control (QC) and quality assurance (QA) re random review of patient test records cover the period from 11/22/2020 to 12/08/2020, out of 60 patient test records reviewed, it we determined that the laboratory failed to ensign followed the adopted FDA EUA IFU, the				Prevention Plan (CA-SAFE-POL-019 v 1.0	, approved	
					by Lab Director, in effect at time of inspect plan describes the measures put in place to		
					contamination that included laboratory des	sign and	
					construction of air lock doors, environmen		
			are it		with separate HVAC systems, unidirection flow, secure PCR plate transport, use of PP	E with	
	subsequent revisions				defined gowning/degowning procedures, d	edicated	
		laboratory's policies ar	nd		equipment and consumables in each room, resistant pipette tips, dedicated refrigerator	s/freezers to	
	procedures.	, ,			separate reagents and samples, and ascepti	c cleaning	
	•				techniques all of work areas and equipmen observation made at time of inspection stat	ed that the	
	Findings included:				lab use of 70% ethanol did not match the E	UA and our	
					procedure (see section 5.7.2). Additionally, Safety statement was included in the techni	a default	
	1. Review of the lab	ooratory's performance			(listed in the findings) that contradicted the	e current	
	-	EUA Instructions for U			approved practice and the Laboratory Qual Management Plan (approved by the director	ity or and in	
		New Coronavirus Nuc	leic		effect at time of inspection (CA-QM-SOP-	001 va	
		nd current policies and			effective 12OCT 2020) did not provide the environmental prevention and decontamin	robust	
	procedures available				initiatives outlined in the Amplicon Containing		
		itory failed to provide the	ne		Prevention Plan.	WI musslis	
	following:				The FDA EUA instructions for use of the P Acid detection kit provided possible action		
	a. Decontamination P	Protocol			preventing contamination; The decontamin	nation	
	a. Decontamination P	1010001			prevention instructions do not impact the process characteristics of the test and it is the Labor		
	i. Review of the labor	ratory's FDA FIIA			Director who determines the contaminatio	n '	
		IFU) for Perkin Elmer N	lew		prevention and decontamination procedur used at the Laboratory. Use of UV light to		
		Acid Detection Kit (Effe			work surface area and the instruments is no	ot approved	
	Date 03/20/2020, Rev				by the Laboratory Director and therefore n in the contamination prevention plan.	ot included	
	01/12/2021) stated ur						
		Sterile centrifuge tubes	and		Based on CDC guidelines and the letter fro corporate quality organization the minimu	om our m percent	
		sposed into a waste bi			ethanol required for decontamination is 60		
	_	dium Hypochlorite solu			(1)Immediate Corrective Action:		
	-	e work area surface an			<ul> <li>Labeling of reagents, materials, and s</li> </ul>	supplies	
		ould be disinfected wit	h a		<ul> <li>Updating of the quality management</li> </ul>	*	
	• • •	Sodium Hypochlorite			(2) Patient Impact: Per Lab Director Dr. Re		
		aned with 75% Ethano			there is no change in diagnosis, treatment, recommended patient action (retesting), ar	nd there	
		rn on UV light to disinf	ect		would not be patient harm. The 70% EtOF	I was	
	working surfaces for 3				expired only a few days indicating that a 60 concentration was still present which meet guidelines		
		servation and interview			(3) <b>Preventative measure:</b> The corrective a	action	
	,	n 12/08/2020, the labor	ratory		includes re-assigned reading on related pro		
	was utilizing 70% Eth	anol as theirgeneral			(4) Monitoring mechanism: Monthly inte	rnal audits	
					are be performed by the laboratory supervi		

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (X5)(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX COMPLETION (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5411 Continued From page 49 D5411 Appendix A: The Quality Management Plan has been decontamination solution. revised and reorganized to consolidated information about existing laboratory processes (CA-QMiii Due to safety concerns with using 10% See Attachment 1. Sodium Hypochlorite solution with VTM, the laboratory used ethanol. The use of 70% EtOH meets the standard set by CDC. Heat inactivation is an effective method to inactivate SARS-CoV-2. Disposal of MTM sample collection iv. However, contrary to the specified ethanol tubes that have been subjected to heat inactivation in bleach is not necessary. Therefore, the area in which concentration in the IFU, the laboratory, used the samples were handled was adequately 70% ethanol, and not 75% ethanol. decontaminated. v. The laboratory failed to follow manufacturer's instructions specified in the IFU. Finding 1b: vi. The laboratory also failed to provide Heat inactivation is a desirable method for ensuring that the infection risk associated with of SARS-CoV-2 performance specification studies showing 70% clinical samples is as low as possible. Validation studies ethanol is an effective decontaminant instead of carried out prior the beginning of testing included LoD 10% Sodium Hypochlorite solution for discarded studies with both heat inactivated and non-heat inactivated samples (see validation report sent to LFS at 1:55pm PST on October the 24th). There was no centrifuge tubes and filter-tips. performance impact on heat inactivation. b. Heat Inactivation of Swab Samples (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dr. Rosendorff, Review of the laboratory's FDA EUA there is no change in diagnosis, treatment, or Instructions for Use (IFU) for Perkin Elmer New recommended patient action (retesting), and there Coronavirus Nucleic Acid Detection Kit (Effective would not be patient harm. Date 03/20/2020, Revised 09/16/2020 and (3) Preventative measure: None 01/12/2021) did not include the heat inactivation procedures for swab samples. (4) Monitoring mechanism: None Finding 1c: Review of the laboratory's policies and Storage Conditions: The long-term storage at -84 --76oC is intended for post-testing storage. This is not a procedures (Policy # CA-EXT-SOP-001 Heat change to the method described in the IFU and has no Inactivation of Viral Swab Samples) indicated impact on the performance of the assay. CA-EXTthe following: SOP-004 has been modified to note that this storage condition is for post-testing. ii.a. Use of oven to 70 degrees Celsius (1) Immediate Corrective Action: None ii.b. Pre-cool centrifuge to 20 degrees Celsius (2) Patient Impact: Per Lab Director Dr. Rosendorff, iii.c. The use of centrifuge at 1200 RPM there is no change in diagnosis, treatment, or for 1 minute recommended patient action (retesting), and there would not be patient harm. (3) Preventative measure: None (4) Monitoring mechanism: None

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY D5411 Continued From page 50 Finding 1d Thermocycler Parameters: The correct collection iii. The laboratory failed to provide performance temperature is 65oC. A universal .trf file containing the specification studies for the heat inactivation of PCR thermocycling conditions is generated by the PCR Janus program at the time a 384-well plate is set-up. swab samples. The .trf file is imported to the AJ thermocycler. This file is correct. Records from the PCR output files for the 60 Storage Conditions for randomly chosen samples demonstrate that the correct temperature is being used (LFS Response Cycling nasopharyngeal, oropharyngeal, and Parameters). Appendix A of CA-PCR-SOP-002v1 contained a typographical error. This error was anterior nasal swabs (Extracted RNA) corrected in v2 (approved 26Jan2021). Review of the laboratory's FDA EUA (1) Immediate Corrective Action: None Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective (2) Patient Impact: No patient impact identified Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated that, "Nasopharyngeal, (3) Preventative measure: None oropharyngeal, and anterior nasal swabs with the (4) Monitoring mechanism: None extracted nucleic acids should be stored at -25 to -15 degrees Celsius. See Attachment 12. Finding 1e: Review of the laboratory's policies and Delayed procedure approval: Please refer to the procedures (Title CA-EXT-SOP-004 Title Viral Analysis Timeline. This timeline reflects the difficulty RNA/DNA Extraction Using the Chemagic 360, in coming to a scientific and clinical consensus on how low viral load (high Ct value - specifically 37 - <42) results should be interpreted. Please refer to Analysis Effective Date 11/03/2020 stated that, "Extracted nucleic acids should be stored at -84 to -76 degrees Celsius for long term storage." Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a The laboratory failed to follow timely manner. Although not approved, a consistent method of interpretation was used (see Analysis manufacturer's instructions specified in the IFU. Timeline below). iv. The laboratory failed to provide performance 28Oct2020 - 11Nov2020 - results were reported specification studies showing the basis for as per the IFU changing the storage conditions requirement for 11Nov2020 - 11Dec2020 - a lower Ct cutoff was set for positive results based on Ct value extracted nucleic acids. observed during validation, reflecting a change in interpretation from the IFU d. Thermal Cycler Parameters 11Dec2020 - present - high Ct values (> 37 - < 42) were interpreted as inconclusive Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the following thermal cycler set-ups:

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) (X4) ID PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) Continued From page 51 D5411 11Dec2020-25Jan2021 or presumptive positive (25Jan2021 -present) Step Temperature Time # of Cycles 1 37 degrees Celsius 2 minutes Due to scientific discussion and disagreement, a final 2 50 degrees Celsius 5 minutes laboratory procedure was not approved by the laboratory directors until 08Dec2020. Additional 42 degrees Celsius 35 minutes versions were requested with delayed approval over 94 degrees Celsius 10 minutes 1 the next week. Although the protocol in use should 94 degrees Celsius 10 seconds have been approved prior to use, mitigating 55 degrees Celsius 15 seconds 45 circumstances to note include: 65 degrees Celsius 45 seconds -Data analysts were trained using the draft protocol, which remained available to them \*Collect fluorescence signal during the final 65 -Changes in the interpretation of results were degrees Celsius step handled in LIMC, not determined by data analysts -An active discussion was held with Review of the laboratory's policies and CDPH directors to bring the procedures (Policy # CA-PCR-SOP-002, Title interpretation to resolution. See: SARS-CoV-2-RT-PCR Using the Analytic, o 01Dec2020 Email CDPH Approval of v1 Effective Date 11/04/2020) stated the following o 08Dec2020\_Email Final SOP Definitions for v1 for thermal cycler parameters: Doc Control o 11Dec2020 Email Changes to Ct Step Temperature Time # of Cycles Reporting 25 degrees Not o 14Dec2020 Email Changes to Ct 2 minutes 1 Celsius indicated Reporting (v2) 50 degrees 15 Not o 16Dec2020 Email Changes to Ct 2 Celsius indicated minutes Reporting (v3.1) 95 degrees Not 3 2 minutes Celsius indicated Not 95 degrees 4 3 seconds Celsius indicated 60 degrees Not 30 5 indicated Celsius seconds

NAME OF PROVIDER OR SUPPLIER   STREET ADDRESS, CITY, STATE, ZIP CODE	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:				PLE CONSTRUCTION 3	(X3) DATE SURVEY COMPLETED		
MAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATORY  28454 LIVINGSTON AVE VALENCIA, CA 91355  (KA) ID RESPIX OR LSC IDENTIFYING INFORMATION)  DFAIL Continued From page 52  iii. Review of the same policies and procedures Title SARS-Cov-2-RT-PCR Using the Analytic Jena, Effective Date 11/04/2020, indicated the following thermal cyclers dated 10/27/2020.  Step Temperature Time # of Cycles 1 25 degrees Celsius 2 minutes 1 2 50 degrees Celsius 2 minutes 1 3 95 degrees Celsius 3 seconds 1 4 95 degrees Celsius 3 oseconds 45  **Collect fluorescence signal during the final 60 degrees Celsius step  iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step"  specified in laboratory procedures identified in d the IFU, which indicated "Collect fluorescence is incorporation in the IFU, which indicated "Collect fluorescence is incorporation and result portion."  STREET ADDRESS. CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE VALENCIA, CA 91355  ID PROVIDER'S PLAN OF CORRECTION (CS)  (EACH OEFICIENCY MUST BE PRECEDED BY FULL REQULATORY PREFIX TAG  PREFIX TAG  PREFIX DROVES PLAN OF CORRECTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION CENTURE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE CENTURE ACTION CENTURE A	VIAD SPVIA	OI CORRECTION	IDENTI IOATIONNOMBI	LIX.	, a Boilebill			
CDPH BRANCH LABORATORY   28454 LIVINGSTON AVE VALENCIA, CA 91355			05D21974	16	B. WING		02/17/2021	
VALENCIA, CA 91355	NAME OF P	ROVIDER OR SUPPLIER		STREET ADDR	ADDRESS, CITY, STATE, ZIP CODE			
Continued From page 52   Iii. Review of the same policies and procedures Title SARS-CoV-2-RT-PCR Using the Analytic Jena, Effective Date 11/04/2020, indicated the following thermal cyclers dated 10/27/2020.   Step Temperature Time # of Cycles 1 25 degrees Celsius 2 minutes 1 2 50 degrees Celsius 2 minutes 1 3 95 degrees Celsius 2 minutes 1 5 60 degrees Celsius 3 oseconds 1 5 60 degrees Celsius 30 seconds 45   Value Step Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step   Iv. The instruction to "Colle	CDPH BI	RANCH LABORATOR	Y					
iii. Review of the same policies and procedures Title SARS-CoV-2-RT-PCR Using the Analytic Jena, Effective Date 11/04/2020, indicated the following thermal cyclers dated 10/27/2020.  Step Temperature Time # of Cycles 1 25 degrees Celsius 2 minutes 1 2 50 degrees Celsius 15 minutes 1 3 95 degrees Celsius 2 minutes 1 4 95 degrees Celsius 3 seconds 1 5 60 degrees Celsius 3 oseconds 1 5 60 degrees Celsius 30 seconds 45  **Collect fluorescence signal during the final 60 degrees Celsius step  iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step" specified in laboratory procedures identified in d (ii) and d (iii) is not the same as the instruction in the IFU, which indicated "Collect fluorescence  iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step" specified in laboratory procedures identified in d (ii) and d (iii) is not the same as the instruction in the IFU, which indicated "Collect fluorescence"  in the IFU, which indicated "Collect fluorescence in the IFU in the	PREFIX	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE		PREFIX	DBE COMPLETION		
signal during the final 65 degrees Celsius step."  v. The laboratory failed to follow manufacturer's instruction specified in the IFU.  vi. The laboratory failed to provide the performance specification studies to support the above-described change in thermal cycler parameters.  e. Interpretation of Test Results  i. Review of the FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the expected results for the kit with valid quality control as:  i.a.SARS-CoV-2 Not Detected  and the policies and procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these samples would now be considered Invalid. See also D5800.  Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm.  A memorandum was provided to Color Genomics and OptumServe for the samples mentioned. They confirmed receipt.  (3) Preventative Action: No revision is placed into use until Dr. Rosendorff has signed off. Monthly audits for data integrity are performed.	D5411	iii. Review of the sam Title SARS-CoV-2-R' Jena, Effective Date following thermal cyc Step Temperature 1 25 degrees Celsi 2 50 degrees Celsi 3 95 degrees Celsi 3 95 degrees Celsi 5 60 degrees Celsi 5 60 degrees Celsi 60 degrees Celsi v. The instruction to during the final 60 despecified in laborator (ii) and d (iii) is not the IFU, which indicasignal during the final v. The laboratory famanufacturer's instruvi. The laboratory famanufacturer's instruvi. The laboratory famanufacturer's instruction of the above-described parameters.  e. Interpretation of i. Review of the FI Coronavirus Nucleic of Date 03/20/2020, Re 01/12/2021) stated the kit with valid quality of the same control of the coronavirus nucleic of the same control of the same	re policies and procedum T-PCR Using the Analy 11/04/2020, indicated to lers dated 10/27/2020.  Time # of Cyclins 2 minutes 1 in 15 minutes 1	cles  60  signal lin d ion in ce tep."  TU.  t der	D5411	Deviation from IFU outcomes: The clinical sighigh Ct values is a subject of scientific debate.  IFU gives only a positive or negative interpretated decision was made to interpret high Ct values from negative or no Ct values:  - Negative (no virus detected)  - Inconclusive / presumptive positive (high Cdd)  37 - < 42)  - Positive (virus detected with Ct value < 37) No post-analytical interpretative decision. This is not the method described in the IFU and has not the performance of the assay.  (1) Immediate Corrective Action: A full-time Laboratory Director, who is directly involved il laboratory operations and result reporting. De regarding data interpretation area now made is manner. Interpretation of Ct values has been to Rosendorff, the CDPH Leadership and the Testorce  (2) Patient Impact: Based on the lookback from 28, 2020 to December 11, 2020, there were 8,73 with results of IC Dropout that were reported with the SOP that was in effect by written appropring the CDPH lab directors. Results were correctly inconclusive pursuant to the lab SOP. However and the policies and procedures were community of finalized in a revised SOP until December indicating these samples would now be considered as a considered patient action (reference) and procedures were community finalized in a revised SOP until December indicating these samples would not be a change in treatment, or recommended patient action (reference) and procedures were community or recommended patient action (reference) and procedures were community or recommended patient action (reference) and procedures were community or recommended patient action (reference) and procedures were community or recommended patient action (reference).  A memorandum was provided to Color Genor OptumServe for the samples mentioned. They receipt.	Although the tion, the differently  t value  ote that is a not a change impact on  c, on-site in day-to-day cisions in a timely etted by Dr. ting Task  oval from oval from reported as r, the IFU v5 icated but 13, 2020 ered Invalid.  the future diagnosis, resting), and inics and confirmed  into use	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/			G	(X3) DATE SUP COMPLET				
	05D21974	116	B. WING		02/17/20				
CDPH BRANCH LABORATORY 284			DDRESS, CITY, STATE, ZIP CODE 4 LIVINGSTON AVE ENCIA, CA 91355						
PRÉFIX (EACH DEFICIENCY N	Y STATEMENT OF DEFICIENC!E MUST BE PRECEDED BY FULL RI CIDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	(X5) COMPLETION DATE			
ii. Based on inter Director on 12/08// laboratory should  ii.a.SARS- ii.b.SARS- ii.c.Inconc ii.d. Invalid  iii. At the time of in 12/09/2020, the la performance spec updated interpreta inconclusive result  2. The following the 60 randomly re covering the perior 12/08/2020, where SARS-CoV-2 tests failed to establish	view with the Laboratory 2020 and 12/09/2020, the be reporting the following CoV-2 Not Detected CoV-2 Detected lusive I respection on 12/08/2020 a boratory failed to provide iffication studies to supportion of test results, to include a coviewed patient test record from 11/22/2020 to sein the laboratory performs and reported results, but its RT-PCR in vitro diagnosted in the listed items "1a	and rt the lude ers of rds led t ostic	D5411	Continued from page 53  (4)Monitoring Mechanism: Recent versic RPT-SOP-002 (v4, v5, and v6) were mad approved in a timely manner. To ensure between LIMC and Color, check of 10 ra are performed each month going forward quality review. An audit was conducted 210 randomly selected samples from Januintegrity between LIMC and Color was c 10 samples via a routine tracer audit perfebeb2021. An audit of an additional 25 be performed beginning 11Mar2021.  Finding 2-4: Please see findings 1a - 1e a See Attachment 9	e and data integrity ndom samples d as part of 26Feb2021 on ary 2021. Data onfirmed for formed samples will				

