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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") test results to the Semanner, and at such the Secretary may provide This Condition is not Based on the number deficiencies cited her the Condition for FAC was not met as mand Title 42 of the Code of Findings included: 1. The laboratory fails contamination of patinstruments, reagents for the laboratory's Contamination of patinstruments, reagents for the laboratory fails contamination of patinstruments, reagents for the laboratory fails contamination of patinstruments, reagents for the laboratory fails procedures to ensure chemical, biochemical materials (See D301.) 3. The laboratory fails test requisitions of all	performs nonwaived to able requirements und 493.1105, unless HHS e that provides equival cified in Appendix C on ual (CMS Pub. 7). S-CoV-2 test results Diergency, as defined in ter, each laboratory that intended to detect agnose a possible caser referred to as a must report SARS-CoV cretary in such form an timing and frequency, rescribe. met as evidenced by: If a severity of the rein, it was determined cillity ADMINISTRAT lated by CLIA in Subpator Federal Regulation. Bed to ensure that ent specimens, equipments, materials, and supplicated (See D3003). Bed to observe safety protection from physical, and biohazardous of the retain records of the retai	dent fithe fithe furing fix e of fix e of fix das fix	D3000	(1 - D3003) The laboratory has an Amplico Contamination Prevention Plan (CA-SAFE 1.0, approved by Lab Director, in effect at inspection. 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 pla use of PPE with defined gowning/degownin procedures, dedicated equipment and conseach room, aerosol-resistant pipette tips, derefrigerators/freezers to separate reagents and asceptic cleaning techniques all of wor equipment. The observation made at time stated that the lab use of 70% ethanol did ne EUA and our procedure. Based on CDC guthe letter from our corporate quality organiminimum 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 approve director with an effective date of 22Oct202 (v6, approved by the director on 26Feb2021 the number of individuals permitted in a BSt time, as established by the manufacturer. Sc D3011 for more details. (3 - D3027) As stipulated in the contractual with the State of California, all requisition collected on the electronic requisition form stored at Color Genomics (CLIA #05D2081 Requisition data are retained by Color Genevars per their policies and procedures. The documents are accessible to CDPH Branch I receives the confirmation of a test requisition system and the CDPH Branch Laboratory's software system. In the event that a test requot available the response from the Color Csystem indicates that the sample is not approcessing and no collection date and time provided. See section D3027 for more details.	rection of several process of the data is that is 492). Omics for 20 see Laboratory aboratory aboratory at the data is. This is cation ftware LIMS unisition is enomics oved for are list.	8Mar2021 X6) DATE
			1	Alosenil	Laboratory Director	30Marc	h2021

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.

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O			PLE CONSTRUCTION	(X3) DATE SUI	
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D3000	Continued From pag	e 1		D3000	Continued from page 1		
	SARS-CoV-2, for at least two years (See D3027). 4. The laboratory failed to retain records of original test reports of all patients tested for SARS-CoV-2, for at least two years (See D3041). FACILITIES			D3003	(4 - D3041) CA-DC-SOP-003 v1 effective at the inspection states that patient results are retained minimum of 3 years. As stipulated in the contra agreement with State of California, all reports are electronically through Color Genomics. Per their and procedures. (CLIA #05D2081492), reports a	8Mar2021	
	The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This Standard is not met as evidenced by: Based on interview with the laboratory staff on December 8, 2020, review of policies and procedures (P/P) for Quality Management Plan and FDA EUA IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, random review of 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 that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was minimized. Findings included: 1. Decontamination Protocol				In the event that a report must be amended, bot and the amended reports are retained. Original versions of the reports affected by the error on 0 have been retained. See section D3041 for more D3003 Finding 1: The laboratory has an Amplicon Contamin. Prevention Plan, CA-SAFE-POL-019 v 1.0, Lab Director, in effect at time of inspection. describes the measures put in place to preve contamination that included laboratory des construction of air lock doors, environment with separate HVAC systems, unidirections flow, secure PCR plate transport, use of PPI defined gowning/degowning procedures, de equipment and consumables in each room, resistant pipette tips, dedicated refrigerators separate reagents and samples, and asceptite techniques all of work areas and equipment observation made at time of inspection state lab use of 70% ethanol did not match the E procedure (See Section 5.7.2). Additionally, Safety statement was included in the technic (listed in the findings) that contradicted the approved practice and the Laboratory Quali Management Plan (approved by the directo effect at time of inspection (CA-QM-SOP-0 effective 01NOV2020) did not provide the renvironmental prevention and decontaming initiatives outlined in the Amplicon Contam Prevention Plan.	and amended 4Dec2020 details. ation approved by This plan the ign and tal controls all sample with edicated aerosol- s/freezers to c cleaning The ed that the UA and our a default cal SOPS current ity r and in 001 va robust ation	

contamination prevention plan.

The FDA EUA instructions for use of the PKI nucelic

preventing 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

Acid detection kit provided possible actions for preventing contamination; The decontamination

Jena).

a. During the laboratory tour at approximately

10:00 a.m., the laboratory staff stated the use of

70% Ethanol to decontaminate the working area

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

at least twice a day for accessioning, heat inactivation, decapping of swab transport tubes