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE		1 ' '	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, STA LIVINGSTON CIA, CA 913	AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOLD CROSS-REFERENCED TO THE APPRIDEFICIENCY)	LDBE	(X5) COMPLETION DATE
D54 <u>11</u>	Continued From pag	je 54		D5411			
							29
	declaration signed by 12/16/2020, the labor	00 SARS-CoV-2 test res	ron				
	12, 2021 at approximal laboratory's failure to instructions specified director also affirmed performance specific modification of the property of the laborato RT-PCR in vitro diag	follow manufacturer's in the IFU. The laborat	tory t the				
D5415	TEST SYSTEMS, ECINSTRUMENTS, RECFR(s): 493.1252(c)	AGENT		D5415			8Mar2021

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER			PLE CONSTRUCTION	(X3) DATE SUF COMPLET		
	05D2197416			B. WING 02/1			7/2021	
	ROVIDER OR SUPPLIER	Y	28454 LI	ADDRESS, CITY, STATE, ZIP CODE  54 LIVINGSTON AVE  LENCIA, CA 91355				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	(X5) COMPLETION DATE		
D5415	Reagents, solutions, materials, calibration supplies, as approprindicate the following (1) Identity and when or concentration.  (2) Storage requirem: (3) Preparation and e Other pertinent information.  This Standard is not Based on direct obselaboratory staff on Dereview of policies and control (QC) and qual random review of pathe period from 11/22 out of 60 patient test determined that the labeled the reagents.  Findingsincluded:  1. Review of the lab procedures (Policy # Labeling of Reagents Date 12/09/2020) staron labeling reagents:  a. Name of the read b. Expiration Date c. Initials of the period. Date of preparat reconstituted by the lee. Storage condition exposure to light, etc. manufacturer	culture media, control materials, and other iate, must be labeled to significant, titer, strengents. expiration dates, mation required for promet as evidenced by: evation, interviews with ecember 8 and 9, 2020 diprocedures (P/P), quality assurance (QA) receitent test records coverient test records coverient test records reviewed, it was as required.  CA-LABGEN-SOP-002 and CA-LABGEN-SOP-002 and Solutions, Effectived the following information, filtered, or aboratory (if applicable ion, filtered, or aboratory (if applicable ins (e.g., temperature,	per use.  ality ords, ing or 60 as ure it	D5415	Finding 1-5:  We acknowledge that labeling of some reagincomplete and are working to improve cor Supervisors and managers were instructed trefamiliarize the staff with proper procedur labeling reagents. Monitoring of labeling is  (1) Immediate Corrective Action:  • Procedures have been reviewed with technical staff have been re-assigned related procedures: CA-LABGEN-SC (Labeling of Reagents and Solutions)  • Supervisor checklists that include revelabeling are now in use.  (2) Patient Impact: Per Lab Director Dr. Here is no change in diagnosis, treatmerecommended patient action (retesting there would not be patient harm.  (3) Preventative Measure:  • An audit carried out 26Feb2021 has bused to provide feedback to Manager Supervisors.  • Supervisor checklists that include revelabeling are now in use.  (4) Monitoring mechanism: Weekly audit performed by the labortory supervisors.  See Attachment 2:	npliance. o o es for ongoing.  staff and all reading of DP-002  riew reagent  Rosendorff, ent, or c), and  seen be s and  riew reagent  tit is		
	manufacturer f. Any relevant bio							

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER.			LE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
	05D2197	416	B. WING		02	/17/2021	
NAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATI	DRY	28454	PRESS, CITY, STA LIVINGSTON ICIA, CA 913	IAVE			
PRETIX (EACH DEFICIENCY I	SUMMARY STATEMENT OF DEFICIENCIES  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY  OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF ( (EACH CORRECTIVE ACTI CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
approximately 10: found with the fol properly:  a. Elution Buffel b. Magnetic Buf c. Milli Q Water person, date  3. The following the 60 randomly r covering the period 12/08/2020, when SARS-CoV-2 test	ratory tour on 12/08/2020 00 a.m., the laboratory wowing reagents not label ex 1- No initial of the pers fer x1 - No initial of the per ex 3- No expiration date, in prepared, storage condition are the accession number eviewed patient test reco d from 11/22/2020 to ein the laboratory perform and reported results but were labeled as required.	vas led  on erson iitial of the on.  ers of rds	D5415				

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WING \_ 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5415 Continued From page 57 D5415 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory's failure to label the reagents utilized for testing. D5417 D5417 8Mar2021 TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure reagents were not used past the labeled

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION מו (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5417 | Finding 1-5: Continued From page 58 The laboratory has an Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved expiration dates. by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and Findings included: construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample During the laboratory tour on 12/08/2020 at flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosolapproximately 10:30 am., the laboratory was observed to have four 70% Ethanol Cleaning resistant pipette tips, dedicated refrigerators/freezers to Solution in dispensing bottles beyond its separate reagents and samples, and asceptic cleaning expiration date. techniques all of work areas and equipment. The observation made at time of inspection stated that the a.1. Lot # 267015, ExpirationDate: lab use of 70% ethanol did not match the EUA and our 12/03/2020 (2 dispensing bottles) procedure (see section 5.7.2). a.2. Lot # A10012002B, ExpirationDate: Additionally, a default Safety statement was included in 12/07/2020 (2 dispensing bottles) the technical SOPS (listed in the findings) that contradicted the current approved practice and the Laboratory Quality Management Plan (approved by the 2. Review of the laboratories policies and director and in effect at time of inspection (CA-QMprocedures (Policy # CA-QM-SOP-001, title SOP-001 va effective 12OCT 2020) did not provide the robust environmental prevention and decontamination initiatives outlined in the Amplicon Contamination Quality Management Plan, Effective Date 11/01/2020) stated that reagents and chemicals Prevention Plan. should be used in testing process within their The FDA EUA instructions for use of the PKI nucelic indicated expiration date. Acid detection kit provided possible actions for preventing contamination; The decontamination prevention instructions do not impact the performance 3. The following are the accession numbers of characteristics of the test and it is the Laboratory the 60 randomly reviewed patient test records Director who determines the contamination prevention covering the period from 11/22/2020 to and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work 12/08/2020, wherein the laboratory performed surface area and the instruments is not approved by the SARS-CoV-2 tests and reported results but failed Laboratory Director and therefore not included in the to ensure reagents were not used past the contamination prevention plan. expiration dates. Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ccession Number ethanol required for decontamination is 60. If continuation sheet Page 59 of 123 Z9Q211 State 2567

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				PLE CONSTRUCTION  3	(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WING		02/1	7/2021
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	ESS, CITY, ST.	ATE, ZIP CODE		
CDPH BR	RANCH LABORATOR	Y		IVINGSTOI CIA, CA 913			
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5417	Continued From pag	e 59		D5417	Continued from page 59		
	4. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,000	poratory's annual testing the laboratory director ratory reported 00 SARS-CoV-2 test res	ron		(1) Immediate Corrective Action:  • Labeling of reagents, materials, and s • Updating of the Quality Managemen (2) Patient Impact: Per Lab Director Dr. I there is no change in diagnosis, treatment, or recommended patient action (retesting), and would not be patient harm. The 70% EtOH expired only a few days indicating that a 60 greater concentration was still present which the CDC guidelines  (3) Preventative measure: The corrective includes re-assigned reading on related pro (4) Monitoring mechanism: Monthly intaudits are be performed by the laboratory s  Appendix A: The Quality Management Plarevised and reorganized to consolidated infabout existing laboratory processes (CA-Q. SOP-001).  See Attachment 1:  The use of 70% EtOH meets the standard s Heat inactivation is an effective method to SARS-CoV-2. Disposal of MTM sample cotubes that have been subjected to heat inactibleach is not necessary. Therefore, the area the samples were handled was adequately decontaminated.	at Plan Rosendorff, or ad there I was % or ch meets  action cedures. ernal upervisors.  In has been formation M-  et by CDC. inactivate ollection tivation in	
	12, 2021 at approxim laboratory failed to m	Director affirmed (Febru lately 2:10 pm) the onitor the expiration da aning solution utilized i	ates				
D5423	ESTABLISHMENT AI PERFORMANCE CFR(s): 493.1253(b)(	ND VERIFICATION OF		D5423			8Mar2021
		modifies an FDA-cleare , or introduces a test s earance or approval					

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBI			PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING_	<u> </u>	02/17/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDRE	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	RANCH LABORATOR	Υ		VINGSTO			
	*		VALENC	IA, CA 91	355		
(X4) ID		TATEMENT OF DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTI	COMPLETION	П
PREFIX TAG		IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	DATE	١
					DEFICIENCY)		
D5423	Continued From pag	je 60		D5423			
	(including methods d	eveloped in-house and					
	standardized method	ls such as text book	- 1				
		a test system in which				N .	-
		ations are not provided	•				-
		st, before reporting pat					- 1
		for each test system the following	ie				- 1
		eristics, as applicable:					-
	(2)(i) Accuracy.	onotion, an approach.					- 1
	(2)(ii) Precision.						
	(2)(iii) Analytical sens	sitivity					
		cificity to include interfe	ring				-
	substances.	smorty to morade intene	11119				- 1
	*	ge of test results for the	e test				- 1
	system.						- 1
		rvals (normal values).					-
		formance characteristic	:				-
	required for test perfo						-
	This Standard is not a						-
		ervation, interviews with ecember 8 and 9, 2020					-
		ry's adopted FDA Appro					-
		er New Coronavirus Nu					-
		al Time Polymerase Cl					-
	Reaction (RT-PCR) p	oolicies and procedures					-
		(QC) and quality assura	ance				
		review of patient test					-
		period from 11/22/2020					
		it of 60 patient test reco					-
	failed to establish and	rmined that the laborat	Uly				
							1
	specifications prior to reporting patient test results.						
	Touris.						
	Findings included:						
	Review of the lab	ooratory's available					
		ation studies, FDA EUA					
		IFU) for Perkin Elmer N					
		Acid Detection Kit, and					

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA			(X2) MULTIPLE CONSTRUCTION (X3) DATE S		(X3) DATE SUF			
AND PLAN O	F CORRECTION	IDENTIFICATIONNUMBI	ER:	A. BUILDING		COMPLETE	ED	
	05D2197416			B. WING			02/17/2021	
NAME OF PR	ROVIDER OR SUPPLIER		STREET ADDRE	SS, CITY, ST.	ATE, ZIP CODE			
CDPH BR	PH BRANCH LABORATORY 284			VINGSTO	NAVE			
	VAL			IA, CA 913	355			
(X4) ID		TATEMENT OF DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTI		(X5) COMPLETION	
PREFIX	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATOR) OR LSC IDENTIFYING INFORMATION)			PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO		DATE	
TAG	OK LGC IDI	-INTIL TINO IN ORMATION		IAG	DEFICIENCY)	,,		
D5422	Continued From page	n 61		D5423				
D5423	current policies and to provide document specifications for the in "a." through "f." as a. Clinical Performa specimens collected individuals.  i. Review of the labor Perkin Elmer New Coronavity of the qualitative det SARS-CoV-2 in humanasopharyngeal swath HCP and anterior naticollected by a HCP of supervision of a HCP including without symmother than the collected by a HCP of supervision of a HCP including without symmother than the collected by a HCP of supervision of the same Elmer New Coronavity (01/12/2021) also MUST further evaluate from ASYMPTOMAT agreed upon post authorized upon post	procedures, the labora ation of established per performance character follows:  Ince Evaluation for from asymptomatic  ratory's FDA EUA and pronavirus Nucleic Acid 2021) stated under the athat, "Your product is section of nucleic acid from an aropharyngeal and be specimens collected under from ANY INDIVIDUA aptoms or other reason affection."  The EUA and IFU for Perrus Nucleic Acid Detection."  The EUA and IFU for Perrus Nucleic Acid Detection."  The EUA and IFU for Perrus Nucleic Acid Detection and Individuals in an FD thorization clinical performation clinical evaluation days of the date of the must be made after the clinical evaluation clinical evaluations and the second and the second and the second and the second action of the se	IFU for datest from by a the st., as to the stion mer unce the stion fitting atting the st. atti	D5423	Finding 1a Clinical performance in asymptomatic peopversion 7 (06Jan2021) of The PerkinElmer' Coronavirus Nucleic Acid Detection Kit IF intended use for the kit is intended for:th qualitative detection of nucleic acid from Sin human oropharyngeal swab and nasophs swab specimens collected by a healthcare p(HCP), and anterior nasal swab specimens an HCP or self-collected under the supervis HCP from any individual, including individual without symptoms or other reasons to susp COVID-19 infection.  The CDPH Branch Laboratory is using this the parameters of intended use.  The IFU also states (page 27): 6. The PerkinElmer New Coronavirus Nucl Detection Kit may be used to test asymptomidividuals, although performance has not demonstrated in an asymptomatic populatiassay has been shown to exhibit high sensit tested with the FDA reference panel.  7. Use of the PerkinElmer New Coronaviru Acid Detection Kit in a general, asymptomascreening population is intended to be used an infection control plan, that may include preventative measures, such as a predefined testing plan or directed testing of high-risk Negative results should not be treated as ded on to preclude current or future infection through community transmission or other Negative results must be considered in the an individual's recent exposures, history, ar of clinical signs and symptoms consistent we COVID-19.  Limitation in the IFU (page 26):  3. Nasal swab specimens self-collected unde supervision of or collected by a healthcare pe tested with the PerkinElmer New Corona Nucleic Acid Detection Kit; however, perfor this specimen type has not been determined  (1) Immediate Corrective Action: None  (2) Patient Impact: Per Lab Director Dr. there is no change in diagnosis, treatment, or recommended patient action (retesting), an would not be patient harm.  (3) Preventive Action: None  (4) Monitoring Mechanism: None	New U, the e e ARS-CoV-2 aryngeal rovider collected by sion of an duals ect kit within leic Acid natic been on. This ivity when s Nucleic atic las part of additional districtional districtional serial individuals. finitive and obtained exposures. context of ad presence with represence with recovered the rovider can avirus remance with recovered the rovider remance with remance with recovered the rovider remance with r		
		uals, as stated by the						

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA A. BUILDING \_\_\_ COMPLETED IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRÉFIX DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5423 Finding 1b: D5423 Continued From page 62 The laboratory has an Amplicon Contamination under the "Conditions of Authorization." Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This v. The laboratory must provide the performance plan describes the measures put in place to prevent contamination that included laboratory design and evaluation for nasal swab specimens construction of air lock doors, environmental controls self-collected under the supervision of or with separate HVAC systems, unidirectional sample collected by a healthcare provider. flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosolb. Decontamination Protocol resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and asceptic cleaning techniques all of work areas and equipment. The i. Review of the laboratory's FDA EUA Instructions for observation made at time of inspection stated that the Use (IFU) for Perkin Elmer New Coronavirus Nucleic lab use of 70% ethanol did not match the EUA and our procedure (See Section 5.7.2). Additionally, a Acid Detection Kit (Effective Date 03/20/2020, Revised default Safety statement was included in the technical 09/16/2020 and 01/12/2021) stated under warnings and precautions #7 that, "Sterile centrifuge tubes and (listed in the findings) that contradicted the current filter-tips should be disposed into a waste bin approved practice and the Laboratory Quality Management Plan (approved by the director and in containing a 10% Sodium Hypochlorite solution. After effect at time of inspection (CA-QM-SOP-001 va the operation, the work area surface and the instrument effective 12OCT 2020) did not provide the robust environmental prevention and decontamination surface should be disinfected with a freshly prepared 10% Sodium Hypochlorite solution, and then cleaned initiatives outlined in the Amplicon Contamination with 75% Ethanol or pure water. Finally, turn on UV Prevention Plan The FDA EUA instructions for use of the PKI nucelic light to disinfect working surfaces for 30 minutes." Acid detection kit provided possible actions for preventing contamination; The decontamination prevention instructions do not impact the ii. Based on direct observation and interview with performance characteristics of the test and it is the the laboratory staff on 12/08/2020, the laboratory Laboratory Director who determines the was utilizing 70% Ethanol as their general contamination prevention and decontamination procedures to be used at the Laboratory. Use of UV decontamination solution. light to disinfect the work surface area and the instruments is not approved by the Laboratory iii Due to safety concerns in using 10% Sodium Director and therefore not included in the contamination prevention plan. Hypochlorite solution with VTM, the laboratory used ethanol. (1)Immediate Corrective Action: Updated all technical protocols to reflect the current disinfectant in use, 70% Ethanol and iv. However, contrary to the specified remove the (See Attachment X for list of ethanol concentration in the IFU, the documents, approval date). AS 70% was already the disinfectant used in the lab, re-training was laboratory used 70% ethanol, and not 75% not required. ethanol. Updated the Quality Management Plan (CA-QM\_SOP-001, Sections 6.3.4.7, 6.5.1, 6.8.1, v. The laboratory failed to follow approved by Lab Director and effective manufacturer's instructions specified in the IFU. 01Mar2021) to reflect contamination prevention and monitoring that is in place, following current Amplicon Contamination Prevention vi. The laboratory also failed to Plan (SAFE-POL-019., v1.1, approved by Lab Director and effective 14Dec202). Staff were provide performance specification

to this document.