D3003 Continued From page 2 b. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) stated only the temperature and humidity monitoring for environmental and safety monitoring. The laboratory failed to have written protocols to ensure the performance, frequency, and documentation of environmental decontamination. c. Review of the laboratory's policies and procedures for accessioning, heat inactivation, decapping, sample transfer, extraction, and PCR (Policy # CA-ACC-SOP-001, Title: Accessioning for SARS-COV-2 Samples, Effective Date 12/05/2020; CA-EXT-SOP-002, Title: Decapping and Batch Preparation for Janus G3, Effective Date 12/03/2020; CA-EXT-SOP-003, Title: Sample Transfer Using the Janus G3, Effective Date 12/03/2020; CA-EXT-SOP-004, Title: Viral RNA DNA Extraction Using the Chemagic 360-D, Effective Date 11/03/2020; Sataed under Section 6.0 Occupational Health and Safety that, "while little is known about this novel virus, the comparable genetic characteristic with SARS-COV and MERS-CoV suggest that 2019-nCoV may likely be susceptible to disinfectants including Sodium Hypochlorite for general surface disinfection, 75% ethanol, 0.5% Hydrogen Peroxide, Quarternary Ammonium, and Phenolic compensoria, if used according to	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
D3003 Continued From page 2 D3003 Continued From page 2 D3005 Review of the laboratory's policies and procedures (Policy # CA-GM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) stated only the temperature and hurnidity monitoring for environmental and safety monitoring. The laboratory failed to have written protocols to ensure the performance, frequency, and documentation of environmental decontamination. C. Review of the laboratory's policies and procedures for accessioning, heat inactivation, decapping, sample transfer, extraction, and PCR (Policy # CA-GN-SOP-001, Title: Accessioning for SARS-CoV-2 Samples, Effective Date 12/05/2020; CA-EXT-SOP-001, Title: Accessioning for SARS-CoV-2 Samples, Effective Date 12/05/2020; CA-EXT-SOP-003, Title: Decapping and Batch Preparation for Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-003, Title: Decapping and Batch Preparation for Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Wiral RNA DNA Extraction Using the Chemagic 360-D, Effective Date 11/18/2020; CA-EXT-SOP-004, Title: Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Caresion of the Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Caresion of the Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-005, Title: Caresion of the Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-004, Title: Caresion of the Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-005, Title: Caresion of the Sample Transfer Using the Janus G3, Effective Date 12/05/2020; CA-EXT-SOP-005, Title: Caresion of the Sample Transfer Usin			05D21974	16	B. WING		02/17/2021		
(EACH DEFICIENCY MUST BE PRECIDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) D3003 Continued From page 2 b. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) stated only the temperature and humidity monitoring for environmental and safety monitoring. The laboratory failed to have written protocols to ensure the performance, frequency, and documentation of environmental adecontamination. c. Review of the laboratory's policies and procedures for accessioning, heat inactivation, decapping, sample transfer, extraction, and PCR (Policy # CA-ACC-SOP-001, Title: Accessioning for SARS-GOV-2 Samples, Effective Date 11/18/2020; CA-EXT-SOP-002, Title: Decapping and Batch Preparation for Janus G3, Effective Date 12/03/2020; CA-EXT-SOP-004, Title: Viral RNA DNA Extraction Using the Chemagic 360-D, Effective Date 11/03/2020; stated under Section 6.0 Occupational Health and Safety that, "while little is known about this novel virus, the comparable genetic characteristic with SARS-CoV and MERS-CoV suggest that 2019-nCoV may likely be susceptible to disinfectants instiction, 75% ethanol, 0.5% Hydrogen Peroxide, Quarternary Ammonium, and Phenolic compounds, if used according to			Y	28454 LI	LIVINGSTON AVE				
b. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) stated only the temperature and humidity monitoring. The laboratory failed to have written protocols to ensure the performance, frequency, and documentation of environmental and safety monitoring. The laboratory failed to have written protocols to ensure the performance, frequency, and documentation of environmental decontamination. c. Review of the laboratory's policies and procedures for accessioning, heat inactivation, decapping, sample transfer, extraction, and PCR (Policy # CA-ACC-SOP-001, Title: Accessioning for SARS-CoV-2 Samples, Effective Date 12/05/2020; CA-EXT-SOP-002, Title: Decapping and Batch Preparation for Janus G3, Effective Date 12/03/2020; CA-EXT-SOP-003, Title: Sample Transfer Using the Janus G3, Effective Date 12/03/2020; CA-EXT-SOP-004, Title: Viral RNA DNA Extraction Using the Chemagic 360-D, Effective Date 11/03/2020; Stated under Section 6.0 Occupational Health and Safety that, "while little is known about this novel virus, the comparable genetic characteristic with SARS-CoV and MERS-CoV suggest that 2019-nCoV may likely be susceptible to disinfectants including Sodium Hypochlorite for general surface disinfection, 75% ethanol, 0.5% Hydrogen Peroxide, Quarternary Ammonium and Phenolic compounds, if used according to	PREFIX	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	D BE	COMPLETION	
manufacturer's recommendations. VTM containing Guanidine may produce cyanide with bleach, therefore not recommended as cleaning agents in CDPH Branch Lab." (1) The laboratory's procedure failed to specify	D3003	b. Review of the laprocedures (Policy # Quality Management 11/01/2020) stated on humidity monitoring from monitoring. The laborotocols to ensure the and documentation of decontamination. c. Review of the laprocedures for access decapping, sample the (Policy # CA-ACC-S for SARS-CoV-2 Sar 12/05/2020; CA-EXT Inactivation of Viral SD Date 11/18/2020; CA-EXT Inactivation of Viral S	boratory's policies and CA-QM-SOP-001, Title Plan, Effective Date of environmental and stratory failed to have write performance, frequent fenvironmental and stratory's policies and estioning, heat inactivation and OP-001, Title: Accessioning, heat inactivation and OP-001, Title: Accessioning, Effective Date CSOP-001, Title: Heat Swab Samples, Effective Date CSOP-002, Title: hereparation for Janus (2020; CA-EXT-SOP-002) are Using the Janus G3, (2020; CA-EXT-SOP-003) are Using the fective Date 11/03/2020; CA-EXT-SOP-004, Extraction Using the fective Date 11/03/2020; CA-EXT-SOP-004, Extraction Using the fective Date 11/03/2020; CA-EXT-SOP-005, Extraction Using the fective Date 11/03/2020; CA-EXT-SOP-006, Extraction Using the fective Date 11/03/2020; CA-EXT-SOP-006, Extraction Using the fective Date 11/03/2020; CA-EXT-SOP-007, Extraction Using the fective Dat	d safety sitten ency, on, PCR oning e s G3, 03, 04, 0) th and novel with effor 0.5% m, and with ening	D3003	Based on CDC guidelines and the letter froi corporate quality organization the minimum ethanol required for decontamination is 60. (1) Immediate Corrective Action: • Updated all technical protocols to reficurrent disinfectant in use, 70% Ethan removal of UV references and the use instead of VTM (See Attachment 1 and associated approval dates). • Updated the Quality Management Pland QM_SOP-001, Sections 6.3.4.7, 6.5.1, approved by Lab Director and effective 01Mar2021) to reflect contamination and monitoring that is in place, follow Amplicon Contamination Prevention (SAFE-POL-019., v1.1, approved by and effective 14Dec2020). (2) Patient Impact: Per Lab Director Dr. R. there is no change in diagnosis, treatment, or recommended patient action (retesting), and not be patient harm. Appropriate quality correactions are helpful in determining whether contamination has occurred. A patient look 28OCT2020 to 08DEC2020) and a patient (09DEC2020 to 08DEC2020) was conducted positive and negative controls to look for the viral targets that could indicate contamination was no evidence of contamination as values below 2% threshold. (See Attachment 1) The downward noted is due to a software change color compensation and better resolution and attributable to EtOH or % of EtOH used. Rosendorff, the current Lab Director, there contamination of patient samples or test resolutions are found. Staff were provided MediaLab for additional references to VT EtOH; none were found. Staff were provided MediaLab to the updated SOPs on the day to Director approved the documents (refer to attachment 1). As this was a correction that	m percent lect the mol, the e of MTM and their an (CA-6.8.1, ye prevention wing current a Plan Lab Director osendorff, or d there would ontrol er chack (from ookforward to review all the presence of ion. There is were well the trend e allowing for not not per Dr. is no sults. Quality nanagement The M and 75% and access via the Lab the SOPs in reflected the		

(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 (EACH CORRECTIVE ACTION SHOULD BE PREFIX TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D3003 D3003 (4) Monitoring Mechanism: Positive and Negative Continued From page 3 controls are monitored by the Sign Out Manager with which disinfectant is being used at the CDPH trending review monthly and signature review by the Branch Lab. Lab Director at the Quality Management Review. Batch runs are monitored for internal quality metrics for non-(2) At the time of the on-site survey on viral peaks and negative control positivity; Documented December 8, and 9, 2020, the laboratory was supervisor review is audited monthly by Quality Dept as using Molecular Transport Media (MTM), not part of the monthly end to end audit (Refer to 2021 Viral Transport Media (VTM). The laboratory was Audit Schedule and the End to End 10 Specimen Audit Plan (CA-QM-FM-016) also using 70% ethanol as a disinfectant, and not any of the disinfectants (75% ethanol, 0.5% Appendix A: The Quality Management Plan has been Hydrogen Peroxide, Quaternary ammonium, and revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 Phenolic compounds) specified in its procedure. ver2.0 approved by Lab Director and effective 01Mar2021. (3) The laboratory failed to provide documentation and written protocol to ensure that 70% ethanol was sufficient to minimize environmental contamination. See Attachment 1. Summary: The laboratory has a plan for Amplicon Contamination Prevention Plan (see CA-SAFEd. Review of the laboratory's FDA EUA POL-019). The use of 70% EtOH meets the standard set Instructions for Use (IFU) for Perkin Elmer New by CDC. Heat inactivation is an effective method to inactivate SARS-CoV-2. Disposal of MTM sample Coronavirus Nucleic Acid Detection Kit (Effective collection tubes that have been subjected to heat Date 03/20/2020, Revised 09/16/2020 and inactivation in bleach is not necessary. Therefore, the 01/12/2021 for version 7.0) stated under area in which the samples were handled was adequately Warnings and Precautions #10 that, "Sterile decontaminated. 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.

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D3	protocol for work are disinfectants, and the disinfectants, and the 2. Decontamination Testing Process a. During the labor 2020 at approximate was observed to have Solution in dispensing expiration date. (1) Lot # 267015, Ex dispensing bottles) (2) Lot # A10012002 12/07/2020 (2 dispensing bottles) b. Review of the laprocedures (Policy # Quality Management 11/01/2020) stated the should be used in testindicated expiration of 3. The following arthe 60 randomly revictive review of the period for 12/08/2020, wherein SARS-CoV-2 tests a failed to ensure contribution of the state of the	illed to provide written ia, and instrument surface use of UV light. In Solution in the ratory tour on Decemberly 10: 30 a.m., the labor of four 70% Ethanol Clear of Solution Date: 12/03/20 is Expiration Date: 12/03/20 is Expiration Date: 12/03/20 is Expiration Date: 13/03/20 is CA-QM-SOP-001, Title that reagents and chemical of the accession number of the accession number of the laboratory performing reported results, but amination of patient ent, instruments, reager	er 8, eatory aning 20 (2 e: cals ein ers of eds eed t	D3003	Finding 2,3,4,5: We acknowledge the failure to discard sor ethanol reagent bottles that were in use pa expiration; 2 bottles 5 days past expiration; 1 day past expiration date. (1) Immediate Corrective Action: • The bottles were discarded and fresh made available. Walkthrough condisupervisory teams ensuring that all of were labelled appropriately and in the policies and procedures outlined Management Plan (CA-QM-SOP-00). • A new SOP, Labeling of Reagents and (CA-LABGEN-SOP-002) was approximated to the policies of improperly labeled reagent MediaLab Admin to all laboratory to no 24Feb2021 with a target completed 23Mar2021 (93% compliance). (2) Patient Impact: A lookback review performed on specimens received fron 1DEC2020 to 12DEC 2020 was conthere was no evidence of contamination samples as a result of the expired 70 QC report in Attachment 2. The posshows the negative control analyzed specified time frame and indicates possible negative contamination (but contamination of patient's sample). Laboratory Director affirms that the contamination impact to patient residuring this time period. (3) Preventative measure: • An audit, specific to compliance with logs and reagent labeling and expiration (2021AUDIT-005) carried out 26Fe been reported to Managers and Sup Response is expected by 15Mar2021 corrective actions and future preventive actions include a reagents in their respective areas to compliance with labeling and expiration action of the proper of the properties of the propertie	and 2 bottles and 3 bottles and 4 bottles and 5 bottles and 5 bottles and 6 bottles and 7 bottles and 8 bottles and 8 bottles and 9	