assigned to read and acknowledge the changes

studies showing 70% ethanol is an

effective

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI			G	(X3) DATE SURVEY COMPLETED
		05D21974	16	B. WING		02/17/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 LI	ESS, CITY, ST. VINGSTO? CIA, CA 91:		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETION
D5423	decontaminant inste Hypochlorite solution tubes and filter-tips. c. Heat Inactivation i. Review of the la Instructions for Use (Coronavirus Nucleic Date 03/20/2020, Re 01/12/2021) did not i procedures for swab ii. Review of the la procedures (Policy # Inactivation of Viral S following:  ii.a.Use of oven to ii.b.Pre-cool centrif ii.c. The use of cer iii. The laboratory fail the heat inactivation d. Storage Condition asopharyngeal, oroanterior nasal swabs ii. Review of the la Instructions for Use (Coronavirus Nucleic Date 03/20/2020, Re 01/12/2021) stated the oropharyngeal, and a extracted nucleic acid-15 degrees Celsius. iii. Review of the la la Review of the la coronavirus Nucleic Date 03/20/2020, Re 01/12/2021) stated the oropharyngeal, and a extracted nucleic acid-15 degrees Celsius.	ad of 10% Sodium in for discarded centrifue in of Swab Samples boratory's FDA EUA IFU) for Perkin Elmer In Acid Detection Kit (Effectivised 09/16/2020 and include the heat inactive is samples. boratory's policies and CA-EXT-SOP-001 Heil wab Samples indicated indicat	New ctive ation at I the sius or 1 minute about New ective the the 25 to	D5423	(2) Patient Impact: Per Lab Director Dr. F. there is no change in diagnosis, treatment, recommended patient action (retesting), awould not be patient harm. Appropriate questions are helpful in determining wheth contamination has occurred. A patient loo 28OCT2020 to 08DEC2020) and a patient (09DEC2020 to 28FEB2021) was conducte positive and negative controls to look for the viral targets that could indicate contamina was no evidence of contamination as value below 2% threshold. (See Attachment 1) The downward noted is due to a software changer for color compensation and better resolutive attributable to EtOH or % of EtOH used. Rosendorff, the current Lab Director, there contamination of patient samples or test recontamination of patient samples or test recontamination has been found.  (4) Monitoring mechanism: The sign out actively monitoring positive and negative the laboratory supervisors are conduct we Contamination Wipe Tests. There has been of contamination on the instruments, worlinstrumentation, equipment, and comput Attachment 1 for examples of last 4 Wipe to Appendix A: The Quality Management Prevised and reorganized to consolidated in about existing laboratory processes (CA-CSOP-001).  See Attachment 1  The use of 70% EtOH meets the standard Heat inactivation is an effective method to SARS-CoV-2. Disposal of MTM sample of tubes that have been subjected to heat in a bleach is not necessary. Therefore, the are the samples were handled was adequately decontaminated.  Finding 1c:  Heat inactivation is a desirable method for that the infection risk associated with of Sclinical samples is as low as possible. Valid carried out prior the beginning of testing studies with both heat inactivated and not inactivated samples (see validation report at 1:55pm PST on October the 24th). The performance impact on heat inactivated and not inactivated samples (see validation report at 1:55pm PST on October the 24th). The performance impact on heat inactivation.  (1) Immediate Corrective Action: None (2) Patient Impact: Pe	or nd there adaltity control er kback (from lookforward d to review all he presence of tion. There is were well he trend ge allowing on and not Per Dr. e is no esults.  as no evidence manager is controls and ekly no evidence careas, lab ers (See ests).  an has been an adaltity of the control of the contro

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (4) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: (X2) MULTIPLE CONSTRUCTION  A. BUILDING		(3) DATE SURVEY . COMPLETED				
		05D219741	16	B. WING		02/17/2021
	OVIDER OR SUPPLIER  ANCH LABORATORY	,	28454 L	ESS, CITY, STA IVINGSTON CIA, CA 913	AVE	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST	ATEMENT OF DEFICIENCIES BE PRECEDED BY FULL REINTIFYING INFORMATION)	GULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROF DEFICIENCY)	DBE COMPLETION
D5423	RNA/DNA Extraction Effective Date 11/03/2 nucleic acids should be degrees Celsius for low specification studies to conditions requirement acids.  e. Thermal Cycler Final in the service of the lab structions for Use (Incoronavirus Nucleic And Date 03/20/2020, Rev 01/12/2021) stated the set-ups:  Step Temperature 1 37 degrees Celsius 42 degrees Celsius 42 degrees Celsius 42 degrees Celsius 55	Using the Chemagic 30 2020 stated that, "Extra be stored at -84 to -76 and term storage."  ed to provide performat o support the storage at for extracted nucleic charameters  coratory's FDA EUA FU) for Perkin Elmer N acid Detection Kit (Effect vised 09/16/2020 and the following thermal cycle at Time # of Cycle at 2 minutes 1 at 35 minutes 1 at 36 minutes 1 at 37 minutes 1 at 37 minutes 1 at 38 minutes 1 at 39 minutes 1 at 30 minutes 1 at 30 minutes 1 at 31 minutes 1 at 32 minutes 1 at 35 minutes 1 at 36 minutes 1 at 37 m	lew stive ster stees	D5423	Finding 1d: Storage Conditions: The long-term stora -76oC is intended for post-testing storage a change to the method described in the I no impact on the performance of the assa SOP-004 has been modified to note that the condition is for post-testing.  (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dr. there is no change in diagnosis, treatment recommended patient action (retesting), a would not be patient harm.  (3) Preventative measure: None (4) Monitoring mechanism: None  Finding 1e: Thermocycler Parameters: The correct colletemperature is 65oC. A universal .trf file conthe PCR thermocycling conditions is gener PCR Janus program at the time a 384-well up. The .trf file is imported to the AJ therm This file is correct. Records from the PCR for the 60 randomly chosen samples demothe correct temperature is being used (LFS Cycling Parameters). Appendix A of CA-PC SOP-002v1 contained a typographical error was corrected in v2 (approved 26jan2021).  (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosi treatment, or recommended patient actior (retesting), and there would not be patient (3) Preventative measure: None (4) Monitoring mechanism: None See Attachment 12.  Finding 1f: Delayed procedure approval: Please refer to Timeline. Due to discussion among Labor Directors, the procedure used in analysis in a consistent method of interpreted. Refer to Timeline. Due to discussion among Labor Directors, the procedure used in analysis approved in a timely manner. Although not a consistent method of interpretation was Analysis Timeline below).  • 28Oct2020 – 11Nov2020 – results was per the IFU  • 11Nov2020 – 11Dec2020 – a lower set for positive results based on Ct vobserved during validation, reflecting in interpretation from the IFU	E. This is not FU and has yy. CA-EXT-his storage  Rosendorff, or and there  ection intaining ated by the plate is set-ocycler. Ocutput files is strate that Response CR-r. This error  s, and there  to the he difficulty ensus on cally >37 - < Analysis atory was not of approved, used (see overe reported)  Ct cutoff was value

	OF DEFICIENCIE F CORRECTION	:S	(X1) PROVIDER/SUPPI				PLE CONSTRUCTION	(X3) DATE SUR	
ANDPLANO	FGORRECTION		IDENTIFICATION NUMBER:						
			05D2 <sup>-</sup>	197416		B. WING		02/17/2021	
NAME OF PR	OVIDER OR SUP	PLIER		S.			ATE, ZIP CODE		
CDPH BR					VINGSTON IA, CA 913				
				VALENC				(VE)	
(X4) ID PREFIX TAG	(EACH DEFICE	ENCY MUST	ATEMENT OF DEFICIE  BE PRECEDED BY FUNTIFYING INFORMATI	ULL REGUL	LATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROP DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5423	Continued F	ed From page 65				D5423	11D 2020 251 2021 1:11	C( 1 (	
	Step	Temperal	ture Time	#of C	vdes		• 11Dec2020 – 25Jan2021 – high ( 37 - < 42) were interpreted as inconclusive		
	1	Temperature Time #of Cycles  25 degrees 2 minutes Not indicated					• 25Jan2021 – present – high Ct v 42) were interpreted as presumptive positiv	re <	
	2	50 degre Celsiu	15 minutes	Not inc	dicated		Due to scientific discussion and disagreemed laboratory procedure was not approved by laboratory directors until 08Dec2020. Addi- versions were requested with delayed appro-	the tional	
	3	95 degre Celsiu	2 minutes	Not inc	dicated		next week. Although the protocol in use she been approved prior to use, mitigating circu note include:	ould have	
	4	95 degre Celsiu	grees 3 seconds Not indicated grees 30 seconds Not indicated				<ul> <li>Data analysts were trained using the drawhich remained available to them</li> <li>Changes in the interpretation of results</li> </ul>	-	
	5	60 degre Celsiu					handled in LIMC, not determined by de-	ata analysts	
	Title SARS-Jena, Effect following the Step Ter 1 25 degr 2 50 degr 3 95 degr 4 95 degr 5 60 degr *Collect fluo degrees Cei iv. The instrusional during "specified in the IFU, v signal during v. The labor specification	CoV-2-RT ive Date of the person color rescence distribution to be color of the final laborator of the final reatory failed a studies to the color of the final reatory failed a studies to the color of the final reatory failed a studies to the color of the final reatory failed a studies to the color of the final reatory failed a studies to the color of the	us 2 minutes us 15 minutes us 2 minutes us 3 seconds	Analytik ated the 2020.  of Cycles 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	S Ce		to bring the interpretation to resolution. S  o 01Dec2020 Email CDPH Approval of v. o 08Dec2020_Email Final SOP Definition Doc Control o 11Dec2020 Email Changes to Ct Report o 14Dec2020 Email Changes to Ct Report o 16Dec2020 Email Changes to Ct Report o 16Dec2020 Email Changes to Ct Report o 16Dec2020 Email Changes to Ct Report Deviation from IFU outcomes: The clinical significance of high Ct values is a subject of debate. Although the IFU gives only a positive interpretation, the decision was noted interpret high Ct values differently from non Ct values: Negative (no virus detected) Inconclusive / presumptive positive (high -> 37 - < 42) - Positive (virus detected with Ct value < 3) Note that is a post-analytical interpretative. This is not a change to the method describ IFU and has no impact on the performance assay.  (1) Immediate Corrective Action: A full-Laboratory Director, who is directly involted-day laboratory operations and result reduced to the performance of the performance	It is for v1 for ing ing (v2) ing (v3.1) all of scientific titive or nade to egative or in Ct value  7) e decision. Seed in the ee of the itime, on-site ved in day-porting. ea now made alues has	

	ENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED				
		<b>05D2197416</b> B. WING				02/17/2021				
NAME OF P	ROVIDER OR SUPPLIER	R OR SUPPLIER STREE			DDRESS, CITY, STATE, ZIP CODE					
CDPH BI	RANCH LABORATOR	Υ		4 LIVINGSTON AVE ENCIA, CA 91355						
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	(X5) COMPLETION DATE				
D5423	Continued From pag	je 66		D5423	Continued from page 66					
	f. Interpretation of Test Results  i. Review of the FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the expected results for the kit with valid quality control as:  i.a. SARS-CoV-2 Not Detected i.b. SARS-CoV-2 Detected i.c. Invalid  ii. Based on interview with the Laboratory Director on 12/08/2020 and 12/09/2020, the laboratory should be reporting the following:  ii.a. SARS-CoV-2 Not Detected ii.b. SARS-CoV-2 Detected ii.c. Inconclusive ii.d. Invalid  iii. The laboratory added "inconclusive" to the list of expected results. At the time of inspection on 12/08/2020 and 12/09/2020, the laboratory failed to provide performance specification studies for updated interpretation of test results.				(2) Patient Impact: Based on the lookbact October 28, 2020 to December 11, 2020, the 8,756 samples with results of IC Dropout reported consistent with the SOP that was written approval from the CDPH lab direwere correctly reported as inconclusive puthe lab SOP. However, the IFU v5 and the procedures were communicated but not firevised SOP until December 13, 2020 indisamples would now be considered Invalid D5800.	that were tin effect by ctors. Results irsuant to policies and inalized in a cating these				
					Additionally, per Lab Director Dr. Rosenc future change in definition would not be a diagnosis, treatment, or recommended pa (retesting), and there would not be patien  A memorandum was provided to Color G	tient action t harm.				
				ÿ	OptumServe for the samples mentioned. To confirmed receipt.  (3) Preventative Action: No revision to SO process is placed into use until the Lab Din Rosendorff, has provided written approval checklist is being completed at shift chang Data Analyst staff and verified by the Sign Manager.	OP or ector, Dr. l. A daily e by the				
	2. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory modified the procedure listed in the IFU of the SARS-CoV-2 EUA, tested and reported results, but failed to demonstrate it established performance specifications for the performance characteristics enumerated in "1 a. through f." above, including step-by-step performance of the procedure, test calculations, and interpretation of results.		the  /-2 to		(4) Monitoring Mechanism: Recent versic RPT-SOP-002 (v4, v5, and v6) were made approved in a timely manner. To ensure d between LIMC and Color, check of 10 ran samples is performed each month going for part of quality review. An audit was condut 26Feb2021 on 10 randomly selected sampl January 2021. Data integrity between LIM was confirmed for 10 samples via a routine audit performed 26Feb2021. An audit of a 25 samples will be performed beginning 1: Finding 2-4:  Please see responses to Findings 1a - 1f absect Attachment 9	and ata integrity dom orward as acted es from C and Color e tracer n additional l Mar2021.				
	Accession Number				See Attachment 9					

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O			PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED			
		05D21974	16	B. WING		02/1	7/2021		
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE				
CDPH BF	RANCH LABORATOR	Y	28454 L	IVINGSTO	N AVE				
			VALEN	ENCIA, CA 91355					
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG		Ь	(X5) COMPLETION DATE		
D5423	Continued From pag	e 67		D5423					
DE 400	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12  4. The Laboratory E 12, 2021 at approximal laboratory failed to proapplicable performance.	0 SARS-CoV-2 test res /16/2020. Director affirmed (Februately 2:10 pm) the ovide documentation force specification studies	on uits uary r the						
D5433		FUNCTION CHECKS		D5433			8Mar2021		

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED A. BUILDING \_ IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION 02/17/2021 05D2197416 B. WING STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES COMPLETION (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE PREFIX OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5433 Continued From page 68 D5433 CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure the established maintenance protocol for centrifuges were performed and documented. Findings included: Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title Quality Management Plan, Effective Date 11/01/2020) stated that, "Logs are annotated every day of laboratory operation. If the instrument is not used during a regular laboratory workday, the log must indicate that the equipment was not used." 2. During the laboratory tour on 12/08/2020 at approximately 11:00 a.m., the laboratory was found with a centrifuge maintenance log which

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5433 D5433 Findings 1-5 Continued From page 69 1. Non-compliance in reagent labeling and did not annotate every day of laboratory completion of instrument logs has been noted operation. (QER-20-014, QER-20-015, QER-20-017, QER-20-036 and CAPA-20-007) and corrective action has been initiated. Centrifuge SN # JBR20K009, not annotated 2. Supervisors and managers were instructed to on 12/02/2020, 12/03/2020, 12/04/2020, and review good documentation practices
3. Instrument forms have been updated to make clear 12/05/2020. appropriate documentation for a shift when instrument is not in use (see centrifuge log as 3. The following are the accession numbers of example). the 60 randomly reviewed patient test records See Appendix A - The Quality Management Plan covering the period from 11/22/2020 to has been revised and reorganized to consolidated information about existing 12/08/2020, wherein the laboratory failed to laboratory processes (CA-QM-SOP-001). ensure the established maintenance protocol See Attachment 2 were performed and documented. (1) Immediate Corrective Action: Accession Number See CAPA-20-007 Procedures have been reviewed with staff and all technical staff have been reassigned reading of related procedures: CA-DC-SOP-002 (Good Documentation Practices) (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. (3) Preventative Action: An audit carried out 26Feb2021 has been used to provide feedback to Managers and Supervisors. Supervisor checklists that include review of these instrument logs are now in use. (4) Monitoring Mechanism: Weekly audit is performed by the laboratory supervisors. If continuation sheet Page 70 of 123

Z9Q211

State 2567

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
05D219		05D21974	16	B. WING		02/17/2021	
NAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATORY  STREET ADDRESS, CITY, STATE, ZIP CODE  28454 LIVINGSTON AVE  VALENCIA, CA 91355							
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)  (X5) COMPLETION DATE		
	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12  5. The Laboratory I (February 12, 2021 a the laboratory failed to maintenance was per ANALYTIC SYSTEM CFR(s): 493.1289(a) (a) The laboratory multiple of the laboratory multiple	poratory's annual testing the laboratory director attory reported 0 SARS-CoV-2 test rest/16/2020.  Director affirmed the approximately 2:10 properties of ensure centrifuge formed and documente SQUALITY ASSESSM(c)  Just establish and follow rocedures for an ongoing the control of the control	on sults m) d.	D5433	Finding 1a - 1d, 2-4:  Appendix A - The Quality Management F been revised and reorganized to consolidatinformation about existing laboratory pro (CA-QM-SOP-001).	nted	
	analytic systems spee §§493.1251 through4 (c) The laboratory musystems assessment. This Standard is not a Based on direct obsel aboratory staff on Dereview of policies and control (QC) and qual random review of patthe period from 11/22 out of 60 patient test determined that the laand follow written policing ongoing mechanism to	93.1283. ist document all analyti activities.	ality ords, ng or 60 as olish or an		Delayed procedure approval: Please refer Analysis Timeline. This timeline reflects the difficulty in coming to a scientific and clin consensus on how low viral load (high Ct value – specifically > 37 - < 42) reshould be interpreted. Please refer to the Analysis Timeline.  • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as pore 11Nov2020 – 11Dec2020 – a lower Ct ct (<37) was set for positive results based on value observed during validation, reflecting change in interpretation from the IFU (11Dec2020 – 25Jan2021 – high Ct value -< 42) were interpreted as inconclusive 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 342)	he nical esults sitive) ttoff Ct ng a s (> 37	

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WING\_ 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5791 Continued From page 71 Due to scientific discussion and disagreement, a final laboratory procedure was not approved by the analytic systems specified in CFR 493.1251 laboratory directors until 08Dec2020. Additional through 493,1254. versions were requested with delayed approval over the next week. Although the protocol in use should Findingsincluded: have been approved prior to use, mitigating circumstances to note include: 1. Review of the laboratory's policies and - Data analysts were trained using the draft procedures (Policy # CA-QM-SOP-001, Quality protocol, which remained available to them Management Plan, Effective 11/01/2020) failed to - Changes in the interpretation of results were include an ongoing mechanism to perform or handled in LIMC, not determined by data analysts document quality issues regarding the following: - An active discussion was held with CDPH directors to bring the interpretation to resolution. a. The laboratory failed to ensure the procedure manuals for the Perkin Elmer New Coronavirus o 01Dec2020 Email CDPH Approval of v1 o 08Dec2020\_Email Final SOP Definitions for v1 Nucleic Acid Detection Kit Real Time Polymerase for Doc Control Chain Reaction (RT-PCR) in vitro diagnostic test o 11Dec2020 Email Changes to Ct Reporting were established, available, and followed by the o 14Dec2020 Email Changes to Ct Reporting (v2) laboratory staff (See D5401). o 16Dec2020 Email Changes to Ct Reporting (v3.1) See Attachment 9 for additional information b. The laboratory failed to ensure the procedure manuals for Perkin Elmer New Coronavirus (1) Immediate Corrective Action: The specimens in Nucleic Acid Detection Kit Real Time Polymerase question were resulted as per SOP (see D5800). Chain Reaction (RT-PCR) in vitro diagnostic test (2) Patient Impact: See D5800. utilizing Chemagic 360 for the isolation of the viral (3) Preventative Action: No revision to SOP or nucleic acids followed by the RT-PCR assay on process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily Analytik Jena Thermal Cycler met all the checklist is being completed at shift change by the requirements specified in 42 CFR 493.1251(b)(1) Data Analyst staff and verified by the Sign Out - (b)(14) (See D5403). (4) Monitoring Mechanism: Monthly audits for data c. The laboratory failed to ensure the updated integrity are performed as stipulated in the 2021 procedure manuals for Perkin Elmer New audit schedule by the Quality organization. A 10Feb2021 Tracer audit of 10 samples confirmed that Coronavirus Nucleic Acid Detection Kit Real Time the results matched the current SOP 100% of the Polymerase Chain Reaction (RT-PCR) in vitro time. An audit of an additional 25 samples will be diagnostic test utilizing Chemagic 360 for the performed beginning 11Mar2021. isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler, were approved, signed and dated by the current Laboratory Director (See D5407). d. The laboratory failed to ensure it followed the adopted FDA EUA IFU, the subsequent revisions