(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 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) 1D SUMMARY STATEMENT OF DEFICIENCIES (EACH CORRECTIVE ACTION SHOULD BE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX 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 29Mar2021 D3011 FACILITIES CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection

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CDPH BRANCH LABORATORY			54 LIVINGSTON AVE ENCIA, CA 91355				
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from physical, chemical, bio electrical hazards, and biohath This Standard is not met as Based on interview with labor December 8, 2020, review of procedures (P/P) for General Plan, random review of test the period from 11/22/2020 to out of 60 patient test records determined that the laborator safety procedures to ensure physical, chemical, biochem biohazardous materials. Findings included: 1. During the laboratory to 2020 at approximately 11:00 staff stated that COVID-19 s process is performed by one one Class II Type A2 Biosafe safely working with material or potentially contaminated biohazardous materials and sterility of the materials inside 2. During the laboratory to 2020, the laboratory was oblaboratory personnel workin Cabinet. 3. Review of the laborator procedures (Policy # CA-SA General Facilities Safety Pla 12/07/2020) failed to indicate laboratory personnel who calensure safety and minimize 4. The following are the active for the facility reviewed personnel working are the active 60 randomly reviewed personnel working facilities 60 randomly reviewed personnel wo	nazardous material sevidenced by: poratory staff on of policies and ral Facilities Safety to records covering to 12/08/2020, for its reviewed, it was ory failed to observe protection from nical, and our on December 8 of a.m., the laborat sample transfer the testing person protection from with infectious or differ maintaining de. our on December 9 of for maintaining de. our on December 9 observed with two ong in one Biosafety and AFE-POL-002, Title an, Effective Date the number of an utilize one BSC occurrences on numbers occession numbers	8, tory er for with	D3011	Findings 1-6: The Biosafety hoods provide secondary cor controls and ventilation controls that only operation and improve the safety of the decoperation. The laboratory contacted NuAir manufacturer of the BSL2 hoods used onsit confirmed there should be no operational phaving 2 personnel working in one cabinet time. In the link provided in the attached docum will see that if the two cabinet operators are with different types of work (dirty and clea would be an issue. However, in this situation personnel would be performing the exact swith the same reagents and materials. (1) Immediate Corrective Action: The POL-002 document was updated to reflect current version is 6 which was approved by Director on 26Feb2021. (2) Patient Impact: Per Lab Director Director on 26Feb2021. (3) Preventative Measures: CA-SAFE-was assigned by MediaLab Admin to the permployees to read and acknowledge the upprocedure by 31Mar2021. (4) Monitoring Mechanism: 21Audit0 23Mar2021, conducted by Quality, will and Extraction Area BSC's for compliance with personnel allowed at BSC at one time. Aud daily check for 30 days with on the spot edu 21Audit009) If compliance is noted, daily cease and this safety observation will be admonthly wet lab departmental audit, conducted Quality (See 2021 Audit Schedule).	benefit the capping re, the te and they problems at any given tentation you to working re, the two ame process to CA-SAFE-this. The rest the process of the control of the		

(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 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) Continued From page7 D3011 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 Based on the laboratory's annual testing

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NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE VALENCIA, CA 91355	4 LIVINGSTON AVE				
(X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE				
D3011 Continued From page 8 declaration signed by the laboratory director on 12/16/20/20, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/20/20 until 12/16/20/20. 6. The Laboratory Director affirmed (February 12, 20/21 at approximately 2.00 pm) the laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. D3027 RETENTION REQUIREMENTS CFR(s), 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This Standard is not met as evidenced by: Based on interviews with staff and the laboratory director on December 8, 20/20, the absence of test requisitions, and random review of test records covering the period from 11/22/20/20 to 12/08/20/20, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to retain records of test requisitions for SARS-CoV-2 patient testing. Findings included: 1. The laboratory performed SARS-CoV-2 RT-PCR laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples under the order of the State Health Officer. 2. Although the laboratory presented a blanket prescribing order for all California patients within the state from the State Health Officer, an authorized person, the laboratory does not	29Mar2021				

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D3027	generate a test requi 3. During the initial California clinical lab requested the labora test requisition that w is only one of the sex prior to receiving a la 10/20/2020, the labo documented titled, "1 19 Sample Requisition though the laboratory requisition that will be not been generating patient. 4. There was no m a test requisition was There was also no m requisitions were reta 5. The following ar the 10 randomly revi covering the period f 12/08/2020, wherein SARS-CoV-2 tests a	sition for each patient stages of its application oratory license, we tory to submit an examination veral requirements to be aboratory license. On ratory submitted a fest Order Requisition on- Example Only v.3." y submitted an example e used, the laboratory la test requisition for each est echanism in place to each a generated for each p enechanism to ensure the ained by the laboratory. The the accession number ewed patient test record	Covid Even e had ach ensure atient. hattest ers of ds	D3027	Findings 1, 4-7 The CDPH Branch Laboratory reconfirmation of a test requisition for eaway of electronically requesting the data coduring the accessioning process. This is cosystem-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 rethe Color Genomics system indicates that the not approved for processing and no collection and the data fields exchanged (1) Immediate Corrective Action: To cooperation with Color Genomics and the data fields exchanged (1) Immediate Corrective Action: To cooperation with Color Genomics and the data fields exchanged (1) Immediate Corrective Action: To cooperation with Color Genomics and the data fields exchanged (1) Immediate Corrective Action: To cooperation with Color Genomics and the data fields exchanged (1) Immediate Corrective Action: To cooperation with Color Genomics and the data fields exchanged (1) Immediate Corrective Action: To cooperation with Color Genomics and the data fields exchanged (1) Immediate Corrective Action: To cooperation data fields exchanged (1) Patient Impact: Per Lab Director Rosendorff, there is no change in diagnosis or recommended patient action (retesting), and there would not be patient to ensure the assurance and laboratory director staff at the Branch Laboratory has access to the Color Genomics, on demand. (4) P	ich sample by imponents impleted by a between the e CDPH. In the event sponse from the sample is ion date and inal Labs or data. Through CDPH e data from tion was nember of the that allows e electronic enomics, on a the use of Training e quality the CDPH Genomics in the use of Training e quality the country	

TAG OR LSC IDENTIFYING INFORMATION) D3027 Continued From page 10 6. 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.	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			1 ' '	PLE CONSTRUCTION G	(X3) DATE SUF COMPLETS				
28454 LIVINGSTON AVE VALENCIA, CA 91355 (X4) ID PRETX TAG (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) D3027 Continued From page 10 6. 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.			05D21974	16	B. WING _		02/17	7/2021		
VALENCIA, CA 91355 (X4) ID PRETIX TAG (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) D3027 Continued From page 10 6. 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.										
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6. 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.	PREFIX	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	(X5) COMPLETION DATE			
affirmed December 8, 2020 at approximately 11:00 a.m. that the laboratory failed to retain records of test requests. Findings 1-7		6. Based on the lat declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 7. The laboratory d affirmed December 8 11:00 a.m. that the la records of test reque RETENTION REQUI CFR(s): 493.1105(a) Test reports. Retain of the original report and corrected report date of reporting. (i) In addition, retain in as specified in 21 CF (ii) and pathology test after the date of report This Standard is not Based on email compliance on email	coratory's annual testing the laboratory director ratory reported 20 SARS-CoV-2 test resected 30 SARS-CoV-2 test r	copy nary, the orts years ords tory ts for		CA-DC-SOP-003 v1 effective at the time of it states that patient results are retained for a m 3 years. As stipulated in the contractual agree State of California, all reports are generated ethrough Color Genomics. Per their policies a procedures. (CLIA #05D2081492), reports ar for 20 years and are accessible to CDPH Brant Laboratory for auditing purposes. In the event that a report must be amended, to 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 AL that have been amended have an accessible or amended report. (1) Immediate Corrective Action: Through with Color Genomics and the CDPH Branch a method to present the data from the electrothe form of a requisition was established. The Director and member of the Quality Assurant received training that allows them to effective efficiently access the electronic requisitions a stored by Color Genomics, on demand. (2) Patient Impact: Per Lab Director Dr. Ro there is no change in diagnosis, treatment, or recommended patient action (retesting), and not be patient harm as the amended reports	inimum of ment with electronically and e retained each ooth the d. Original by the error L results riginal and a cooperation a Laboratory, onic order in the Laboratory are team ely and and reports sendorff, there would	29Mar2021		

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D3041	SARS-CoV-2 but she laboratory process end. 3. CDPH Branch lataboratory about the which amended report 12/07/2020. 4. CDPH Branch Late the test results for SA provide the original to 12/04/2020 and ame. 5. The following and the 10 reviewed patient the laboratory desired from 12/02 wherein the laboratory desired tests and reported reoriginal test reports for Accession Number. 6. Based on the late declaration signed by 12/16/2020, the laboratory declaration signed by 12/16/2020 and ame.	buld have been invalid a pror on 12/04/2020. Aboratory informed Color test results reported in a part were issued on a part of the access where it is the accession number of	gron sults	D3041	Continued from page 11: (3) Preventative Measures: Throug CA-PER-FM-031, Pre/Post Analytical QA Checklist, the lab will continue to ensure th assurance and laboratory director staff at th Branch Laboratory has access to the Color Content of System and can effectively and efficiently actored by Color Genomics, on demand. (4) Monitoring Mechanism: Audit Amended Reports to ensure compliance with (availability of original report, original resure on the Amended Report, and confirmation Report notification to client and/or patient incorporated into the 2021 Audit Schedule audit, performed by the quality organization in the Quality Management Review. See attachment 5.	Fraining e quality e CDPH Genomics cess the data of ALL th SOP lts included of Amended is as a monthly		

(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 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION DATE (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) Continued From page 12 D3041 D5300 D3041 reports. CDPH Branch Laboratory receives all samples via Testing Task Force collection sites. These sites are D5300 D5300 PREANALYTIC SYSTEMS 8Mar2021 registered with Color Genomics and operate under a CFR(s): 493.1240 standing order from Dr. Erica Pan, Acting State Health Officer, State Epidemiologist, Deputy Director, Center for Infectious Disease, CDPH. Each laboratory that performs nonwaived testing (5301/5305/5313) All data, including collection date and must meet the applicable preanalytic system(s) collection time, are collected on the electronic requisition requirements in §§493.1241 and 493.1242, form that is stored at Color Genomics (CLIA unless HHS approves a procedure, specified in #05D2081492). All CLIA required requisition elements Appendix C of the State Operations Manual are included in the electronic requisition. Requisition data are retained by Color Genomics for 20 years per (CMS Pub. 7), that provides equivalent quality their policies and procedures. These documents are testing. The laboratory must monitor and accessible to CDPH Branch Laboratory for auditing evaluate the overall quality of the preanalytic purposes. Manual paper requisition forms are available systems and correct identified problems as for use in extreme emergent priority as requested by CHHS and documented as deviation from standard specified in §493.1249 for each specialty and procedure. subspecialty of testing performed. See section 5301, 5305, 5313 for more details. This Condition is not met as evidenced by: (5311) During the initial planning and execution of the CDPH Branch Laboratory project the laboratory team provided feedback to the state of California on the Based on the number and severity of the deficiencies cited herein, it was determined that collection process and media. Specifically, the team the Condition for PREANALYTIC SYSTEMS was outlined the process for administering the nasal swab sample, the contents of the collection kit, packaging, not met as mandated by CLIA in Subpart K of infectious agents' identification (UN3373) label, storage Title 42 of the Code of Federal Regulation. at room temperature, and shipping timeline. This information was then collated into the Testing Taskforce Playbook and the processes at the collection site and Findings included: laboratory procedure CA-CLSRV-SOP-002. Color Genomics provides COVID-19 testing through its 1. The laboratory failed to ensure it retained test own laboratory. References to their corporate site requisitions for SARS-CoV-2 patient testing (See collection materials is specific to their laboratory. Color D5301). Genomics is contracted by CDPH Branch Laboratory to provide kits that are comprised of a sample collection tube prefilled with MTM and barcoded with two 2. The laboratory failed to ensure test identifiers, one collection card for the patient with a requisitions included necessary information for matching barcode, and an absorbent pad. All samples accurate reporting of test results (See D5305). tested to date were collected in Color collection kits containing MTM. 3. The laboratory failed to ensure written policies Procedure CA-CLSRV-SOP-002 specifies use of MTM. Procedure CA-ACC-ACC-001 incorrectly used VTM and procedures for specimen submission and (viral transport media) as a generic term. This has been handling were followed (See D5311). corrected to MTM; however, the rejection criteria in the procedure are sufficient since samples sent outside of the 4. The laboratory failed to ensure it documented Color system are "Not Approved". the date and time of receipt of all patient See section 5311 for more details. specimens for SARS-CoV-2 testing (See D5313).

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D5300	5. The laboratory failed to ensure it established written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic system (See D5391). TEST REQUEST			D5300 Continued from page 13 (5391) The lab acknowledges that its written policies and procedure to monitor, assess, and when indicated, to correct problems identified were not clearly defined in an overall plan and were scattered throughout multiple SOPs. In acknowledgement of this observation, the laboratory completed a major revision of its Quality Management Plan (CA-QM-SOP-001, v2), approved by the Lab Director and effective as of 01MAR2021. Refer to the Appendix A, Section 5.5.1 for specific preanalytical measure that are assessed at CDPH Branch Laboratory. Refer to Sections 6.1 for Leadership Oversight and Section 6.4 for Continuous			29Mar2021
	CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This Standard is not met as evidenced by: Based on interviews with testing personnel and				Inforce activities that Section 6.4 for Cocurrence Management a 6.5 for Process Management of all 3 of the pha testing (preanalytical, analytical and post analyaddition, a new SOP, PreAnalytical QA Proces SOP-003 v1, approved by Lab Director on 24F created to define the procedural guidelines for sample tracking for quality assurance purposes for specific details.	nd Section ses of lab rtical). In ss (CA-ACC- EB2021 was internal	
	the laboratory director on December 8, 2020, the absence of written policies and procedures (P/P) for retaining test requisitions, the absence of test requisitions for each patient tested, and random review of 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 retain records of test requests for SARS-CoV-2 patient testing.				D5301 Findings 1-3, 5-7 Per contractual agreement with CHHS and CI Branch Laboratory, all information is collected electronic requisition form at established colle operating under the standing order from Dr. I. Requisition form information is stored at Colc (CLIA #05D2081492; see D5311). Data needs is transferred to CDPH Branch Laboratory. Redata are retained by Color Genomics for 20 ye policies and procedures. These documents are CDPH Branch Laboratory for auditing purpod did create a paper requisition to be used in extemergency and/or downtime procedures; it wintended for routine use as stipulated in the coarrangement between CDPH and CHHS.	I on the ction sites Pan. Pan. Pan. To Genomics of for testing equisition ars per their accessible to ses. The lab reme	
	1. The laboratory performed SARS-CoV-2 RT-PCR laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples under the order of the State Health Officer. 2. Although the laboratory presented a blanket prescribing order for all California patients within the state from the State Health Officer, an authorized person; the laboratory does not generate a test requisition for each patient. 3. During the initial stages of its application for a California clinical laboratory license, we asked the				(1) Immediate Corrective Action: CA-C SOP-002 was updated on 11Mar2021 to refle acceptance of Dr. Pan's standing order. Also QMP (CA-QMP-SOP-001 v2, approved by L on 01MAR2021), Section 5.5.1.1 outlining the test order management and the use of a stand from Dr. Pan, as stipulated by CHHS. Refer to A. (2) Patient Impact: Per Lab Director Dr. there is no change in diagnosis, treatment, or recommended patient action (retesting), and not be patient harm. (3) Preventative Measures: Through the CA-PER-FM-031, Pre/Post Analytical QA Tr. Checklist, the lab will continue to ensure that future quality assurance staff and laboratory of at CDPH Branch Lab have the knowledge and monitor, and produce when requested, a patir equisition from the Color Genomics database	ect the updated ab Director he process of ling order o Appendix Rosendorff, there would use of the raining current and director(s) d training to ent	