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED IDENTIFICATION NUMBER: A. BUILDING AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION. SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5791 D5791 Continued From page 72 Finding 1e - 1f, 2-4: to the EUA IFU, and changes made in the See Attachment 2 and D5415 and D5417: Summary: In summary, expired reagents, such as the 70% EtOH, laboratory's policies and procedures (See were only expired by a few days. Since the main D5411). concern of aging EtOH is evaporation and CDC states over 60% EtOH is effective, the risk posed is low. Corrective actions are being taken. The laboratory failed to ensure it labeled reagents as required (See D5415). (1) Immediate Corrective Action: Please see D5415 and D5417 The laboratory failed to ensure it monitored (2) Patient Impact: Please see D5415 and D5417 decontamination solution used for SARS-CoV-2 (3) Preventative Action: Please see D5415 and D5417 RT-PCR have not exceeded the expiration date (4) Monitoring Mechanism: Please see D5415 and (See D5417). D5417. Findings 1g, 2-4. The laboratory failed to ensure it established, See Attachment 13 and D5423: verified, and documented the performance Summary: The laboratory is using this kit within the specification characteristics for its modified FDA limits of the intended use. approved SARS-CoV-2 RT-PCR (See D5423). (1) Immediate Corrective Action: Please see D5423. (2) Patient Impact: Please see D5423. The laboratory failed to ensure the (3) Preventative Action: Please see D5423. established maintenance protocol for centrifuges were performed and documented (4) Monitoring Mechanism: Please see D5423. (SeeD5433). Findings 1h, 2-4: See Attachment 2 and D5433: Summary: In summary, issues with maintenance logs The following are the accession numbers of are primarily good documentation practice and the 60 randomly reviewed patient test records properly completing logs when an instrument is not in covering the period from 11/22/2020 to use. A corrective action plan is in place. 12/08/2020, wherein the laboratory failed to (1) Immediate Corrective Action: Please see D5433. establish and follow written policies and (2) Patient Impact: Please see D5433. procedures for an ongoing mechanism to monitor, assess, and when indicated, correct (3) Preventative Action: Please see D5433. problems identified in the analytic systems (4) Monitoring Mechanism: Please see D5433. If continuation sheet Page 73 of 123 Z9Q211

State 2567

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(XI) PROVIDENSOFFLIER/OLIA		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416		16	B. WING		02/1	7/2021
CDPH BRANCH LABORATORY 28454			28454 LI	ESS, CITY, ST VINGSTOI IA, CA 91:			
			VALENC	IA, CA 51.	J55		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY:  OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVEACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	.DBE	(X5) COMPLETION DATE
D579	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12  4. The Laboratory I 12, 2021 at approxim	0 SARS-CoV-2 test reservine (Februare) 2:10 pm) the neuron there was an ongo, assess and when	ults	D5791			
D5800	POSTANALYTIC SYS CFR(s): 493.1290	STEMS		D5800			8Mar2021
	must meet the applica	performs nonwaived te able postanalytic system .1291 unless HHS app	ms				

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/ IDENTIFICATIONNUME				PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
	05D2197			B. WING		02/17/2021	
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		SS, CITY, ST. VINGSTOR	N AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PROVIDER'S PLAN OF C PREFIX (EACH CORRECTIVE ACTION TAG CROSS-REFERENCED TO THE DEFICIENCY		SHOULD BE COMPLETIO	
D5800	a procedure specified Operations Manual (requivalent quality tesmonitor and evaluate postanalytic systems problems as specifies specialty and subspecialty and	d in Appendix C of the CMS Pub. 7) that provising. The laboratory must the overall quality of the and correct identified d in §493.1299 for each cialty of testing perform met as evidenced by: y of the deficiencies citained that the condition is was not met as mand of Title 42 of the Code ailed to ensure the electroacted and reliably pecific data from the poort destination. (See ailed to ensure its test reinterpretation for 15805).  Tailed to ensure its accurate authorized person, or a for using the test resultation of the condition of the condi	des ust he h ned. ed lated e of tronic bint of esults rate tory ults		(5801/5805/5807/5809/5821) In regard to the samples in question (D5801), we have verifies amples were handled in accordance with the operating procedure (SOP) in place on Dece 2020 (CA-SOP-RPT-002). Based on the input CDPH laboratory directors', it was determine results with IC dropout were better characte Invalid results. This change in classification implemented via the onsite CDPH lab direct discretion on December 11, 2020 with the SC on December 13, 2020. During these two daywere manual reported and staff were trained CDPH lab directors until the LIMC changes implemented. On December 13, 2020, a LIM was implemented into production to automacode calculation thereby reducing any manuintervention by the data analyst staff.  It was observed that the LIMC result of Not listed on the Color patient report as Negative Detected). This has been changed so that in banner (Not Detected) has also been placed. It was observed that the Color patient report values for N and ORF1ab. The CT values have removed and are no longer present on the C as of December 16, 2020.  A memorandum was provided to Color Gen OptumServe for the samples mentioned. The receipt.  Please refer to the Analysis Timeline.  28Oct2020 – 11Nov2020 – results were per the IFU (cutoff < 42 as positive)  11Nov2020 – 11Dec2020 – a lower Ct was set for positive results based on Ct observed during validation, reflecting interpretation from the IFU  11Dec2020 – 25Jan2021 – high Ct value 42) were interpreted as inconclusive  25Jan2021 – present – high Ct values (were interpreted as presumptive position the State of California. The laboratory report of samples to the Testing Test Force, CDPH and Dr. Pan nightly (see VBL Updates). Per laboratory contract with the state, the experimental control failures (invalid) or samples unsatisfactory for testing. The current rate has a supplemented to the control failures (invalid) or samples unsatisfactory for testing. The current rate has a supplemented to the control failures (invalid) or samples unsatisfactory for testin	e standard mber 10, it from the moder 10, it from the led that rized as was ors' DP approved ys, results by the were it compared it is showed CT we been older report omics and ey confirmed it is showed CT with the green there as well. It is showed CT we been older report omics and ey confirmed it is showed CT with the green there as well. It is showed CT we been older report omics and ey confirmed it is showed CT with the green in it is showed it is that were has been it is showed	
	patient test results or	ı tım <b>ie</b> (See D5815).			consistently ~0.5%. Several factors contributingly	te to this	

NAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATORY  STREET ADDRESS, CITY, STATE, ZIP CODE  28454 LIVINGSTON AVE  VALENCIA, CA 91355  DEADLY  GRACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  DESON  Continued From page 75  6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821)  7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)  D5801  D5801  TEST REPORT  CFR(s): 493.1291(a)  The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:  (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically transmitted results and patient-specific data electronically reported from calculated data. (a)(2) Results and patient-specific data electronically remained or electronically transmitted results and patient-specific data electronically reported from calculated data. (a)(3) Manually transcribed or electronically transmitted results and patient-specific data electronically reported from counts and patient-specific data electronically reported from calculated data. (a)(3) Manually transcribed or electronically transmitted results and patient-specific data electronically reported from calculated data. (a)(3) Manually transcribed or electronically transmitted results and patient-specific data electronically reported from calculated data. (a)(3) Manually transcribed or electronically transmitted results and patient-specific data electronically reported on the work of the patient specific dat	STATEMENT	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C	LIA	(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY	
STREET ADDRESS, CITY, STATE, JP CODE 28464 LIVINGSTON AVE VALENCIA, CA 91355  DESCRIPTION MUST BE PRECEDED BY FULL REGULATORY TAG  CONTINUED From page 75  6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821)  7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)  D5801  TEST REPORT  CFR(s): 493.1291(a)  D5807  The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific data electronically reported directly or upon receipt from outside referral laboratories, satellite or outside referral labora	AND PLAN OF CORRECTION IDENTIFICATIONNUMBER:				A. BUILDING		COMPLETED	
COPH BRANCH LABORATORY   28454 LIVINGSTON AVE VALENCIA, CA 91355			05D21974	16	B. WING		02/17	7/2021
Summary STATEMENT OF DEFICIENCIES   PROVIDER'S PLAN OF CORRECTION   CASO   CA	NAME OF PR	OVIDER OR SUPPLIER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE		
D5800 Continued From page 75  6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821)  7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)  D5801 TEST REPORT CFR(s): 493.1291(a)  The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:  (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported directly or upon receipt from outside referral laboratories, satellite or policit of care resting logistics.	CDPH BR	ANCH LABORATOR	Υ	28454 LI	VINGSTO	NAVE		
DS800   Continued From page 75				VALENC	IA, CA 913	355		
6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821)  7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)  TEST REPORT CFR(s): 493.1291(a)  The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:  (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically transmitted results and patient-specific (adata electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.	PREFIX	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	D BE	COMPLETION
6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821)  7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)  D5801  TEST REPORT CFR(s): 493.1291(a)  The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:  (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems.  (a)(3) Manually transcribed or electronically transmitted results and patient-specific data electronically reported directly or upon receipt from outside referral laboratories, satellite or outside referral laboratories, satellite or outside referral laboratories, satellite or outside referral laboratories, as allelite or one of the patient specific on the color patient report as Negative variety and reliably served that the LIMC result of Not Detected was listed on the Color patient report as Negative variety and reliable to result and patient-specific or the color patient report as Negative variety and reliable to result of Not Detected was listed on the Color patient report as Negative variety of the Color patient report as Negative variety to the Color patient report as Negative variety to the color patient report as Negative variety and reliable to result of Not Detected was listed on the Color patient report as Negative variety and reliable to result of Not Detect	D5800	Continued From page	e 75		D5800	Continued from page 75		
This Standard is not met as evidenced by:  Based on direct observation, interviews with  laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure  (Not Detected). This has been changed so that in the green banner (Not Detected) has also been placed there as well.  It was observed that the Color patient report showed CT values for N and ORF1ab. The CT values have been removed and are no longer present on the Color report as of December 16, 2020.  A memorandum was provided to Color Genomics and OptumServe for the samples mentioned. They confirmed receipt.		6. The laboratory fanotified and issued cauthorized person or results and maintaine report (See D5821)  7. The laboratory fawritten policies and pmechanism to monitorindicated, correct propostanalytic systems. TEST REPORT CFR(s): 493.1291(a)  The laboratory must be electronic system(s) results and other pata accurately and reliabentry (whether interfainal report destination includes the following (a)(1) Results report (a)(2) Results and pate electronically reported systems.  (a)(3) Manually transtransmitted results a information reported outside referral laboratory staff on Dreview of policies and control (QC) and quarandom review of pathe period from 12/0 out of 32 patient test	ailed to ensure it promporrected reports to the individual using the test of duplicates of the original duplicates of the original duplicates of the original duplicates for an ongoing assess, and when oblems identified in the (See D5891)  The ave an adequate manual in place to ensure test itent-specific data are ly sent from the point of aced or entered manual in, in a timely manner. It is a timely manner. It is a timely manual in a timely manner. It is a timely manual in a timely manner. It is a timely manual in a timely manual in a timely manner. It is a timely manual in a t	st inal low ing ing for 32 as		a. Staff "superuser" training b. Improvement to Janus Reformatter and C protocols c. Evidence provided at on-site inspection as CAPA-20-002 Both the LIMC User Specification and the L Acceptance forms were signed by both Labo Directors is provided. The effective date 290 the date the blank form (template) was effect In summary, there is scientific and clinical or regarding the best interpretation of high Ct reports issues did match the analysis rules in time of sample processing. To manage this field, a full-time, on-site Laboratory Directo directly involved in day-to-day laboratory o and result reporting has been hired so that or regarding data interpretation area now mad manner, with consultation of CDPH Leader Testing Taskforce  The below details are for D5801, D5805, D5809, D5821  In regard to the 19 samples in question (D have verified that the samples were handla accordance with the standard operating p (SOP) in place on December 10, 2020 (CA RPT-002). Based on the input from the Cl laboratory directors', it was determined th with IC dropout were better characterized results. This change in classification was in via the onsite CDPH lab directors' discret December 11, 2020 with the SOP approve December 13, 2020. During these two day were manual reported and staff were train CDPH lab directors until the LIMC chang implemented. On December 13, 2020, a L was implemented into production to auto code calculation thereby reducing any ma intervention by the data analyst staff.  It was observed that the LIMC result of N was listed on the Color patient report as N (Not Detected). This has been changed so green banner (Not Detected) has also been there as well.  It was observed that the Color patient report as of December 16, 2020.  A memorandum was provided to Color G and OptumServe for the samples mention	s part of  User Variatory Oct 2020 is tive. We be be the values. All a place at the evolving r, who is perations lecisions e in a timely ship, the  D5807,  D5807,  D5807,  D5801), we did in roccedure 1-SOP-DPH water results was Invalid mplemented ion on d on s, results led by the test were iMC update mated result nual  ot Detected Legative that in the a placed wort showed we have on the Color enomics	8Mar2021

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION  A. BUILDING		(X3) DATE SURVEY COMPLETED				
	05D2197416				B. WING 02/17/2021				
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		ESS, CITY, ST. VINGSTOI CIA, CA 91:	NAVE				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE COMPLETION DATE			
D5801	the electronic system reliably transmitted point of data entry to Findings included:  1. The laboratory sand postanalytic phaentity, COLOR.  2. The following 13 emailed by the laboratory to the laboratory to the exa 12/22/2020 showed sSARS-CoV-2.  b. The final test resishowed a final result Nor DETECTED No.	atient-specific data, from final report destination final report destination subcontracts the preanalises of testing to an out of the final patient test report atory on 01/06/2021 were for SARS-CoV-2.  LIMC LIS report sent by the final patient sent by the final on a result of "Not Detected stult generated by COLC state of the final patient sent by the final patient sent sent sent sent sent sent sent s	m the slytic side the difference of the DR	D5801	Continued from page 76  Please refer to the Analysis Timeline.  • 28Oct2020 – 11Nov2020 – results we reported as per the IFU (cutoff < 42)  • 11Nov2020 – 11Dec2020 – a lower ( (37) was set for positive results bas value observed during validation, rechange in interpretation from the IF   • 11Dec2020 – 25Jan2021 – high Ct variety of the conclus of the conclusion of the conc	as positive) Ct cutoff ed on Ct flecting a EU alues (> 37 ive d as es (> 37 - < al reports in original  MS API EDIE and lifornia al public  specimens in k forward , 2020 er SOP emoved from , 2020. ck from there were that were s in effect by ectors. clusive EU v5 and the ated but not r 13, 2020 onsidered was provided sible for ent that these			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING \_ AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE **VALENCIA, CA 91355** SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (X4) ID ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5801 D5801 Continued From page 77 Continued from page 77 Additionally, per Lab Director Dr. Rosendorff, the 3. Review of the e-mail communication sent by future change in definition would not be a change in the Director of Clinical Informatics on 12/13/2020, diagnosis, treatment, or recommended patient action and review of the 32 patient test records obtained (retesting), and there would not be patient harm. by the examiners on December 16, 2020 showed: (3) Preventative Action: No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, Thirteen (13) patient results were reported has provided written approval. A daily checklist is being completed at shift change by the Data Analyst staff and as "Not Detected" when it should have been verified by the Sign Out Manager. reported "Inconclusive" on December 10, 2020. (4) Monitoring Mechanism: Monthly audits for data integrity are performed as stipulated in the 2021 audit Reported as Not Detected, but should be schedule by the Quality organization. A 23Feb2021 Tracer audit of 10 samples confirmed that the results reported as Inconclusive matched the current SOP 100% of the time. An audit of an additional 25 samples will be performed beginning 11Mar2021. Appendix B Sample Look Back and Look Forward 2021 Audit Schedule End to End Audit Plan 2021Audit-004 Report Color Genomics - Memorandum to File OptumServe - Memorandum to File Dr\_Pan\_Receipt\_of\_Corrected\_Letters Corrected Letters Draft Corrected Reports Original Reports Dr\_Pan\_Receipt\_of\_Draft\_Corrected\_Reports OptumServe\_Receipt\_Memorandum Color Genomics\_Receipt\_Memorandum b. Nineteen (19) patient results were reported as "Inconclusive" when it should have been reported as "Invalid" on December 10, 2020.