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D5301	laboratory to submit a that will be used. A to the several requirement receiving a laboratory the laboratory submit "Test Order Requisition- Example laboratory submitted will be used, the laboratory submitted will be used, the laboratory fapolicy on the use of some chanism in place requisition was generated. 5. The following are the 10 randomly review covering the period from 12/08/2020, wherein SARS-CoV-2 tests are to provide test requisition.	an example test requisitest requisition is only of ents to be met, prior to a license. On 10/20/2020 ted a documented title on Covid 19 Sample on Covid 19 Sample on Covid 19 Sample on example requisition ratory had not been uisition for each patient atled to provide a writtest anding orders. There are to ensure a test rated for each patient. The the accession number of the laboratory performed reported results but the title of the patient test record on 11/02/2020 to the laboratory performed reported results but tions for each patient test record the laboratory performed reported results but the laboratory patient test record the laboratory performed reported results but the laboratory patient test record the laboratory performed reported results but the laboratory patient test record the laboratory performed reported results but the laboratory patient test record the laboratory performed the laboratory per	ne of 20, d, h the that t. n was rs of ds ed failed ested.	D5301	2021 to determine availability and compliar required elements are performed by the quorganization. The availability of the requisit confirmed for 10 samples via a routine trac performed 26Feb2021. An audit (2021Audiadditional 25 samples was initiated to verificate requisitions are available and include all nerequisitions are available and include all nerequisition elements. See attachment 4 and appendix A (Quality Findings 1, 4-7 The CDPH Branch Laboratory receives the confirmation of a test requisition from regicollection sites operating under Dr. Pan's sor order for each sample by electronically requidata components during the accessioning pis completed by a system-to-system communicated the CDPH Branch Laboratory's software system. In the event that a test requot available the response from the Color Constraint and the CDPH Branch Laboratory's software system indicates that the sample is not appiprocessing and no collection date and time provided. The Color API for External Labs document outlines the process for data tranand the data fields exchanged. (1) Immediate Corrective Act Through cooperation with Color Genomics CDPH Branch Laboratory, a method to prefrom the electronic order in the form of a rewas established. The Laboratory Director and the Quality Assurance team received trainallows them to effectively and efficiently accelectronic requisitions and reports stored by Genomics, on demand. (2) Patient Impact: Per Lab Directo Rosendorff, there is no change in diagnosis, or recommended patient action (retesting), would not be patient harm.	nce with all ality tion was er audit it-008) of an y that cessary Mgmt Plan) stered tanding uesting the process. This inication of tware tall the process is coved for are [External] is mission ion: ion: iand the sent the data equisition and member ning that the process the y Color r Dr. treatment, and there			
	6. 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) Preventative Measures: Through the CA-PER-FM-031, Pre/Post Analytical QA T Checklist, the lab will continue to ensure the assurance and laboratory director staff at the Branch Laboratory has access to the Color C system and can effectively and efficiently acceptate and can effectively acceptate acceptate and can effectively acceptate and can effectively acceptate and can effectively acceptate acceptate and can effectively acceptate acceptate acceptate and can effect acceptate a	raining e quality e CDPH Genomics cess the			

(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) 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 Continued from page 15 Monitoring Mechanism: Monthly audits for FY 7. The laboratory director and testing personnel 2021 to determine availability and compliance with all required elements are performed by the quality affirmed (December 8, 2020 at approximately organization. The availability of the requisition was 11:00 a.m.) that the laboratory did not have test confirmed for 10 samples via a routine tracer audit requisitions for each patient or policies to address performed 26Feb2021. An audit of an additional 25 samples was initiated on 11Mar2021, (see standing orders. 2021AuditPlan-008) D5305 TEST REQUEST D5305 29Mar2021 Reference attachment 4 CFR(s): 493.1241(c) Findings 1-6 The laboratory must ensure the test requisition All information, including Dr. Pan's information as the solicits the following information: ordering provider, is collected on the electronic (1) The name and address or other suitable requisition form that is stored at Color Genomics (CLIA identifiers of the authorized person requesting the #05D2081492) at established collection sites (see D5311). Manual paper requisition forms are available test and, if appropriate, the individual responsible for use in extreme emergent priority as requested by for using the test results, or the name and CHHS and documented as deviation from standard address of the laboratory submitting the procedure. Data needed for testing is transferred to specimen, including, as applicable, a contact CDPH Branch Laboratory. Requisition data are retained person to enable the reporting of imminently life by Color Genomics for 20 years per their policies and threatening laboratory results or panic or alert procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. values. (2) The patient's name or unique patient identifier. The inspectors observed paper manifests (finding 2) (3) The sex and age or date of birth of the patient. accompanying the specimens. These are the shipping (4) The test(s) to be performed. manifests from the collection sites and are date/time (5) The source of the specimen, stamped at receipt and are recorded into the electronic when appropriate. Specimen Delivery Logs (CA-ACC-SOP-004 Day Shift and CA-ACC-SOP-005 Night Shift) from the computers (6) The date and, if appropriate, time of specimen located near the receiving area. Specimen count, time received, sending facility, verification of manifest, (7) For Pap smears, the patient's last menstrual courier company, name of the Driver and any period, and indication of whether the patient had discrepancies are noted (cancelled specimens, a previous abnormal report, treatment, or biopsy. unacceptable specimens). The shipping manifests are (8) Any additional information relevant and scanned electronically, emailed to the Operations necessary for a specific test to ensure accurate Manager who stores the reports. All manifests are available for audit. The SOPS mentioned above are listed and timely testing and reporting of results, in Attachment 4. including interpretation, if applicable. This Standard is not met as evidenced by: The required requisition elements as stipulated in CFR: Based on interviews with laboratory staff and the 493.1241c are collected during the collection site laboratory director on December 8, 2020, the registration process. (Refer to the documents in absence of written policies and procedures (P/P) Attachment 4 titled (1) COLOR Registration

Experience, (2) the CDPH Playbook to Collection Sites and Quality Management Plan (Section. 5.5.1.1) in

for ensuring test requisitions solicited required

information, the absence of test requisitions for

(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 (X4) ID ID PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5305 D5305 Continued From page 16 Continued from page 16 each patient tested, and random review of test (1)Immediate Corrective Action: Through cooperation records covering the period from 11/22/2020 to with Color Genomics and the CDPH Branch Laboratory, 12/08/2020, for 10 out of 10 patient test records a method to present the data from the electronic order in reviewed, it was determined that the laboratory the form of a requisition was established. The Laboratory failed to ensure test requisitions included Director and member of the Quality Assurance team necessary information for accurate reporting of received training that allows them to effectively and test results for COVID-19 Reverse efficiently access the electronic requisitions and reports stored by Color Genomics, on demand. Transcriptase-Polymerase Chain Reaction (RT-PCR). (2)Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would Findings included: not be patient harm. (3)Preventative Measures: Through the use of the CA-1. The laboratory utilized SARS-CoV-2RT-PCR PER-FM-031, Pre/Post Analytical QA Training Checklist, diagnostic laboratory developed test (LDT) forthe the lab will continue to ensure that current and future direct detection of SARS-CoV-2 virus RNA from quality assurance staff and laboratory director(s) at patient samples. It utilizes Chemagic 360 for the CDPH Branch Lab have the knowledge and training to isolation of the viral nucleic acids followed by the monitor, and produce when requested, a patient RT-PCR assay on Analytik Jena Thermal Cycler. requisition from the Color Genomics database. (4)Monitoring Mechanism: Monthly audits for FY 2021 2. During the laboratory tour on 12/08/2020 at are conducted by the quality assurance organization to approximately 10:00 a.m., the laboratory staff determine availability and compliance of the electronic stated that CDPH Branch Lab has been working requisition and the required elements. with another CLIA certified laboratory to help healthcare providers in ordering the test for patients diagnosed with possible Covid-19 infections. It was observed that along with the patient sample was only a "paper manifest" indicating the total number of samples received, site point of contact, tracking company number, collective date for sample collected, site name and address. The laboratory failed to provide test See attachment 4 requisitions for each patient sample received which included information, such as the name and address of the authorized person requesting the test, patient's name or unique identifier, sex, age, date of birth, tests to be performed, source of specimen, date and time of collection, and any additional information relevant to COVID-19 test

(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 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5)COMPLETION (EACH DEFICIENCY MUST BE PRÉCEDED BY FULL REGULATORY PREFIX (EACHCORRECTIVEACTION SHOULD BE PREFIX TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5305 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 29Mar2021 REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O IDENTIFICATION NUMBI		A. BUILDING	PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED	
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	ROVIDER OR SUPPLIER RANCH LABORATOR	Υ "	28454 L	ADDRESS, CITY, STATE, ZIP CODE 54 LIVINGSTON AVE LENCIA, CA 91355			
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D5311	policies and procedurif applicable: (1) Patient preparation (2) Specimen collection (3) Specimen labeling unique patient identification in the procedure identification in the patient identification identification in the patient identification ide	res for each of the follown. on. on. g, including patient namfier and, when appropriate and preservation. ecimen transportation. sing. ability and rejection. I. met as evidenced by: with laboratory staff on eview of policies and specimen collection, g, and random review of period from 11/02/2020 ut of 10 patient test recommined that the laborate written policies and men submission and ed. tilized SARS-CoV-2 RT developed test (LDT) for the submission and ed.	ftest 0 to ords forthe from r the y the	D5311	Findings 1-6 Instruction for collection: During the initial planning and execution of Branch Laboratory project the laboratory tea feedback to the state of California on the coll process and media. Specifically, the team out process for administering the nasal swab same contents of the collection kit, packaging, infeidentification (UN3373) label, storage at root temperature, and shipping timeline. This infethen collated into the Testing Taskforce Play processes at the collection site and laboratory CA-CLSRV-SOP-002. Instructions for obtaining sample kits (via Cofor CDPH Branch Laboratory), collection an samples is provided to collection sites set up 1 Task Force. See attachment 6. Please note, Color Genomics provides COVI through its own laboratory. Color assembles distributes collection kits on the processes and eveloped in their laboratory. These activities completely separate from the CDPH Branch activities and have no bearing on the CDPH. Therefore, it is inappropriate to compare infethe Color website with procedures at the CDP Laboratory. As it relates to testing that occurs at the CDP Laboratory the state of California has contract purposes: sample kit distribution and testing operations. Color Genomics is contracted by CDPH Branch.	m provided ection lined the uple, the ctious agents mormation was book and the procedure lolor Genomic dishipping of by the Testing and dimethods sare Laboratory laboratory. Demandion on PH Branch ted for two site	
	RT-PCR assay on Analytik Jena Thermal Cycler. 2. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002, Title: Specimen Collection, Storage, and Shipping, Effective Date 12/07/2020) stated that "Collection kits with instructions for collection, packaging and shipping are provided to the collection sites through a third-party vendor. A specimen that is				Laboratory to provide kits that are comprised collection tube prefilled with MTM and bard two identifiers, one collection card for the paratching barcode, and an absorbent pad. An of sample kit received is not intended for the Branch Laboratory and is not tested. All samples tested to date were collected in Collection kits containing MTM (see MTM A Letter from Color; Purchase order from Primin attachment 6)	d of a sample oded with tient with a sy other type CDPH	

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
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D5311	not collected correctives ults." The laboratory failed provided to all staff in procurement process. a. Correct speciment the appropriate technic containers. b. Specimen labeling unique identifier, and c. Proper storage and d. Proper transportate. Specimen accepts and disposition. 3. During the labor approximately 11:00 stated that they only in Molecular Transportative The laboratory coord Laboratory for speciments only incomplete at 2-8 Dehours, or -20 Degree specimen is to be subtimesting to the subtimesting to the subtimesting to the subtimesting to the subtimesting the	to provide the instruction the collection using inique and including patient named specimen source dispersion of the laboratory tour on 12/08/202 a.m., the laboratory star process samples collection Media (MTM), transity, and stable for seven of linates with COLOR men collection and a Branch Lab. OR website for specime dicated VTM or UTM measures Celsius within 2 as Celsius on dry ice if is bmitted >24 hours. ailed to provide the cliection and the reference ments for swab	ons	D5311	Procedure CA-CLSRV-SOP-002 specifies to Procedure CA-ACC-SOP-001 incorrectly to (viral transport media) as a generic term. He rejection criteria in the procedure are suffices amples sent outside of the Color system and Approved" and section 8.3.3 would be folloom. The lab acknowledges that its written preare policies and procedures and Quality Managlacked the detail necessary to follow a specithrough the preanalytical phase of testing. (1) Immediate Corrective Action: • The Laboratory completed a major resulting its Quality Management Plan (CA-QSOP-001 v2), approved by the Lab Deffective on 01MAR20201. Section 5. provides detailed overview of the preprocesses relating to test order manaspecimen collection and acceptability for testing. (Refer to Appendix A). • Created a new SOP, PreAnalytical Q (CA-ACC-SOP-003 v1), approved by Director on24Feb2021 defining currefor tracking internal samples and clespecifies the process in place of accepsamples received only through Colon (See D5391 for specific details). Then one type of collection device and methat is used for clinical lab testing of CoV-2. • CA-ACC-SOP-001 Sample Collection and Shipping, which incorrectly state (viral transport media) as a generic to been corrected to the MTM (molecul transport media); See Section 5.1 of approved 09Feb2021 by Lab Director See Section 5.1. (2) Patient Impact: Per Lab Director Dr. Resulting in the correct specimen collection MTM was used for all testing.	ased VTM Itowever, the cient since re "Not based. Inalytical gement Plan men evision of pM- birector and to birector and to samples A Process yethe Lab ent practice arry potting references. The since of the process re is only dia (MTM) SARS- In the storage end VTM erm, has lar version 4.1 r. It cosendorff, age in the ient action	

(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 (X5) COMPLETION (X4) ID PROVIDER'S PLAN OF CORRECTION ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5311 D5311 Continued From page 20 Continued from page 20 4. The following are the accession numbers of the 10 randomly reviewed patient test records (3) Preventative Measures: Lab Director and Quality covering the period from 11/02/2020 to staff to continue with timely document review 12/08/2020, wherein the laboratory tested and following Document Management procedures and making revisions and edits when errors or changes in reported SARS-CoV-2 RT-PCR patient test processes are identified. results, but failed to ensure written policies and (4) Monitoring Mechanism: Continue to document procedures for specimen submission and and monitor unsatisfactory specimens handling using MTM were available and followed. (Unsatisfactory_1 Improper specimen transport medium) received and Accessioning Supervisor/ Manager to discuss any increased trends with COLOR Accession Number and CHHS teams to determine if changes were made to collection kits. See attachment 6 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 written policies and procedures for specimen submission and handling were available and followed. SPECIMEN SUBMISSION, HANDLING, AND D5313 REFERRAL D5313 29Mar2021 CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This Standard is not met as evidenced by:

STATEMENT	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA		HA	(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY	
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CDPH BR	RANCH LABORATOR	T .		IA, CA 913			
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D5313	Continued From pag	ne 21		D5313	Findings 1-6		
		with laboratory staff on					
		eview of available police			All information is collected, including date collection, and is on the electronic requisition		
), and random review of			is stored at Color Genomics (CLIA #05D20	81492). Data	
	patient test records of	covering the period from	ı		needed for testing is transferred to CDPH B	ranch	
		2020, for 10 out of 10 p			Laboratory. Requisition data are retained by Genomics for 20 years per their policies and	l procedures.	
		d, it was determined that			These documents are accessible to CDPH B	ranch	
	laboratory failed to e	nsure the date and time	e of		Laboratory for auditing purposes.		
		he laboratory for each			The submission of a printed manifest with 6	every sample s	
	specimen for SARS-	CoV-2 patient testing w	ras		hipment is a requirement to ensure that the ved activated samples that can be processed	lab only recei	
	documented.				provided to the collection sites by the Testin		8
					mandate the submission of a printed manife time of initial inspection on 08Dec2020, del	est. At the	
	Findings included:				ocumented on an incoming log with noted	date/time of	
					receipt and the location of collection site. The	he lab had	
		tilized SARS-CoV-2RT			just implemented (first of December) documentation of handwritten date/time receipt on the manifest that		
,	based diagnostic l	based diagnostic laboratory developed test			contained the sample ID's. Specimens are n	ot held at	
		t detection of SARS-Co			receiving, but are immediately unboxed and At the time of accessioning the received da	l accessioned.	
		tient samples. It utilize			are logged. In the requisitions and reports f	le located in	
		the isolation of the vira			attachment 4, the 'Accession at' field repres received date and time.	ent the	
		wed by the RT-PCR as	Say		received date and time.		
	on Analytik Jena 1				As noted at the inspection on 08Dec2020, thandwriting the date/time of receipt on the was not consistent.	ne process of manifest	
	During the labor	atory tour on 12/08/202	20 at		was not consistent.		
	approximately 10:	00 a.m., the laboratory	staπ		For additional information see D3027.		
		Branch Lab has been			(1) Immediate Corrective Action:		
		ner CLIA certified labor				. ,	T.
	to neip nealthcare	providers in ordering to	ile.		Through cooperation with Color Gen	omics and	
	test for patients po	ossible with Covid-19 observed that along wit	h the		the CDPH Branch Laboratory, a met		
	notiont comple was	is only a "paper manife	et ⁱⁱ		present the data from the electronic of form of a requisition was established.	order in the	
	indicating only the	date for all the sample	is.		Laboratory Director and member of	the Quality	
	collected at the co	Nection site. It did not			Assurance team received training that	t allows	
	collected at the collection site. It did not indicate the date and time of collection for individual patient samples.		nr .		them to effectively and efficiently acc Color Genomics database the electro		
			"		requisitions that contains the specime		
					date/time.		
	3. Review of the la	boratory's policies and			An electronic date/time stamp was property.	ırchased	
	procedures (Polic	y # CA-CLSRV-SOP-00	02		and installed in the receiving area on all manifests are date/time stamped.	1/Dec2020;	
		ollection, Storage, and			an manness are dute, time stamped.		
	Shipping, Effective	e Date 12/07/2020) did	not				
		ement to document the					
		collection for SARS-Co\					
	RT-PCR specime						

	T OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING		(X3) DATE SURVEY COMPLETED				
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D5313	D5313 Continued From page 22 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		nd	(2) Patient Impact: Per Lab Director Dr. Rosendorf there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. (3) Preventative Measures: • Through the use of CA-PER-FM-031, Pre/Post Analytical QA Training Checklist, the lab will continue to ensure the quality assurance and laboratory director staff at the CDPH Branch Laboratory has access to the Color Genomics system and can effectively and efficiently access the data stored by Color Genomics, on demand. • The Operations Manager and/or Accessioning Supervisors reviews the manifests (paper or scanned) prior to electronic storage. Any date time stamp omission is documented as except on the Accessioning Exception log, monitored trends, and enters the QER process if issues an identified. (4) Monitoring Mechanism: Monthly end to end		e/Post lab will lace and Branch nomics latly access n demand. essioning per or lace or	
			on ults		tracer audit (FÝ2021) includes a lookback of random samples; availability of the receiptr verifying that manifest is scanned and date/t stamped and that a requestion replete with a data elements is available are included in thi monitoring mechanism. The availability of a requisition and date/time stamp of manifest confirmed by the scheduled 26FEB2021 21. 10 specimens audit and unscheduled 11MA 21AUDIT009 25 specimen audit.	Fat least 10 manifest, ime ll required s complete s was AUDIT004, LR2021	
	laboratory failed to endocumented the date receipt.	sure the laboratory and time of specimen			on receipts (and reports) AND for examples of Specimen Receipt Date/Time stamped on the man		
D5391	PREANALYTIC SYSTASSESSMENT CFR(s): 493.1249(a)	PREANALYTIC SYSTEMS QUALITY ASSESSMENT			D5391 Findings 1-5 As stated in D5300, the lab acknowledges th written policies and procedures to monitor, when indicated, correct identified problems clearly defined in the original Quality Mana	asses, and were not gement	29Mar2021
	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 preanalytic systems specified at §493.1241		tten		Plan (1.0, approved by Lab Director 20Oct2 were scattered through multiple procedural D5311 and D5313 responses provide docun that an electronic requisition and specimen date/time were available and that the interir documenting time of receipt on the paper n not being performed consistently.	2020) and SOPs. nentation collection n step of	

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES 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 CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY 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 The corrective, preventative and monitoring actions to through 493.1242. address those observations are not addressed again in this particular response that focuses on finding 2(b) how to determine specimen acceptability based on sample stability of 7 days at room temperature. There This Standard is not met as evidenced by: Based on interview with the laboratory staff on was no clearly defined process for evaluating whether December 8, 2020, review and the lack of samples were tested within 7 days of collection. documentation of policies and procedures (P/P) for Test Requisition, it was determined that the (1) Immediate Corrective Action: To ensure that the lab has an ongoing mechanism to perform and laboratory failed to establish written policies and document quality issues in the preanalytical system procedures for an ongoing mechanism to monitor, assess, and when indicated, correct • The Quality Management Plan has been revised problems identified in the preanalytic systems and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 specified at CFR 493.1241 through 493.1242. ver2.0 approved by Lab Director and effective 01Mar2021.The MediaLab Admin assigned the performing employee to read and acknowledge Findings included: the changes to this document by 31Mar2021. Created a new SOP, PreAnalytical QA Process Review of the laboratory's policies and (CA-ACC-SOP-003 v1), approved by the Lab procedures (Policy # CA-QM-SOP-001, Title: Director on 24Feb2021 to capture processes already in use defining current practice for Quality Management Plan, Effective Date tracking internal samples and document quality 11/01/2020) did not include an ongoing issues in the preanalytical systems. mechanism to perform and document quality CA-ACC-SOP-001 revised (v4) and approved by issues regarding the lack of test requisition with Lab Director on 09Feb2021. complete information necessary to ensure o Added specimen rejection criteria for a maximum 72 hour window from accurate test results reporting (See D5301 and specimen collection to Color test order D5305); as well as specimen submission and approval and receipt at CDPH Branch Laboratory. See Section 8.3.3. Importantly this is NOT due to solely handling (See D5311 and D5313). specimen stability, but based on decision by CHHS to balance clinical The laboratory uses off-site collection utility with sample stability. Note that facilities. The laboratory failed to establish this particular criteria has changed policies and procedures to ensure proper again and has been extended to ≤ 96 accountability or tracking of specimens from time hours from time of collection (v6.0, approved by Lab Director on of collection to receipt in the laboratory. 24Mar2021). If sample scans as NOT APPROVED, laboratory staff follow the algorithm a. At the time of the on-site survey on specified in the Section 8.3.3. If sample December 8, 2020, the laboratory was only using registration date is ≥ 12 hours from Molecular Transport Media (MTM) to transport current time sample is coded as UNAC2 (Inappropriate timing of swab specimens, with a stated stability of seven collection relative to specimen receipt). days at room temperature. If difference between collection date/ time and sample registration date/time

is ≥96 hours, it remains coded

UNAC2, and the client is notified.

receipt

In the absence of documented specimen

collection date and time, and specimen

(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 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (X4) ID ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG **DEFICIENCY**) D5391 Continued From page 24 D5391 Continued from page 24 date and time into the laboratory, laboratory staff • To determine if any delayed samples (>7 days will not be able to determine specimen from collection time) had been received and tested, a retrospective search of all samples acceptability based on sample stability of seven received by the laboratory (~1.6 million) was days at room temperature. conducted (28Oct2020 to 11Feb2021). o 129 specimens received more than 168 3. The following are the accession numbers of hours (7 days) post collection date/ the 10 randomly reviewed patient test records time were identified. covering the period from 11/02/2020 to o To determine potential impact on these samples, the manufacturer of the 12/08/2020, wherein the laboratory tested and MTM sample collection tubes, reported SARS-CoV-2 RT-PCR patient test Longhorn Vaccines and Diagnostics, results, wherein the laboratory failed to ensure LLC provided data from multiple there was an ongoing mechanism to perform and studies that demonstrated extended document quality issues in the preanalytic stability of RNA in MTM up to 30 systems. days, room temperature, after collection. Of note, 107 / 129 were received on the 8th days. (Refer to Accession Number MTM Attestation Letter from Color in Attachment7) o Only 1 specimen received (08Dec2020) more than 820 hours (30 days) post collection date/time (05Nov2020) was identified and tested with a report date of 11Dec2020. However due to aging of the initial order, Optum Serve made the decision to 'incomplete' the order and notified the patient to retest with 2nd collection on 09Nov2020 (D-2627446715) and a reported result 4. Based on the laboratory's annual testing 11Nov2020. Both samples tested negative. declaration signed by the laboratory director on (2) Patient Impact: Referencing the look back above, 12/16/2020, the laboratory reported per Lab Director Dr. Rosendorff, there is no change in approximately 430,000 SARS-CoV-2 test results diagnosis, treatment, or recommended patient action from 11/02/2020 to 12/16/2020. (retesting), and there would not be patient harm since the manufacturer has demonstrated stability of samples The laboratory director affirmed (February in MTM 30 days after collection, and the one patient 12, 2021 at approximately 2:00 pm) that the whose sample was tested outside of demonstrated stability, was retested only 4 days after the initial laboratory failed to ensure they have an ongoing specimen was collected. mechanism to perform and document quality issues in the preanalytic systems. ANALYTIC SYSTEMS D5400 8Mar2021 D5400