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/ AND PLAN OF CORRECTION IDENTIFICATION NUMBER					(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WING		02/17/2021	
	NAME OF PROVIDER OR SUPPLIER  CDPH BRANCH LABORATORY			ESS, CITY, ST.			
(X4) ID PREFIX TAG	FIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL RECARD OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5801	Continued From pag	ge 78		D5801			
	Reported as Inconcluas Invalid.	usive but should be rep	orted				
127			9				
						,	
			9				
	LIMC LIS, and the ou	ailed to show the itted results between its tside entity subcontract tre periodically verified	ed				
	declaration signed by 12/16/2020, the labo	00 SARS-CoV-2 test res	ron		×		

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES IDENTIFICATIONNUMBER: A. BUILDING \_ COMPLETED AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES ΙD (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PRETIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5801 D5801 Continued From page 79 patient-specific data, from the point of data entry to final report destination. D5805 8Mar2021 D5805 TEST REPORT See response started in D5801 CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure its test report provided the correct interpretation for SARS-CoV-2. Findings included: 1. Based on interview with the laboratory director on 12/08/2020, there were several patient test results reported in error as a result of incorrect data analysis and interpretation, such "Not Detected" for SARS-Cov-2 should have

	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/ ID PLAN OF CORRECTION IDENTIFICATIONNUMBER				PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
	05D2197416			16	B. WING		02/1	7/2021
NAME OF PE	ROVIDER OR SUPPLIER	***		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Υ			VINGSTO			
				VALENC	IA, CA 913	355		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATOR)  OR LSC IDENTIFYING INFORMATION)				ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	ULD BE	(X5) COMPLETION DATE
D5805	Continued From pag	ne 80			D5805			
00000	been "Inconclusive" b. "Inconclusive" for SARS-CoV-2 should have been true "Invalid"  2. Based on review of CDPH Branch Lab LIMC LIS reports emailed on 12/22/2020 and SARS-CoV-2 final patient test reports emailed by the laboratory director on 01/06/2021 from COLOR, the laboratory failed to provide the correct interpretation of results to the patients, and how the laboratory conveyed this information				20000			
				have				
				ed by				
						•		
	to its clients.							
	a. In an e-mail com							
	laboratory director or							
	asked if corrected reparted affected patients. The			ie				
	indicated that reports							
	provide the correct in							
	because COLOR did			stem				
	to issue corrected rep	ports.						
	NOT DETECTED	Reported	Correct Int	erpretation				
	NOT DETECTED	Negative	-	clusive				
		Negative		clusive				
		Negative	Incon	clusive				
		Negative	Incon	clusive				
		Negative		clusive				
	_	Negative		clusive				
		Negative		clusive				
	-	Negative Negative		clusive clusive				
	-	Negative		clusive				
		Negative	\$	clusive				
		Negative		clusive				
		Negative	Incon	clusive				
		Negative	Incon	clusive				
	_	Negative	Incon	clusive				
		Negative	Incon	clusive				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
			05D21974	16	B. WING		02/1	7/2021
NAME OF PR	OVIDER OR SUPPLIER	-		STREET ADDRE	SS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATO	RY		28454 LÌ	VINGSTON	NAVE		
				VALENC	IA, CA 913	355		
(X4) ID			F DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTI		(X5) COMPLETION
PREFIX TAG	(EACH DEFICIENCY MU			GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO		DATE
IAG	OR LSC IDENTIFYING INFORMATION)			170	DEFICIENCY)			
D5805	5 Continued From page 81			D5805				
	INCONCLUSIVE	Reported	Correct Interp					
		Inconclusive	ilsvali	41791414141414141414141				
	****	Inconclusive Inconclusive	ilgynl ilgynl					
		Inconclusive	Invali					
	***	nconclusive	Invali					
		nconclusive	Invali	***************************************				
		nconclusive	Invali					
	Inconclusive Invalid Inconclusive Invalid Inconclusive Invalid Inconclusive Invalid		đ					
			đ					
			1474774					
		nconclusive	Invali					
	***	nconclusive	Invali	***************************************				
		Inconclusive Inconclusive	ilsvali Invali					
	******	nconclusive	Invali					
		nconclusive	ilevni	1-140				
	*****	Inconclusive	Invali					
		Inconclusive	Invali	d				
				21				
	3. Based on the la	ahoratory's	annual testin	a				
	declaration signed I							
	12/16/2020, the lab	•	-					
	approximately 430,0			sults				
	from 11/02/2020 to							
	4. The Laboratory	Director af	firmed					
	(01/12/2021 at appi							
	through email comr			atory				
	failed to ensure its t							
	correct interpretatio	n for SARS	-CoV-2.					
	TEST REPORT			,	D5807	See response started in D5801		8Mar2021
D5807	CFR(s): 493.1291(d	4)						
	O. 11(0). 400.1201(0	^/						
	Pertinent "reference	e intervals" o	or "normal" v	alues,				
	as determined by the							
	tests, must be avail							
	who ordered the tes							
	individual responsib		•					

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CL IDENTIFICATION NUMBER				PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/1	7/2021
CDPH BRANCH LABORATORY 2845			28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91			V
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5807	This Standard is not Based on direct obse and procedures, qua assurance (QA) reco conducted with the la laboratory failed to erintervals determined available for the auth responsible for using Findings included:  1. Based on review SARS-CoV-2, the labtest result and specific value, "To learn more of the test, please se limitation section."  2. Review of the test limitation section did laboratory determined Negative, Inconclusive The report also indicated Elmer New Coronavirus (IFU)."  Review of Perkin Elmandid Detection Kit FD New Coronavirus Nuro 3/20/2020, Revised	met as evidenced by: ervation, review of policility control (QC) and quited, and interviews aboratory staff, the insure its accurate refer by the laboratory were orized person, or individent test results.  If of patient test reports for about the test methodology at reports methodology not indicate how the dist results (Positive, re, and Invalid).  The test reference, "Per rus Nucleic Acid Detect AUS Instructions for Later New Coronavirus Nucleic Acid (Effective Date of the policy of the	for the d(Ct) etails and and kin tion lise licleic or PE	D5807			

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED A. BUILDING \_ AND PLAN OF CORRECTION IDENTIFICATION NUMBER: 05D2197416 B. WING \_ 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5807 D5807 Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations a. Detected b. Not Detected c. Inconclusive d. Invalid 3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results. INCONCLUSIVE **NOT DETECTED** (Should be Invalid) ff continuation sheet Page 84 of 123 Z9Q211 State 2567

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATIONNUMBER: A. BUILDING AND PLAN OF CORRECTION 02/17/2021 B. WING\_ 05D2197416 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5)PROVIDER'S PLAN OF CORRECTION ID SUMMARY STATEMENT OF DEFICIENCIES COMPLETION (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5807 Continued From page 84 D5807 Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed on (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results. **TEST REPORT** 8Mar2021 D5809 See response started in D5801 D5809 CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients regarding changes in the interpretation of results. Findings included: Based on email communication with the 1.

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED. A. BUILDING \_ IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5)PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES COMPLETION (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5809 D5809 Continued From page 85 laboratory director on 01/12/2021, and review of patients reported on 12/10/2020: a. Results were reported as "Not detected" or "Negative" but should have been reported as "Inconclusive" b. Results were reported as "Inconclusive "but should have been true "Invalid" The laboratory failed to ensure it updated their clients regarding change in the interpretation of results. The laboratory's outside entity subcontractor, failed to issue corrected reports because the current system it used is not capable of issuing corrected reports. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure it updated their clients regarding changed in the interpretation of results. Below are test results that were reported as "Negative", but the correct result should have been "Inconclusive" **Final Test Report** NOT DETECTED LIMC Report Negative for SARS-CoV-2 Not Detected Negative for SARS-CoV-2 Not Detected Negative for SARS-CoV-2 Not Detected Not Detected Negative for SARS-CoV-2 Negative for SARS-CoV-2 Not Detected Not Detected Negative for SARS-CoV-2 Negative for SARS-CoV-2 Not Detected Negative for SARS-CoV-2 Not Detected Negative for SARS-CoV-2 **Not Detected** Negative for SARS-CoV-2 Not Detected If continuation sheet Page 86 of 123 Z9Q211

State 2567

	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
			05D21974	16	B. WING		02/17/2021	
NAME OF PR	OVIDER OR SUPPLIER	₹		STREET ADD	DRESS, CITY, ST.	ATE, ZIP CODE	-	
CDPH BR	ANCH LABORA	TORY			LIVINGSTO			
				VALEN	ICIA, CA 913	355		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ARY STATEMENT O Y MUST BE PRECED .SC IDENTIFYING IN	DED BY FULL RE		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETIC	ON
D5809	Continued From page 86			D5809				
	b. Below are test results that were reported as "Inconclusive", but the correct result should have been "Invalid"							
	INCONCLUSIVE	Reported	Correct Inte	rpretation		8		
		Inconclusive	Inva					
		Inconclusive	Inva	******				
		Inconclusive Inconclusive	Inva Inva	******				
		Inconclusive	Inva					
		Inconclusive	Inva					
		Inconclusive	Inva	******				
		Inconclusive	Inva	lid				
		Inconclusive	Inva	lid				
		Inconclusive	Inva					
		Inconclusive	Inva					
		Inconclusive	Inva					
7		Inconclusive Inconclusive	Inva Inva					
		Inconclusive	Inva	***************************************				
		Inconclusive	Inva				20	
		Inconclusive	Inva					
		Inconclusive	Inva	lid				
		Inconclusive	Inva	lid				
				1.				
							_	
				.22				2
						_		
								- 1

STATEMENT OF DEFICIENCIES (X AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/O IDENTIFICATIONNUMB				(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
	ROVIDER OR SUPPLIER	v			ATE, ZIP CODE		
CDFN B				LIVINGSTO ICIA, CA 91			
(X4) ID PREFIX TAG				ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROFILE (PROVIDER OF THE APPROFILE OF	DBE	(X5) COMPLETION DATE
D5809	Continued From pag	e 87		D5809			
	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12  5. The Laboratory I (01/12/2021 at 11:58 communication that the signature of the signatu	0 SARS-CoV-2 test res /16/2020. Director affirmed a.m.) through email he laboratory failed to dients regarding changlesults because the	r on sults			×	
D5815	TEST REPORT CFR(s): 493.1291(h)  When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.  This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time.  Findings included:  1. Review of the laboratory's policies and		D5815	Finding 1-5  1. The only client of the CDPH Branch Lat the State of California. The laboratory repostatus of samples to the Testing Test Force Leadership, and Dr. Pan nightly (see VBL) 2. Per the laboratory contract with the state expectation is to meet the 48hr TAT in 959 (1) Immediate Corrective Action: None (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosit treatment, or recommended patient action (retesting), and there would not be patient (3) Preventative Action: None (4) Monitoring Mechanism: The operatimanagers send a daily email summarizing status to CDPH Partners, Color, OptumSe the Task Force.  See Attachment 14	orts the components t	8Mar2021	
	Specimen Collection, Effective Date 12/07/2	CA-CLSRV-SOP-002, Storage, and Shipping 2020) stated, "The for the results is withir	J.				

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CL IDENTIFICATION NUMBER			LIA ER:		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
		05D2197416			B. WING		02/17/	2021
		VIDER OR SUPPLIER	Y		SS, CITY, STAT VINGSTON IA, CA 9135	AVE		,
	(X4) ID PREFIX TAG				ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
		the laboratory directive laboratory start of the samples get to the sa	communication with or on 01/08/2021, that counting for TAT when he laboratory.  It sampling covering the part of 12/10/2020, the laborator of 32 SARS-Coverith no documentation of atient test results.  It sampling covering the part of 12/10/2020, the laborator of 32 SARS-Coverith no documentation of atient test results.  It sampling covering the part of 12/10/2020 of 12/10/2020.  It is a sampling covering the part of 12/10/2020 of 12	Result Inconclusive Inconclusiv	D5815			
	D5821	TEST REPORT CFR(s): 493.1291(l	<b>(x)</b>		D5821	See response started in D5801		8Mar2021
		When errors in the are detected, the la following:	reported patient test real boratory must do the	sults				
			~					

		(X1) PROVIDER/SUPPLIER/C		1	PLE CONSTRUCTION 3	(X3) DATE SURVEY COMPLETED	
	. 55/4/20/10/4					John LETED	
		05D21974	16	B. WING		02/17/2021	
	ROVIDER OR SUPPLIER				ATE, ZIP CODE		
CDPH BR	RANCH LABORATOR	Y		IVINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID <del>PREF</del> IX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	.DBE COMPLETION	
D5821	821 Continued From page 89			D5821			
	(k)(1) Promptly notify ordering the test and, using the test results (k)(2) Issue corrected authorized person or applicable, the individual (k)(3) Maintain duplicable, the individual as the corrected. This Standard is not reported and procedures, qual assurance (QA) recorded assurance (QA) recorded with the late laboratory through Copromptly notified and the authorized person results, and maintained report.  Findings included:  1. Based on email of laboratory director on patients reported on a through COLOR failed.  a. Notification and Is Reports  i. Based on email of laboratory director on	the authorized person if applicable, the indiv of reporting errors. I reports promptly to the dering the test and, if dual using the test resu ates of the original report. The report is evidenced by: evation, review of policity control (QC) and quity control (QC) and quity control (QC) and quity control (QC) and quity control failed to ensure issued corrected report in or individual using the ed duplicates of the original report is evaluated to perform the following suance of Corrected communication with the 01/12/2021, and review 12/10/2020, "Not detect "Inconclusive," and build have been true cory failed to ensure it mended reports to the	idual e lts. ort, as ies ies iality it is to test inal e v of ory ong:				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION			ER/SUPPLIER/C			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
			05D21974	16	B. WNG		02/1	7/2021	
NAME OF PE	ROVIDER OR SUPPLIER			STREET ADD	RESS, CITY, ST	ATE, ZIP CODE			
CDPH BF	RANCH LABORATOR	Υ			LIVINGSTO				
				VALEN	ICIA, CA 913	355			
(X4) ID PREPIX TAG	(EACH DEFICIENCY MUS	ST BE PRECE	F DEFICIENCIES DED BY FULL RE DEORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF COI (EACH CORRECTIVEACTION CROSS-REFERENCED TO THE DEFICIENCY)	ISHOULD BE	(X5) COMPLETION DATE	
D5821	Continued From pag	ge 90			D5821				
	ii. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported 13 out of 13 "Not Detected" but should have been "Inconclusive" and 19 out of 19 "Inconclusive" but should have been "Invalid" for SARS-CoV-2 patient test results.  NOT DETECTED Reported Correct Interpretation			ory ted" out		¥			
	NOT DETECTED	Reported	Correct Inte	rpretation					
		Negative	Inconc						
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
		Negative	Inconc	lusive					
			•						

		T			i i			
	OF DEFICIENCIES		ER/SUPPLIER/CLI		1	PLE CONSTRUCTION	(X3) DATE SU	
AND PLAN O	F CORRECTION	IDENTIF	CATIONNUMBER	₹:	A. BUILDING	3	COMPLE	TED
			050240744		D 14810		1	
			05D2197410	0	B. WING		02/1	7/2021
NAME OF PF	OVIDER OR SUPPLIER			STREET ADDI	RESS, CITY, ST.	ATE, ZIP CODE		
CDPH BR	RANCH LABORATO	RY	- 1	28454 L	LIVINGSTO	N AVE		
			1	VALEN	CIA, CA 913	355		
/Y4) ID	SHMMAD	STATEMENT OF	DEFICIENCIES		ID			(X5)
(X4) ID PREFIX	(EACH DEFICIENCY M			ULATORY	PREFIX			(X5) COMPLETION DATE
TAG	OR LSC	IDENTIFYING INF	FORMATION)		TAG			DAIL
D5821	Continued From p	age 91			D5821			
	INCONCLUSIVE	Reported	Correct Interp	retation				
		Inconclusive	Invali	d				
		Inconclusive	Invali	d				
		Inconclusive	Invali	đ				
	Inconclusive invalid		d					
		Inconclusive	Invafi	d				
		Inconclusive	Invali	d				
		Inconclusive	Invali	<u>d</u>				
	190	Inconclusive	Invali					
	**	Inconclusive	Invali					
	100	Inconclusive	Invali				W.	
	***	Inconclusive	Invali	***************************************				
	and the second s	Inconclusive	Invali	***************************************				
		Inconclusive	Invali					
	The second secon	Inconclusive Inconclusive	Invalid					
	***	Inconclusive	Invali Invali					
	***	Inconclusive	Invali					
	-	Inconclusive	Invali					
		Inconclusive	Invali					
	<ul> <li>b. Maintain dupli</li> </ul>	cates of the o	riginal report					
				1				
	i. Based on revi							_
	emailed by the labo							
	the laboratory thro							
	reports on 12/07/2			V-2				
	results on 12/04/20 original report.	20 williout pi	oviding the					
	ongmaneport.							
	ii. The following	10 out of 109	ARS-CoV-2					
	patient test results							
	F3.10.11 100 100 0110	5.5 amond				100		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
40		05D2	197416	B. WING		02/17/2021	
NAME OF PR	ROVIDER OR SUPPLIER	*	\$TREET AD	DRESS, CITY, STATE	E, ZIP CODE		
CDPH BR	RANCH LABORATOR	RY		LIVINGSTON A			
			VALE	NCIA, CA 9135	5		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE COMP	K5) PLETION ATE
D5821	Continued From page 92		D5821				
		Original Report	Amended				
	Accession #	12/04/2020	12/07/2020				
		Detected	*			80	
		Detected	*				
		Detected	*				
		Not Detected	*			_	
	<u> </u>	Detected	*				
	*****	Detected	*				
		Detected	*				
	•	Detected	*				
		Detected	*				
		Detected	*				
	*Unable to return results for this sample.  Please disregard any previous reports as they were issued in error.  Amended Report: The previously reported result (detected/not detected) is not valid due to a lab process error (Accession #s), Covid-19 Test.  Report Test Date: December 4, 2020  Recommendation: This patient should be retested.  2. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.  3. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report.						

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		1, ,	PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
NAME OF D	OVIDED OD SUIDSUIED		STREET ADDR	ESS CITY ST	ATE ZIR CODE		
	ROVIDER OR SUPPLIER	,					
CDPH BI	RANCH LABORATOR'			IVINGSTOI CIA, CA 91			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIONS (EACH CORRECTIVE ACTIONS HOUL CROSS-REFERENCED TO THE APPROFIDERICIENCY)	DBE	(X5) COMPLETION DATE
	Continued From pag	e 93					
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)		itten	D5891	Finding 1a - b, e-h, o-p:  1. The inconclusive rate for this assay monitored daily. Summaries are sen Testing Task Force daily. Currently, inconclusive samples include only the state of the sample o	it to the	8Mar2021
	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291.				internal control failures (invalid) or that were unsatisfactory for testing. current rate has been consistently ~0.5%. Several factors contribute to including:  a. Staff "superuser" training	samples The	
	This Standard is not met as evidenced by:  1. Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality		2020, ality	£ .	<ul> <li>b. Improvement to Janus Ref and Chemagic protocols</li> <li>c. Evidence provided at on-si inspection as part of CAPA-20-002</li> </ul>		
	control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure there was a mechanism to periodically verify calculated results, results sent to interfaced systems, and patient specific data for SARS-CoV-2.  Findings included:		ing or 32 as ure		<ol> <li>Lack of signed analysis SOP: see Data Analysis Results for 32 samples: see Data Analysis Interpretation Response</li> <li>LIMC documentation: Provided. Please following:         <ul> <li>Both the User Specification and the Acceptance forms signed by both Ladirectors is provided.</li> <li>The effective date 29Oct2020 is the blank form (template) was effective</li> </ul> </li> </ol>	sis and e note the User aboratory date the	
	a. Prior to the scheduled on-site inspection, Laboratory Field Services (LFS) sent an e-mail communication on November 13, 2020, wherein we informed the laboratory that we will be looking into the report of increased number of inconclusive patient test results, published in a news article on November 10, 2020. Below is the except of the e-mail communication:  "Please refer to the following media report:  https://www.newsweek.com/spike-bad-test-result s-californias-new-120m-covid-19-testing-lab-com es-amid-tighter-restrictions-1546522		nail erein oking n a is the		See Attachment 11 and Attachment 14.		

	STATEMENT OF DEFICIENCIES (X1) PROVIDER AND PLAN OF CORRECTION IDENTIFIC		R/SUPPLIER/C			PLE CONSTRUCTION	(X3) DATE SURV COMPLETED			
### COPH BRANCH LABORATORY    28454 LIVINGSTON AVE VALENCIA, CA 91355					05D21974	16	B. WING		02/17/	2021
CAPID BRANCH LABORATORY   28454 LIVINGSTON AVE VALENCIA, CA 91355     CAPID SUMMARY STATEMENT OF DEPICIENCIES   CAPID STREET   CAPID STATEMENT OF DEPICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG   CROSS-REPSEMBLED TO THE APPROPRIATE   DEPICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG   CROSS-REPSEMBLED TO THE APPROPRIATE   DEPICIENCY	NAME OF PE	ROVIDER OR SUPPL	IFR			STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE		
DATE   SUMMARY STATEMENT OF DEFICIENCIES   PROVIDERS PLAN OF CORRECTION   PROPRIETS   PROVIDERS PLAN OF CORRECTION   CAMPAC   PROVIDERS PLAN OF CORRECTION   CAMPAC   CAMPAC   PROVIDERS PLAN OF CORRECTION   CAMPAC   CA				Y		28454 L	LIVINGSTON AVE			
D5891   Continued From page 94	ODI II DI		JATOK	•						
LFS expects full documentation of:  * Evaluation of reported patient tests results during the affected time period. Patient look-back.  * How the lab identified the problem and the corresponding solution.  * What is the corrective action?  * How the lab is monitoring the corrective action?  * How the lab is monitoring the corrective action on 12/08/2020, we interviewed laboratory directors and senior operations personnel, and requested for the laboratory's documented investigation and corrective action regarding the increased number of inconclusive patient results.  c. We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the laboratory adopted test method, Perkin Elmer New Coronavirus Nucleic Acid Detection Kit. The "Examination and Interpretation of Patient Specimen Results" section showed a table listing the expected results for the kit with valid positive and negative control.  **Allow threets with the section of the targets undetermined or >42	PREFIX	(EACH DEFICIEN	NCY MUS	T BE PRÉCEDE	ED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	D BE	(X5) COMPLETION DATE
* Evaluation of reported patient tests results during the affected time period. Patient look-back.  * How the lab identified the problem and the corresponding solution.  * What is the corrective action?  * How the lab is monitoring the corrective action. Is if the fix working?**  b. During the first day of the on-site inspection on 12/08/2020, we interviewed laboratory directors and senior operations personnel, and requested for the laboratory's documented investigation and corrective action regarding the increased number of inconclusive patient results.  c. We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the laboratory's adopted test method, Perkin Elmer New Coronavirus Nucleic Acid Detection Kit. The "Examination and Interpretation of Patient Specimen Results" section showed a table listing the expected results for the kit with valid positive and negative control.    Cycle threshold   Result Interpretation   Inc (VIC/HEX)   NIFAMI, ORFITAB ROX)   SABS-Cov-2 Detected   Invalid result, specimen   In	D5891	1 Continued From page 94				D5891	Continued from page 94			
IC (VIC/HEX) N(FAM), ORF1ab ROX)  Set N(FAM), ORF1ab ROX)  Set No Both targets Undetermined or > 42  J Both targets ≤ 42  J One of the targets ≤ 42  SARS-COV-2 Not Detected  J One of the targets ≤ 42  SARS-COV-2 Detected  Invalid result, specimen  Needs to be re-tested from Undetermined  Undetermined or > 42  Undetermined or > 42  Undetermined or > 42  Visit N(FAM), ORF1ab ROX)  SARS-COV-2 Not Detected  Invalid result, specimen  Needs to be re-tested from Undetermined or > 42  Visit N(FAM), ORF1ab ROX)  Visit N(FAM), ORF1ab ROX)  SARS-COV-2 Not Detected  Undetermined or > 42  Visit N(FAM), ORF1ab ROX)  SARS-COV-2 Not Detected  Visit N(FAM), ORF1ab ROX)  Visit N(FAM), ORF1ab ROX)  Visit N(FAM), ORF1ab ROX)  Visit N(FAM), ORF1ab ROX  Visi		LFS expects full documentation of:  * Evaluation of reported patient tests results during the affected time period. Patient look-back.  * How the lab identified the problem and the corresponding solution.  * What is the corrective action?  * How the lab is monitoring the corrective action. Is it the fix working?"  b. During the first day of the on-site inspection on 12/08/2020, we interviewed laboratory directors and senior operations personnel, and requested for the laboratory's documented investigation and corrective action regarding the increased number of inconclusive patient results.  c. We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the laboratory's adopted test method, Perkin Elmer New Coronavirus Nucleic Acid Detection Kit. The "Examination and Interpretation of Patient Specimen Results" section showed a table listing the expected results for the kit with valid positive			(2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnost treatment, or recommended patient actio (retesting), and there would not be patient.  (3) Preventative Action: No revision is use until Dr. Rosendorff has signed off. Maudits for data integrity are be performed.  (4) Monitoring Mechanism: Recent ver CA-RPT-SOP-002 (v4, v5, and v6) were approved in a timely manner. A delay repinconclusive and invalid samples is share Testing Task Force, OptumServe, and CD partners. The quality organization is resp	c: is, n it harm.  placed into fonthly . sions of nade and out of d with the DPH onsible for				
IC (VIC/HEX) N(FAM), ORF1ab ROX)  Set N(FAM), ORF1ab ROX)  Set Not targets Undetermined or > 42  I Both targets < 42  Set					1					
SARS-COV-2 Not Detected Undetermined or > 42  I Both targets ≤ 42 SARS-COV-2 Detected  I One of the targets ≤ 42 SARS-COV-2 Detected  Invalid result, specimen needs to be re-tested from Undetermined Undetermined or > 42 re-extraction or recollected			***************************************	***************************************	Result Interpr	etation				
Value   Saks-CoV-2 Not Detected					<u> </u>					
/ Both targets ≤ 42 SARS-CoV-2 Detected  / One of the targets ≤ 42 SARS-CoV-2 Detected  Invalid result, specimen  >40 or Both targets needs to be re-tested from  Undetermined Undetermined or > 42 re-extraction or recollected		W 45			SARS-CoV-2 No	t Detected				
/ One of the targets < 42 SARS-COV-2 Detected  Invalid result, specimen  >40 or Both targets needs to be re-tested from  Undetermined Undetermined or > 42 re-extraction or recollected				***************************************	CADC-C-11-3 C-	dacted				
Invalid result, specimen  >40 or Both targets needs to be re-tested from  Undetermined Undetermined or > 42 re-extraction or recollected				-)	-	44				
>40 or Both targets needs to be re-tested from Undetermined Undetermined or > 42 re-extraction or recollected		1	one of th	e talkerz 2 44						
Undetermined Undetermined or > 42 re-extraction or recollected										
						1 1				
		from patient for test.								

	OF DEFICIENCIES	, ,	1) PROVIDER/SUPPLIER/CLIA		PLE CONSTRUCTION	(X3) DATE SURVEY	
AND PLAN O	F CORRECTION	IDENTIFICATIONNUMBE	ER:	A. BUILDING	3	COMPLETE	ED
		05D21974	16	B. WING		02/17	7/2021
NAME OF PR	ME OF PROVIDER OR SUPPLIER STREET AL			SS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Υ	28454 LIV	VINGSTO	N AVE		
			VALENC	IA, CA 913	355		
(X4) ID		TATEMENT OF DEFICIENCIES		ID	PROVIDER'S PLAN OF CORRECTION		(X5) COMPLETION
PREFIX TAG	`	T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO		DATE
		,			DEFICIENCY)		
D5891	Continued From pag	e 95		D5891	Finding 1c, e-h, o-p:		
	d In order to comp	are how the laboratory v	Nae		C Att. d		
	calculating and interp		,,,,,		See Attachment 9 and D5411 In summary, there is scientific and clinical	debate	
		oratory on December	8,		regarding the best interpretation of high Coreports issues did match the analysis rules in	values. All	
	2020, to provide the	LIMC Laboratory Inforn	nation		the time of sample processing. To manage	this evolving	
		policy and procedure for	or		field, a full-time, on-site Laboratory Direct directly involved in day-to-day laboratory	or, who is	
	interpretation of patie	ent specimen results.			and result reporting has been hired so that	decisions	
	a. A policy and proce	dure signed by the			regarding data interpretation area now ma- timely manner, with consultation of CDPH	[	
		vailable on December 8	3.		Leadership, the Testing Taskforce and other professionals as appropriate.	r	
	2020.				(1) Immediate Corrective Action: Please s	ee D5411	
	h Noither an uneign	ed policy and procedure	was .		(2) Patient Impact: Please see D5411		
	available on Decemb	per 8, 2020.	).		(3) Preventative Action: Please see D5411		
					(4) Monitoring Mechanism: Please see D5	411	
		rs with the laboratory dir ated there was a possib			Finding 1d-h:		
		its were reported in erro			See Attachment 11 and D5407:		
	a result of incorrect of				Contrary to Laboratory Director affirmation		
	interpretation.				Specification and Acceptance Testing form signed.	s were	
		y on 12/09/2020, we ampling of an additiona	ol 32		Please note, the effective date 29Oct2020 is blank form (template) was effective.	the date the	
	patient test records v	vith specimens collecte	d		For evolution of the interpretation of Ct va see Attachment 9.	lues, please	
	during the first week [	December until 12/08/20	020.		(1) Immediate Corrective Action: Please s	ee D5407	
	g. On December 1	6, 2020, we wentback			and D5891 1a - 1b.		
	on-site at the laborate	ory to retrieve the addit			(2) Patient Impact: Please see D5407 and I lb.	O5891 1a -	
	patient test records.	We also asked the a e-mail, the requested			(3) Preventative Action: Please see D5407	and D5891	25
	records and its policy				la - 1b.		
	interpretation of patie				(4) Monitoring Mechanism: Please see D5 D5891 1a - 1b.	407 and	
	. 300 10 7 10		:1		D3071 1a - 10.		
	h. The policy and procedure sent via e-mail on		ii on				
	Dec. 16, 2020 showed the following:						
	(i) An annotation on the top portion of						
	document indicated,						
	10/29/2020" the document version history :						
	(ii) It was an Initial of	document, Version 1.0,	with				
					16 -	ontinuation sheet	D 00 of 100

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:				PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
	05D2197416				B. WING	<u> </u>	02/17/2021
	ROVIDER OR S	SUPPLIER BORATOR	Y	28454 LI	ESS, CITY, ST. IVINGSTOI		
(X4) ID PREHX TAG	(EACH DE	FICIENCY MUS	TATEMENT OF DEFICIENCES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETION
D5891	an effective date of December 13, 2020.  (iii) The Software Name was identified as LIMC, version 1.2  i. The Detailed User Requirements Specifications section of the document showed the following policy for interpretation of patient specimen results.				D5891	Findings 1i-k, o-p  1. The inconclusive rate for this assay is no daily. Summaries are sent to the Testing Todaily. Currently, inconclusive samples indiction those with internal control failures (invaluants) samples that were unsatisfactory for testing current rate has been consistently ~0.5%. factors contribute to this including:  a. Staff "superuser" training  b. Improvement to Janus Reformatter and Chemagic protocols  c. Evidence provided at on-site inspect of CAPA-20-002	Fask Force clude only id) or ng. The Several and
	User Requirement Number		Description			<ul><li>2. Lack of signed analysis SOP: see Data A Interpretation Response</li><li>3. Results for 32 samples: see Data Analys</li></ul>	
	UR001	"Not Detecte     FAM and I instead of "Not D     IC Failure sa	ule for the new SOP:  cd" Ct cutoff changed from 37 to 42  ROX >37 and <=42 will be called letected".  copies (HEX=0 or >40) will be released to controls and "Detected" rules			Interpretation Response  4. LIMC documentation: Provided. Please following:  • Both the User Specification and the User Acceptance forms signed by b Laboratory Directors is provided.  • The effective date 29Oct2020 is the date the blank form (template) was	oth
	j. Comparative review of the IFU for the laboratory's adopted EUA method, and the laboratory's policy for interpreting patient specimen results, showed the laboratory added a result category of Inconclusive.  k. There was no indication that this document identified as User Requirement Specifications CA-COMP-FM-001 Version 1.0, was approved, signed, and dated by the Laboratory Director.  l. This policy and procedure did not include the laboratory's signature. There was also no indication or verification that the laboratory director affixed a digital signature approving signing and dating the document.  m. In addition to failing to have available, a		nent ns ved, or. le the		effective  See Attachment 11.  (1) Immediate Corrective Action: CAPA provided at on-site inspection  (2) Patient Impact: Per Lab Director Dr. there is no change in diagnosis, treatment recommended patient action (retesting), a would not be patient harm.  (3) Preventative Action: No revision are into use until Dr. Rosendorff has signed o audits for data integrity is performed.  (4) Monitoring Mechanism: Recent vers. RPT-SOP-002 (v4, v5, and v6) were made approved in a timely manner. A delay repinconclusive and invalid samples is sharer Testing Task Force, OptumServe, and CT The quality organization is responsible for review and signoff of future SOPs.	Rosendorff, , or and there  be placed ff. Monthly  ions of CA- and ort of l with the DPH partners.	
	m. In ac	idition to fai olicy and pr	iling to have available, a ocedure for interpreting	d			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1)		(XT) PROVIDER/SUPPLIER/CLIA			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
	05D2197416			B. WING		02/17/2021		
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 LI	DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE ICIA, CA 91355				
(X4) ID PR⊟FIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE COMPLETION DATE		
D5891	patient sample result to show it validated it category of "Inconclupatient test results or o. Review of the 32 retrieved on Decemb (i) Thirteen (13) pas "Not Detected" whreported "Inconclusive Reported as Inconclusive reported as Inconclusive whreported as "Inconclusive" whreported as "Invalid"	s, the laboratory also for s LIS to include a result sive" prior to reporting a 11/02/2020. (See D542 patient test records er 16, 2020 showed: attent results were reported in the should have been seen on December 10, 20 ected, but should be	orted orted orted orted orted	D5891	Contrary to Laboratory Director affirmatic LIMC User Specification and Acceptance forms were signed. Both the User Specific the User Acceptance forms signed by both Laboratory Directors is provided. The effedate 29Oct2020 is the date the blank form (template) was effective Delayed procedur approval: This timeline reflects the difficuctoming to a scientific and clinical consens how low viral load (high Ct value – specification of the beginning of testing and was approved Lab Director.  Findings 10-p  See Attachment 9 and D5411  In summary, there is scientific and clinicategarding the best interpretation of high Call reports issues did match the analysis replace at the time of sample processing. To this evolving field, a full-time, on-site Lab Director, who is directly involved in day-tlaboratory operations and result reporting hired so that decisions regarding data interpretation area now made in a timely with consultation of CDPH Leadership, the Taskforce and other professionals as approximation of CDPH Leadership, the Taskforce and other professionals as approximation of CDPH Leadership, the Call of	Testing ation and in ective are alty in sus on icially > he VBL are since it by the are altered at the control of the control		

OT A TEAMENT	OF PERIODENOIS	(X4) PROMPERIOURN IERIO	N. I.A.	(X2) MULTIE	PLE CONSTRUCTION	T	
	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBE			G	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		25:	7/0004
		00021914				02/1	7/2021
	ROVIDER OR SUPPLIER				ATE, ZIP CODE		
СОРН ВР	RANCH LABORATOR	Y		LIVINGSTOI CIA, CA 91:			
			VALEN	CIA, CA 91	355		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACHCORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	ULD BE	(X5) COMPLETION DATE
D5891	Continued From pag	e 98		D5891			
	declaration signed by 12/16/2020, the laboratory 430,00 from 11/02/2020 to 15 p. The Laboratory (February 12, 2021 at the laboratory failed to periodically verify sent to interfaced systems of the sent to interface of the se	20 SARS-CoV-2 test re- 2/16/2020.  Director affirmed t approximately 2:10 pr to ensure was a mecha calculated results, result stems, and patient spect 2.  iew with the laboratory 20, 12/09/2020 and il communication on 120, 01/06/2021 and f policies and procedure and quality assurance ( mined that the laboratory d follow written policies	sults m) that nism lts cific				

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION COMPLETION DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PRÉFIX PREFIX TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY D5891 Continued From page 99 D589 $|_{Finding 2}$ problems identified in the postanalytic systems See Attachment 9 and D5411 specified in CFR 493.1291 (a)-(k). In summary, there is scientific and clinical debate Findings included: regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this Review of the laboratory's policies and evolving field, a full-time, on-site Laboratory Director, procedures (Policy # CA-QM-SOP-001, Quality who is directly involved in day-to-day laboratory Management Plan, Effective 11/01/2020)showed operations and result reporting has been hired so that the laboratory failed to include an ongoing decisions regarding data interpretation area now made mechanism to perform or document quality in a timely manner, with consultation of CDPH issues regarding the following: Leadership, the Testing Taskforce and other professionals as appropriate. b. The laboratory failed to ensure the electron Appendix A - The Quality Management Plan has been system(s) it used, accurately and reliably trans na revised and reorganized to consolidated information patient-specific data from the point of data entry to fi about existing laboratory processes (CA-QM-SOP-001). report destination (See D5801). (1) Immediate Corrective Action: Please see D5411, D5800 The laboratory failed to ensure its test result provided the correct interpretation for (2) Patient Impact: Please see D5411, D5800 SARS-CoV-2 (See D5805). (3) Preventative Action: Please see D5411, D5800 d. The laboratory failed to ensure its accurate (4) Monitoring Mechanism: Please see D5411, D5800 reference intervals determined by the laboratory based on LOD were available for the authorized person, or individual responsible for using the test results (See D5807). The laboratory failed to ensure its clients were updated regarding changes in the interpretation of results (See D5809). The laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time (See D5815). g. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original

report (See D5821).

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
05D2197416		16	B. WING		02/1	7/2021	
NAME OF PRO	VIDER OR SUPPLIER		STREET ADDRI	ESS, CITY, ST.	ATE, ZIP CODE		
	NCH LABORATORY			VINGSTO			
02				IA, CA 91			
							(VE)
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY  OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5891	Continued From pag	ge 100		D5891		0	
h. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, showed that for 32 out of 32 results records reviewed, the laboratory tested and reported SARS-CoV-2 results, but failed to ensure there was an ongoing mechanism to identify issues in the postanalytic systems.							

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O IDENTIFICATIONNUMB			PLE CONSTRUCTION  G	(X3) DATE SU COMPLET	
05D2197416		16	B. WING		02/1	7/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADD	DRESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Y		LIVINGSTO ICIA, CA 91			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5891	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 j. The Laboratory I 12, 2021 at approximately 12 in the laboratory failed to make the signature of the laboratory failed to make the laboratory failed the laboratory failed the laboratory failed the laboratory failed th	poratory's annual testing the laboratory director ratory reported 20 SARS-CoV-2 test resected 2/16/2020.  Director affirmed (Februartely 2:10 pm) that the conitor, assess, and wholems identified in the	r on sults uary	D5891			
D6076			of ent of Based ein, it	D6076	To manage the laboratory effectively, a fusite Laboratory Director, has been hired v directly involved in day-to-day laboratory and result reporting. The Laboratory Dire MD, Board Certified in Clinical Patholog Laboratory Director is responsible for the items in response to the findings in D607 related subsections.  • (6082) Ensure data analysis continuhappen only onsite at the VBL  • (6083) Ensure environmental conducted are established at the VBL are approximated as a safe from physical, chemical and hazards  • (6093) Ensure quality control programments of the safe from physical and the programments of	who is y operations ector is an y. The below 6 and its  des to  itions that opriate for  ntinue to biological	8Mar2021
	quality of service pro- system when the labor documentation of train assessment, and con- telephone, as necessing personnel specific re- reapportioned to tech supervisor, and clinic	sultation electronically cary, delegated to quali sponsibilities which car unical supervisor, gener	or by fied i be		<ul> <li>(6093) Ensure quality control prograre established continue to be main to identify failures in quality as the</li> <li>(6094) Ensure quality assurance act have been established continue to b maintained and to identify failures as they occur</li> <li>(6101) Ensure the laboratory conting have the adequate number of person appropriate training to perform tes</li> <li>(6102) Ensure the laboratory staff of the demonstrate competency prior to reporting patient results</li> </ul>	tained and occur ivities that ee in quality nues to nnel with ting ontinues	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI		A. BUILDING	PLE CONSTRUCTION  3	(X3) DATE SURVEY COMPLETED
		05D21974	16	B. WING		02/17/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454	DRESS, CITY, ST LIVINGSTOI ICIA, CA 91:	N AVE	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETION
D6076	analysis and reporting taking place at a local known physical located State and CLIA applications. The Laboratory Disenvironmental conditional appropriate for the testing personnel we chemical and biological. The Laboratory quality control programaintained to assure provided, and to identify control programaintained by the laboratory quality assurance acting assurance acting and to identify as they occur.  The Laboratory Disaboratory staff demonstratory staff demonstratory staff demonstratory staff demonstratory patient testing and to identify a staff demonstration and the identification according to the identification according to the identification and the identification according to the identification accordin	g of patient test results ation outside of the lister ion of the laboratory in cations (See D6082).  rector failed to ensure thin to a string performed (See Director failed to ensure resafe from physical, cal hazards (See D6084).  Director failed to ensure resafe from physical, cal hazards (See D6084).  Director failed to ensure resulting the quality of services tify failures in quality as and to identify failures (See D6094).  Perctor failed to ensure in laboratory personnel for the appropriate training regly (See D6101).  Director failed to ensure in laboratory personnel for the appropriate training regly (See D6101).  Director failed to ensure in laboratory personnel for the appropriate training regly (See D6101).	ed and its  that are 06083).  e that  4).  re and they  they  in tutilized or high to provide  re the prior to	D6076	Continued from page 102  (1) Immediate Corrective Action: As the delegated Lab Director (27JAN2021), all dand processes for sample workflow (preansanalytical, and postanalytical as well as the system essentials that support them are ure to determine if they are in compliance with requirements and reflect actual lab practice Quality Management Plan underwent a mareorganization following initial review; nor deliberate review of the policies and processupport that plan are being carefully review that there are 243 documents, this process To date, 153 documents (63%) have been media Lab, with 40 documents revised/app.  (2) Patient Impact: Based on the deficience under D6076 we believe that the impact to had the potential to be significant. In partial, 4,6,5,7 could have negatively impacted the invalid/cancelled specimens, and potential turnaround times, thereby causing a delay identification of patients at risk of COVID treatment. However, our TAT time for No December averaged 37.39 hours which is we 24-48 hour target with continued trend to TAT. Based on lookback audit of laborator generated 28Oct2020 - 31Dec2020 and a prinspection lookback at results generated to 28Feb2021, QC values were within accepta (see attached report (therefore we do not be these deficient practices impacted the accupatient testing or a delay in timely treatment.  (3) Preventative Action: Dr Rosendorff, L to continue to review and approve docume understand processes in place and revise a necessary to ensure that regulatory guideling followed, that quality assurance activities a measurable and timely and the corrective a documented, resolved in timely manner and advented and	ocuments alytical, e quality oder review or regulatory e. The ajor w a dures that wed. Given is ongoing, eviewed in proved.  ies listed patient care cular items are volumes of ly impacted in and timely evember and within the evards faster rry results post Jan2021 – ble ranges elieve that racy of int.  ab Director, ents and is he deems ness are recictions are 8Mar2021
	systems developed a	or must ensure that tes and used for each of the oratory provide quality or all aspects of test			(4) Monitoring Mechanism: Include % of Approval of Documents as a reportable Qu Continue to monitor existing quality indic	ality Metric.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WING \_ 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION COMPLETION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6082 Continued From page 103 D6082 Finding 1-2: performance, which includes the preanalytic, See Attachment 4 and D3207, D5301 analytic, and postanalytic phases of testing. This Standard is not met as evidenced by: All information is collected on the electronic requisition form that is stored at Color Genomics 1. Preanalytic System (Test Requisition) (CLIA #05D2081492) at established collection sites (see D5311). Data needed for testing is transferred to CDPH Branch Laboratory. Requisition data and Based on interviews with staff and the laboratory laboratory reports are retained by Color Genomics for director on December 8, 2020, the absence of 20 years per their policies and procedures. These test requisitions, and random review of test documents are accessible to CDPH Branch records covering the period from 11/22/2020 to Laboratory for auditing purposes. 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the Laboratory Director failed to ensure the quality of service provided in the preanalytic system when records of test requisitions for SARS-CoV-2 patient testing was not retained. (1) Immediate Corrective Action: Please see Findings included: D3027, D5301 (2) Patient Impact: Please see D3027, D5301 a. The Laboratory Director failed to ensure it retained records of test requisitions of all patients (3) Preventative Action: Please see D3027, D5301 tested for SARS-CoV-2, for at least two years (4) Monitoring Mechanism: Please see D3027, (See D3027). Postanalytic System (Test Report) Based on email communication with the laboratory director on 12/24/2020, the absence of original test reports, and review of test records covering the period from 12/02/2020 to 12/04/2020, for 10 out of 10 patient test records reviewed, it was determined that the Laboratory Director failed to ensure the quality of service provided in the postanalytic system when records of original test reports for SARS-CoV-2 patient testing were not retained. Findings included: a. The Laboratory Director failed to ensure it

STATEMENT OF DEFICIENCIES		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED		
AND PLAN OF CORRECTION				A. BUILDING				
05D219		05D21974	16	B. WNG		02/17/2021		
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDRE	ESS, CITY, ST.	ATE, ZIP CODE			
	RANCH LABORATOR	Y	28454 LI	VINGSTO	NAVE			
			VALENC	IA, CA 913	355			
(VA) ID	SI IMMADY S	FATEMENT OF DESIGNATION		ID	PROVIDER'S PLAN OF CORRECTION	ON	(X5)	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	LD BE COMPLETION		
D6082	Continued From page 104			D6082	Finding 3			
	retained records of original test reports of all patients tested for SARS-CoV-2, for at least two years (See D3041).  3. Postanalytic System (Training, Competency Assessment, Consultation, and Delegation of Duties to Qualified Personnel in Remote Data Analysis)  Based on email communication with the Director of Informatics on 12/16/2020, interviews with the laboratory staff on 12/08/2020, review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, the Laboratory Director failed to demonstrate quality of service provided in the postanalytic system when the laboratory failed to provide documentation on training, competency assessment, and consultation electronically or by telephone, as necessary; or delegated to qualified personnel specific responsibilities which can be reapportioned to technical supervisor, general supervisor, and clinical consultant during the time data analysis and remote reporting of patient test results were taking place at a location outside of the laboratory facility.  Findings included:  a. Based on interview with the laboratory staff on 12/08/2020, a laptop computer was issued to nine data analysis laboratory personnel which would enable access to the laboratory's information system and facilitate patient test reporting remotely.  Data Analysis Staff  Perkin Elmer Computer VPN  a. SS  VALLL015  b. RR  VALLL014  c. AE  VALLL020  d. SM  VALLL013				1. For the purposes of data analysis, the statuse a (1) secure data repository and (2) a Politims web based application. 2. Both of these are hosted within the Perkinetwork and are secured behind a firewall. a. This infrastructure configuration elimina ability for individuals to access the site and repository from an external location on a guinternet connection. b. Data is never transferred to the location or remote (offsite) person.	ithin the PerkinElmer ithin the PerkinElmer ind a firewall. uration eliminates the ss the site and file ocation on a general		
					3. The only method to access the systems re through a secured VPN tunnel using a Perl issued set of credentials on a PerkinElmer i laptop. During any remote session the data being accessed are located on the prior mer internal IT systems hardware.  4. The two data analysts who performed reanalysis were trained and qualified to do so a. EV – Trained in data analysis and delegaresponsibilities of a General Supervisor b. MN – CLS trained in data analysis  5. CMS has made an exception to allow patother healthcare professionals to work rem the pandemic. CAP concurred with this exceedant the pandemic of the concurred with this exceedant to the concurred that they may not analyze data reaction.  (1) Immediate Corrective Action: Analyst instructed that they may not analyze data recommended patient action (retesting), and would not be patient harm.  (3) Preventative Action: Data analysts havinformed that remote analysis is not permit (4) Monitoring Mechanism: Query perfort 26Feb2021 demonstrated no remote release.	cinElmer ssued and system and system and itioned mote ted the hologist and otely during ception.  s were emotely. osendorff, or d there e been tted. med		

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING \_ COMPLETED 05D2197416 B. WNG\_ 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) (X4) ID COMPLETION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) Continued From page 105 D6082 e. FJ VALLL017 f. MW VALLL021 g. YZ VALLL002 h. WT VALLL033 i. MN VALLL023 b Based on email communication with the Director of Clinical Informatics on 12/16/2020. remote workers need to connect to VPN to be able to login to LIMC (LIS), so their IP addresses are Perkin Elmer IP address. The CDPH Branch Laboratory Valencia lab IP address range is 165.88.16.###. Non-Valencia IP Addresses Login 1. By EV 2. By MN 165.88.255.136 165.88.254 165.88.254 165.88.176.91 165.88.192.131 165.88.176.64 165.88.254.202 c. Review of the laboratory's policies and procedures (Policy # CA-RPT-SOP-002, Title: Analysis and Reporting of SARS-CoV-2 Assay, Version 1 Effective Date 12/8-13/2020, Version 2.0 Effective Date 12/13-16/2020, Version 3.0 Effective Date 12/16/2020, and Version 3.1 Effective Date 12/16/2020), the Laboratory Director failed to demonstrate quality of service provided in the postanalytic system when the laboratory failed to provide documentation on training. competency assessment, and consultation electronically or by telephone, as necessary; or delegate to qualified personnel specific responsibilities which can be reapportioned to technical supervisor, general supervisor, and clinical consultant during the time data analysis and remote reporting of patienttest

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D2197416		B. WING		02/17/2021		
				ADDRESS, CITY, STATE, ZIP CODE				
COPH B	RANCH LABORATOR'	Y		LIVINGSTON AVE NCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE COMPLETION		
D6082	Continued From pag	e 106		D6082				
	results were taking place at a location outside of the laboratory facility.							
	results were taking place at a location outside							

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D2197416		B. WING		02/17/2021		
ANALY OF PROMUNES OF CHIEF ADD			STREET ADDR	ESS CITY STA	ATE 7ID CODE	J	77,2021	
	STATE OF THE STATE							
CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355								
(X4) ID	SUMMARY STATEMENT OF DEFICIENCIES				ID PROVIDER'S PLAN OF CORRECTION			(X5)
PREFIX TAG	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DATE		
D6082	Continued From page 107			D6082				
	Data Analyzed by EV	Data Analyzed by FV						
		Date Reported	IP Ac	idress				
		11/22/2020	165.88	255.136				
		11/22/2020		255.136				
		11/22/2020	165.88.	255.136				
		11/22/2020	165.88	255.136				
		11/23/2020	165.88	.176.91				
		11/23/2020	165.88	.176.91				
		11/23/2020	165.88	.176.91				
		11/23/2020	165.88	.176.91				
		11/24/2020	165.88.	192.131				
		11/24/2020	165.88.	192.131				
		11/24/2020	165.88.	192.131				
		11/24/2020	165.88.	192.131		•		
		11/25/2020	165.88	.176.64				
		11/25/2020	165.88	.176.64				
		11/25/2020	165.88	.176.64				
		11/25/2020	165.88	.176.64				
		11/27/2020	165.88	.176.64				=
		11/27/2020	************************	1.176.64				
		11/27/2020		.176.64				
		11/27/2020		.176.64				
		11/28/2020		254.202				
		11/28/2020		254.202				
				254.202				
		11/28/2020	***************************************	254.202				
10		11/29/2020		254.202				
		11/29/2020	*****************	254.202				
		11/29/2020		254.202				
		11/29/2020		254.202				
		11/30/2020		254.202 254.202				
		11/30/2020	103.55.	LJ4.EUZ				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		051	21974	16	B. WING		02/	17/2021
NAME OF PR	ROVIDER OR SUPPLIER			STREET ADD	RESS, CITY, STA	TE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Υ		28454	LIVINGSTON	AVE		
				VALEN	CIA, CA 913	55		
(X4) ID	SUMMARY S	TATEMENT OF DEFI	CIENCIES	3	ID	PROVIDER'S PLAN OF COR	RECTION	(X5)
PREFIX TAG	(EACH DEFICIENCY MUS OR LSC ID	ST BE PRECEDED BY ENTIFYING INFORM		EGULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	COMPLETION DATE
D6082	Continued From pag	ge 108			D6082			
	See table below for data analyzed by MN:		IN:					
- 1	Data Analyzed by M	N:		b				
		Date Reported	IP	Address				
		12/07/2020		8.254.222				
		12/07/2020	<b></b>	8.254.222				
		12/07/2020	<b></b>	8.254.222				
		12/07/2020	<b></b>	8.254.222				
		12/07/2020	<b></b>	8.254.222				
		12/07/2020	<b></b>	8.254.222				2 0
		12/07/2020	165.8	8.254.222				
		12/07/2020	·····	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/07/2020	165.8	8.254.222				
		12/08/2020	165.8	8.254.200				
		12/08/2020	165.8	8.254.200				
		12/08/2020	165.8	8.254.200				
		12/08/2020	165.8	8.254.200				
		12/08/2020	165.8	8.254.200				
		12/08/2020	****************	8.254.200				
		12/08/2020		8.254.200				
		12/08/2020	***************************************	8.254.200				
		12/08/2020	***************************************	8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200 8.254.200				
		12/08/2020	100.6	8.254.200				=

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/G IDENTIFICATIONNUMB			S		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02	/17/2021	
	ROVIDER OR SUPPLIER  RANCH LABORATOR	Y		ESS, CITY, ST. VINGSTOR	AVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	SUMMARY STATEMENT OF DEFICIENCIES  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  TAG  PREFIX  (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)				TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE	
D6082	Continued From pag	e 109		D6082				
D0062	The total number of r from 12/07/2020 to 1 g. The total number from 11/22/2020 to 11 h. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 i. The Laboratory Direp.m.) through email of analysis personnel at CoV2 amplification to failed to provide doct assessment, and contelephone, as necess personnel specific recreapportioned to tech supervisor, and clinic analysis and remote	results reported by MN 2/08/2020 was 1,974.  r of results reported by I/30/2020 was 13, 291.  poratory's annual testing the laboratory directoratory reported 00 SARS-CoV-2 test results.	g r on sults  220 at 12:15 two data he SARS- boratory competency or by ualified n be ral he time data t results	D0002				
		Ÿ						

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA ND PLAN OF CORRECTION IDENTIFICATION NUMBER:					(X3) DATE SUF	
74407040	001412011011					001111111111	
		05D21974		B. WING		02/1	7/2021
	ROVIDER OR SUPPLIER				ATE, ZIP COD€		
CDPH BE	RANCH LABORATOR	Y		IVINGSTOI IA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE		(X5) COMPLETION DATE
					DEFICIENCY)		
D6083	Continued From page 110		Based It the 10 out lens, s, and erse	D6083	D6083/D6084 Finding 1:  The laboratory has an Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and asceptic cleaning techniques all of work areas and equipment. The observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our procedure (see section 5.7.2).  Additionally, a default Safety statement was included in the technical SOPS (listed in the findings) that contradicted the current approved practice and the Laboratory Quality Management Plan (approved by the director and in effect at time of inspection (CA-QM-SOP-001 va effective 12OCT 2020) did not provide the robust environmental prevention and decontamination initiatives outlined in the Amplicon Contamination Prevention Plan.  The FDA EUA instructions for use of the PKI nucelic Acid detection kit provided possible actions for preventing contamination; The decontamination prevention instructions do not impact the performance characteristics of the test and it is the Laboratory Director who determines the contamination prevention and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work surface area and the instruments is not approved by the Laboratory Director and therefore not included in the contamination prevention plan. Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for		
D6084	instruments, reagents for the laboratory's C	s, materials, and suppl OVID-19 Reverse erase Chain Reaction		D6084	organization the minimum percent ethanol decontamination is 60.  (1) Immediate Corrective Action:  • Labeling of reagents, materials, and s		8Mar2021
	LABORATORY DIRE CFR(s): 493.1445(e): The laboratory direct physical plant and en provide a safe enviro	CTOR RESPONSIBIL			• Updating of the Quality Managemen  (2) Patient Impact: Per Lab Director Dr. Ethere is no change in diagnosis, treatment, crecommended patient action (retesting), an not be patient harm. The 70% EtOH was exfew days indicating that a 60% or greater co was still present which meets the CDC guid  (3) Preventative measure: The corrective includes re-assigned reading on related proceed to the control of the corrective includes re-assigned reading on related proceed to the corrective includes re-assigned reading on related proceed to the corrective includes re-assigned reading on related proceed to the corrective includes re-assigned reading on related proceed to the corrective includes re-assigned reading on related proceed to the corrective includes re-assigned reading on related proceeding the correction of the c	t Plan Rosendorff, or	

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION  A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WNG _		02/17/2021		
	ROVIDER OR SUPPLIER RANCH LABORATOR	Υ	28454 L	REET ADDRESS, CITY, STATE, ZIP CODE  28454 LIVINGSTON AVE  VALENCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL RECORD OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		
D6084	biological hazards. This Standard is not a Based on interview of the December 8, 2020, reprocedures (P/P) for Plan, and review of the period from 11/22/20 of 60 patient test recordetermined that the Lensure safety procede employees from physicand biohazardous materials included:  1. The laboratory faprocedures to ensure chemical, biochemical materials (See D301: LABORATORY DIRECFR(s): 493.1445(e): The laboratory direct quality control programaintained to assure services provided and as they occur.  This Standard is not a Based on direct observoided with the lata 12/08/2020 and 12/08/2020, for 60 our reviewed, it was determined to assure the stabilished and laboratory to assure the sta	met as evidenced by: with laboratory staff on eview of policies and General Facilities Safe est records covering the 20 to 12/08/2020, for 6 ords reviewed, it was aboratory Director faile ures were in place to p sical, chemical, biocher aterials.  Alled to observe safety protection from physical, and biohazardous 1).  CTORRESPONSIBILIT (5)  or must ensure that the ms are established and the quality of laborator d to identify failures in or met as evidenced by: evation, interviews boratory staff on 2/2020, and review of the period from 11/22/2020 at of 60 patient test recommend that the Labora ure quality control active maintained by the the quality of services	e of to protect mical,  al,  TIES  d ory quality  est o to ords atory eities	D6084	Appendix A: The Quality Management Pla revised and reorganized to consolidated in about existing laboratory processes (CA-Q: See Attachment 1.  Summary: The laboratory has a plan for Ar Contamination Prevention (see CA-SAFEThe use of 70% EtOH meets the standards Heat inactivation is an effective method to SARS-CoV-2. Disposal of MTM sample cothat have been subjected to heat inactivation not necessary. Therefore, the area in which were handled was adequately decontaminate where handled was adequately decontaminate the time of sample processing. To manage field, a full-time, on-site Laboratory Direct directly involved in day-to-day laboratory and result reporting has been hired so that regarding data interpretation area now matimely manner, with consultation of CDPI the Testing Taskforce and other profession appropriate.  See full responses in IDs D5415, D5417, D	I debate ct values. All in place at this evolving tor, who is operations t decisions ade in a H Leadership, nals as	8Mar2021	
	provided, and to ident occur (See D5400).	ify failures in quality as	they					

-	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/O IDENTIFICATIONNUMB			G	(X3) DATE SUR COMPLETE	
		05D21974	16	B. WING		02/17	7/2021
	OVIDER OR SUPPLIER	Y	28454 L	RESS, CITY, ST. IVINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC' (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D6093	Continued From pag	ge 112			(1) Immediate Corrective Action: Please D5415, D5417, D5423, D5433.	see D5411,	
	Findings included:				(2) Patient Impact: Please see D5411, D5 D5423, D5433.	415, D5417,	
	<ol> <li>The laboratory failed to ensure procedure manuals were established, available to, and followed by laboratory personnel (See D5401).</li> </ol>				<b>Preventative Action:</b> Please see D5411, D5415, 4417, D5423, D5433		
					<b>4) Monitoring Mechanism</b> : Please see D5411, D5415, D5417, D5423, D5433		
	manuals met the req	ailed to ensure the produirements specified in )-(b)(14) (See D5403).					
	manuals were updat	ailed to ensure procedu ed, approved, signed a Laboratory Director (S	ind		. '		
5	4. The laboratory failed to ensure it followed the adopted FDA EUA IFU, the subsequent revisions to the EUA, and changes made in the laboratory's policies and procedures (See D5411).		isions				
	5. The laboratory for labeled as required (	ailed to ensure reagent See D5415).	s were				
			oV-2				
	and verified performa	ailed to ensure it establi ance specifications pric results using its modif S-CoV-2 RT-PCR (See	or to				
=	established mainten centrifuges were per	ailed to the ensure the ance protocol for formed and documente					
D6094	LABORATORY DIRI	ECTOR RESPONSIBIL	LITIES	D6094			8Mar2021
State 2567	CFR(s): 493.1445(e)				Z9Q211	f continuation sheet	Page 113 of 123

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D6094 Continued From page 113 D6094 Finding 1-3: The laboratory director must ensure that the See Attachment 9 quality assessment programs are established and maintained to assure the quality of laboratory In summary, there is scientific and clinical debate services provided and to identify failures in quality regarding the best interpretation of high Ct values. as they occur. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory This Standard is not met as evidenced by: Director, who is directly involved in day-to-day Based on direct observation, interviews laboratory operations and result reporting has been conducted with the laboratory staff on hired so that decisions regarding data interpretation 12/08/2020 and 12/09/2020, and review of test area now made in a timely manner, with records covering the period from 11/22/2020 to consultation of CDPH Leadership, the Testing 12/08/2020, for 60 out of 60 patient test records Taskforce and other professionals as appropriate. reviewed, it was determined that the Laboratory See full responses in IDs D5391, D5791, D5891 Director failed to ensure quality assurance (1) Immediate Corrective Action: Please see activities were established and maintained by the D5391, D5791, D5891. laboratory to assure the quality of services (2) Patient Impact: Please see D5391, D5791, provided, and to identify failures in quality as they occur. (3) Preventative Action: Please see D5391, D5791, D5891. Findings included: (4) Monitoring Mechanism: Please see D5391, 1. The Laboratory Director failed to ensure it D5791, D5891. establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems (See D5391). 2. The Laboratory Director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791). 3. The Laboratory Director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891) 8Mar2021 LABORATORY DIRECTOR RESPONSIBILITIES D6101

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) Continued From page 114 D6101 D6101 Finding 1-5 1. Supervisory staff onsite on 12Dec2020 CFR(s): 493.1445(e)(11) included: The laboratory director must employ a sufficient Sean Evans, PhD (Extraction) b. Jared Hoffman, MS (PCR) number of laboratory personnel with the Reza Davoodi, PhD (Analysis) c. appropriate education and either experience or d. Gail Teske (Lab Manager) training to provide appropriate consultation. Note – the hiring process for much these staff were properly supervise and accurately perform tests not complete at the time CMS 209 was submitted and report test results in accordance with the on 15Oct2020. personnel responsibilities described in this 2. PerkinElmer is contracted by the state to subpart. provide testing services. The CDPH Branch This Standard is not met as evidenced by: Laboratory has extensive support from the wider Based on direct observation, interviews PerkinElmer team (see org chart). conducted with the laboratory staff on The PerkinElmer Genomics GM Global 12/08/2020, 12/09/2020, and 12/16/2020, and Laboratory Operations, who is an experienced ACSPreview of test records covering the period from certified molecular geneticist, does function in an 11/22/2020 to 12/08/2020, for 60 out of 60 patient advisory capacity for the laboratory (as he did on 16Dec2020); HOWEVER, he is not a laboratory test records reviewed, it was determined that the supervisor and does not perform this function for the Laboratory Director failed to ensure there was an clinical laboratory staff. The GM Global Lab Ops may adequate number of supervisors for high provide oversight and instruction for R&D / complexity testing, with appropriate education, development work being done in the laboratory that training and experience in order to provide is separate from clinical activities. accurate and reliable test performance and The Principal Scientist Molecular and reporting. Special Diagnostic team member is not a supervisor. As part of the PerkinElmer team, this individual deployed to CDPH Branch Laboratory, submitted Findings included: credentials, and completed training. She has functioned as a technologist in the analysis area. 1. Analytic Testing Supervision Technologists may participate in training of staff and sharing knowledge pertaining to the work being Based on interview with the laboratory staff performed. designated as Perkin Elmer Genomics GM (1) Immediate Corrective Action: None Global Laboratory Operations who was providing supervision to the analytic testing laboratory staff, (2) Patient Impact: Per Lab Director Dr. Rosendorff, and observation of laboratory personnel on there is no change in diagnosis, treatment, or 12/16/2020, lack of training documents, lack of recommended patient action (retesting), and there written delegation of duties, it was determined would not be patient harm. that there was inadequate supervision of the (3) Preventative Action: None analytic phase of testing. (4) Monitoring Mechanism: None b. Review of CMS 209, signed and dated by the Laboratory Director on 10/15/2020, did not

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED A. BUILDING \_ IDENTIFICATION NUMBER: AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY **VALENCIA, CA 91355** (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PRETIX (EACH CORRECTIVE ACTION SHOULD BE DATE PREFIX CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D6101 Continued From page 115 indicate the name of the interviewed general supervisor, who was providing supervision to the analytic testing laboratory staff on 12/16/2020. Data Analysis Supervision Based on direct observation and interview with the laboratory staff designated as Principal Scientist Molecular and Special Diagnostics Supervisor who was providing supervision to a Clinical Laboratory Scientist performing data analysis on 12/08/2020, lack of training documents, lack of written delegation of duties, it was determined that there was inadequate supervision of laboratory personnel performing data analysis. b. Review of CMS 209, signed and dated by the Laboratory Director on 10/15/2020, did not indicate the name of the general supervisor interviewed providing supervision to the data analysis personnel. Based on interview with the Laboratory Director on 12/16/2020, the Principal Scientist Molecular and Special Diagnostics Supervisor interviewed on 12/08/2020 was no longer available on site because the person was only requested to help during the inspection on 12/08/2020. The two general supervisors listed on CMS 209 were also not available onsite. Random patient sampling covering the period from 11/22/2020 to 12/08/2020, showed the laboratory tested and reported 60 out of60 SARS-CoV-2 patient test results, when there was inadequate supervision of laboratory personnel performing data analysis. Accession Number

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/O			PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED		
		05D21974	16	B. WING _		02/1	7/2021	
	ROVIDER OR SUPPLIER RANCH LABORATOR'	Υ	28454 L	DRESS, CITY, STATE, ZIP CODE  LIVINGSTON AVE  NCIA, CA 91355				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE	(XS) COMPLETION DATE	
D6101	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12.  5. The Laboratory E (12/16/2020 at 1:00 p	oratory's annual testin the laboratory director atory reported 0 SARS-CoV-2 test res /16/2020.	on sults	D6101				

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION ID PRETIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D6101 Continued From page 117 D6101 D6102 - Finding 1-4 for high complexity testing with appropriate training to provide supervision accordingly. 1. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer D6102 LABORATORY DIRECTOR RESPONSIBILITIES D6102 8Mar2021 LIMS web based application. CFR(s): 493.1445(e)(12) 2. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. The laboratory director must ensure that prior to a. This infrastructure configuration eliminates the testing patients' specimens, all personnel have ability for individuals to access the site and file the appropriate education and experience, repository from an external location on a general receive the appropriate training for the type and internet connection. complexity of the services offered, and have b. Data is never transferred to the location of the remote (offsite) person. demonstrated that they can perform all testing operations reliably to provide and report accurate 3. The only method to access the systems remotely is results. through a secured VPN tunnel using a PerkinElmer This Standard is not met as evidenced by: issued set of credentials on a PerkinElmer issued laptop. Based on direct observation, interviews During any remote session the data and system being accessed are located on the prior mentioned internal IT conducted with the laboratory staff on systems hardware. 12/08/2020, 12/09/2020 and 12/16/2020, and 4. The two data analysts who performed remote analysis review of test records covering the period from were trained and qualified to do so: 11/22/2020 to 12/08/2020, for 60 out of 60 patient a. EV - Trained in data analysis and delegated the test records reviewed, it was determined that the responsibilities of a General Supervisor Laboratory Director failed to ensure all laboratory b. MN – CLS trained in data analysis 5. CMS has made staff received appropriate training prior to an exception to allow pathologist and other healthcare reporting patient test results. professionals to work remotely during the pandemic. CAP concurred with this exception. Findings included: The data analysts are trained based on the current version of CA-RPT-SOP-002 (v6, effective date M/D/Y) Data Analysis Performed at CDPH Branch Lab See Attachment 10. (1) Immediate Corrective Action: Analysts were Based on direct observation and interview instructed that they may not analyze data remotely. with the Clinical Laboratory Scientist (CLS) performing data analysis on 12/08/2020, it was (2) Patient Impact: Per Lab Director Dr. Rosendorff, determined that the CLS was not updated on the there is no change in diagnosis, treatment, or laboratory's current data analysis policies and recommended patient action (retesting), and there procedures. would not be patient harm.

(3) Preventative Action: Data analysts have been

informed that remote analysis is not permitted.

(4) Monitoring Mechanism: Query performed

26Feb2021 demonstrated no remote release of results.

b. Review of policies and procedures for data

been utilizing two existing data analysis policies

analysis, it was determined at the time of inspection on 12/08/2020, the laboratory has

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O		1	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
711076111	or connection						
		05D21974		B. WING		02/17/2021	
I	ROVIDER OR SUPPLIER RANCH LABORATOR'	v		RESS, CITY, ST IVINGSTOI	ATE, ZIP CODE		
CDPH B	RANCH LABORATOR	ī		CIA, CA 91:			
(X4) ID PREFIX		TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE		ID PREFIX	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU	D.RE COMPLETION	
TAG		ENTIFYING INFORMATION)		TAG	CROSS-REFERENCED TO THE APPRO DEFICIENCY)		
D6102	02 Continued From page 118			D6102			
	and procedures.						
7	c. The following are	the accession number	rs of				
		ewed patient test recor	ds				
	covering the period from 12/08/2020, wherein	the laboratory tested a	ınd				
	reported 60 out of 60	SARS-CoV-2 patient	test				
		ensure all laboratory sta training prior to reporti					
	patient test results.						
	Accession Number						

	T OF DEFICIENCIES DF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		IPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED			
2		05D21974	16	B. WING _		02/17/2021			
NAME OF P	ROVIDER OR SUPPLIER		STREET ADD	RESS, CITY, S	TATE, ZIP CODE				
CDPH BE	RANCH LABORATOR	Y		4 LIVINGSTON AVE					
	T			ICIA, CA 91	355		,		
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG		(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE			
D6102	2. Data Analysis Per CDPH Branch Lab (R)  a. Based on review determined that the typerformed data analysis the CDPH Branch Lad documentation on hor reporting, direction and or by telephone when delegated personnel typerformed data analysis.  b. Review of policies CA-PER-SOP-002, Transessment) failed to remote reporting.  c. Random review of period from 11/22/202 laboratory tested and SARS-CoV-2 patient laboratory personnel soutside the location of Valencia without document of the period for EV and MN,	erformed Outside temote Reporting)  of test records, it was to laboratory staff who sis from the location or be did not have training we to handle remote described to a consultation electronist the Laboratory Director were not with them dures and procedures (Policitle Competency include training for of test records covering 0 to 12/08/2020, the reported 60 out of 60 test results, showed two perform data analysis of CDPH Branch laborationented training for results resentative examples	ttside  cally r and ing  the  os tory in	D6102					

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05	D2197416	B. WING		02/17/2021	
	OVIDER OR SUPPLIER ANCH LABORATOR	Y	28454	DRESS, CITY, STATI LIVINGSTON A NCIA, CA 9135	AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEF T BE PRECEDED E ENTIFYING INFORI	Y FULL REGULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROVIDENCY)	D BE	(X5) COMPLETION DATE
D6102	Continued From pag	e 120		D6102			
	Data Analyzed by EV	1:					
		Date Reported	IP Address				
		11/22/2020	165.88.255.136				
	••••	11/22/2020	165.88.255.136				
	••••	11/22/2020	165.88.255.136				
		11/22/2020	165.88.255.136				
		11/23/2020	165.88.176.91				
		11/23/2020	165.88.176.91				
		11/23/2020	165.88.176.91				
		11/23/2020	165.88.176.91				
		11/24/2020	165.88.192.131				
		11/24/2020	165.88.192.131				
		11/24/2020	165.88.192.131				
		11/24/2020	165.88.192.131				
		11/25/2020	165.88.176.64				
		11/25/2020	165.88.176.64				
		11/25/2020	165.88.176.64				
		11/25/2020	165.88.176.64				
		11/27/2020	165.88.176.64				
		11/27/2020	165.88.176.64	15			
		11/27/2020	165.88.176.64				
		11/27/2020	165.88.176.64				
		11/28/2020	165.88.254.202				
		11/28/2020	165.88.254.202				
	ė	11/28/2020	165.88.254.202				
	····	11/28/2020	165.88.254.202				
		11/29/2020	165.88.254.202				
		11/29/2020	165.88.254.202				
		11/29/2020	165.88.254.202				
		11/29/2020	165.88.254.202				
		11/30/2020	165.88.254.202				
		11/30/2020	165.88.254.202				

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
		05E	21974	16	B. WING		02/17/2021	
1	OVIDER OR SUPPLIER			STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Υ			IVINGSTO			
(X4) ID PREFIX	SUMMARY ST (EACH DEFICIENCY MUS	TATEMENT OF DEFI			ID PREFIX	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL		(X5) COMPLETION
TAG	•	ENTIFYING INFORMA			TAG	CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		DATE
D6102	Continued From pag				D6102			
	Data Analyzed by M		- 10					
	Accession Number	Date Reported		Address				
		12/07/2020		88.254.222				
	12/07/2020     165.8       12/07/2020     165.8       12/07/2020     165.8		8.254.222					
				8.254.222				
			8.254.222					
			·····	8.254.222				
		12/07/2020		8.254.222		Va		
		12/07/2020		8.254.222				
		12/07/2020	·····	8.254.222				
		12/07/2020		8.254.222				
		12/07/2020		8.254.222				
		12/07/2020		8.254.222				
		12/07/2020		8.254.222				
		12/07/2020		8.254.222				
		12/07/2020		8.254.222				
		12/07/2020 12/08/2020		8.254.222 8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200		-		
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200			y	
		12/08/2020		8.254.200				
		12/08/2020		8.254.200		726.		
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020		8.254.200				
		12/08/2020	***************************************	8.254.200				
		12/08/2020		8.254.200				
	e. The total number from 12/07/2020 to 12 f. The total number from 11/22/2020 to 11	r of results repor 2/08/2020 was 1 r of results repor	ted by ,974. ted byE	MN				

	FOF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/G IDENTIFICATIONNUMB		1 '	CONSTRUCTION	(X3) DATE SI COMPLE		
		05D21974	16	D. WING	<del>.</del>	02/	17/2021	
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 L	DDRESS, CITY, STATE, ZIP CODE 4 LIVINGSTON AVE ENCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATOR OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE API DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
D6102	3. Based on the lab declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 4. The Laboratory (12/16/2020 at 1:00 pensure the laboratory)	poratory's annual testing the laboratory director ratory reported 00 SARS-CoV-2 test resect 16/2020.	r on sults	D6102				