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D5391	Continued From pag	e 24		D5391	Continued from page 24			
	date and time into the laboratory, laboratory staff will not be able to determine specimen acceptability based on sample stability of seven days at room temperature. 3. 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, wherein the laboratory failed to ensure there was an ongoing mechanism to perform and document quality issues in the preanalytic systems. Accession Number 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) that the laboratory failed to ensure they have an ongoing mechanism to perform and document quality issues in the preanalytic systems.		even rs of ds nd		 (3) Preventative Measures: Lab Director, Technical & General Supervisors, and Quality staff to continue with timely document review following Document Management procedures and making revisions and edits when errors or changes in process are identified. Worked with our partner, Color Genomics to institute an automated specimen rejection process. The first of February both CDPH Branch Lab and Color Genomics previewed a > 96-hour cancellation policy for CDPH Branch Laboratory samples, therefore, any sample accessioned at the Laboratory after 96 hours will register as canceled, automatically; no manual entry required. COLOR would implement first, scheduled for 15Feb2021, followed by LIMC update estimated to release on 15Mar2021. As of the date of this response, implementation has been delayed. Due to the delay, an additional lookback was taken 11Feb2021 to 15Mar2021. An additional 20 samples received >96 hours post-collection were identified (19/20 within 7 days and 1 on the 8th day). After discussion with Color, this was unexpected and CDPH Branch Laboratory will implement the automated cut-off instead 			
				Supervisors to document performing compliance with correct assignment or unsatisfactory specimens during speciments, 12 month and annual compe observation and record reviews. Quality staff conduct monthly audits Receipt Cancellations (FY2021 Audit to confirm that samples with delayed documented as unsatisfactory and are the Accessioning staff. ACC-SOP-001 Specimen Accessionin MTM/Longhorn Stability Study ACC-SOP-003 PreAnalytical QA Read Acknowledgement – CA-AC Specimen Accessioning 2021 Audit Schedule – Delayed ReCancellation Report Data for > 7 days - Pivot table	of fifted 6 tency of Delayed Schedule) receipt are canceled by			
D5400	ANALYTIC SYSTEMS	3		D5400			8Mar2021	

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: 05D2197416 в. Wi з 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 DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRETIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5400 Continued from page 25 D540 Continued From page 25 (5401/5403/5407) During the initial planning and CFR(s): 493.1250 execution of the CDPH Branch Laboratory project the laboratory team provided feedback to the state of Each laboratory that performs nonwaived testing California on the collection process and media. Specifically, the team outlined the process for must meet the applicable analytic systems administering the nasal swab sample, the contents of the requirements in §§493.1251 through 493.1283, collection kit, packaging, infectious agents' identification unless HHS approves a procedure, specified in (UN3373) label, storage at room temperature, and Appendix C of the State Operations Manual shipping timeline. This information was then collated into the Testing Taskforce Playbook and the processes at (CMS Pub.7), that provides equivalent quality the collection site and laboratory procedure CA-CLSRVtesting. The laboratory must monitor and SOP-002. evaluate the overall quality of the analytic Color Genomics provides COVID-19 testing through its systems and correct identified problems as own laboratory. References to their corporate site collection materials is specific to their laboratory. Color specified in §493.1289 for each specialty and Genomics is contracted by CDPH Branch Laboratory to subspecialty of testing performed. provide kits that are comprised of a sample collection tube prefilled with MTM and barcoded with two This Condition is not met as evidenced by: identifiers, one collection card for the patient with a Based on the number and severity of the matching barcode, and an absorbent pad. All samples tested to date were collected in Color collection kits deficiencies cited herein, the Condition: containing MTM. ANALYTIC SYSTEM was not met. Procedure CA-CLSRV-SOP-002 specifies use of MTM. Procedure CA-ACC-ACC-001 incorrectly used VTM Findings included: (viral transport media) as a generic term. This has been corrected to MTM; however, the rejection criteria in the procedure are sufficient since samples sent outside of the The laboratory failed to ensure procedure Color system are "Not Approved". manuals were established, available to, and To determine if any delayed samples (> 7 days) had been followed by laboratory personnel (See D5401). received, a retrospective search of all samples received by the Laboratory (~1.6 million) was conducted. 129 samples 2. The laboratory failed to ensure the procedure received more than 168 hours (7 days) were identified. To determine potential impact on these samples, the manuals met the requirements specified in 42 manufacturer of the MTM sample collection tubes, CFR 493. 1251 (b)(1)-(b)(14) (See D5403). Longhorn Vaccines and Diagnostics, LLC provided data from multiple studies that demonstrated extended 3. The laboratory failed to ensure procedure stability of RNA in MTM up to 30 days after collection. For the purposes of data analysis, the staff members use a manuals were updated, approved, signed and (1) secure data repository and (2) a PerkinElmer LIMS dated by the current Laboratory Director (See web based application. Both of these are hosted within the D5407). PerkinElmer network and are secured behind a firewall. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer The laboratory failed to ensure it followed the issued set of credentials on a PerkinElmer issued laptop. adopted FDA EUA IFU, the subsequent revisions During any remote session the data and system being to the EUA, and changes made in the laboratory's accessed are located on the prior mentioned internal IT policies and procedures (See D5411). systems hardware. See sections 5401, 5403, 5407 for more details. 5. The laboratory failed to ensure reagents were

(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 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID COMPLETION (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5400 D5400 Continued From page 26 Continued from page 26 labeled as required (SeeD5415). (5401/5407) There is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues 6. The laboratory failed to ensure the did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day decontamination solution used for SARS-CoV-2 RT-PCR were not used past the labeled laboratory operations and result reporting has been hired so expiration dates (See D5417). that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. 7. The laboratory failed to ensure it established Contrary to Laboratory Director affirmation, LIMC User and verified performance specifications prior to Specification and Acceptance Testing forms were signed. Both the User Specification and the User Acceptance forms reporting patient test results using its modified signed by both Laboratory Directors is provided. The effective date 29Oct2020 is the date the blank form FDA EUA IFU SARS-CoV-2 RT-PCR (See (template) was effective Delayed procedure approval: This D5423). 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. 8. The laboratory failed to the ensure the The VBL Playbook has been in use by the Task Force since established maintenance protocol for the beginning of testing and was approved by the Lab centrifuges were performed and documented Director. (SeeD5433). Test results are transmitted to from the LIMS API thorough the Color Platform to both CalREDIE and CalOES. CalREDIE transmits results to California county public 9. The laboratory failed to establish and follow health authorities and federal public health authorities as required by law. written policies and procedures for an ongoing mechanism to monitor, assess, and when See section 5401 and 5407 for more details. indicated, correct problems identified in the (5401/5411/5417/5423/5791) The laboratory has an D5401 Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of analytic systems (D5791). 8Mar2021 D5401 inspection. This plan describes the measures put in place to PROCEDURE MANUAL prevent contamination that included laboratory design and CFR(s): 493.1251(a) construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/ A written procedures manual for all tests, assays, degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, and examinations performed by the laboratory dedicated refrigerators/freezers to separate reagents and must be available to, and followed by, laboratory samples, and asceptic cleaning techniques all of work areas and equipment. The observation made at time of inspection personnel. Textbooks may supplement but not stated that the lab use of 70% ethanol did not match the replace the laboratory's written procedures for EUA and our procedure (see section 5.7.2). Based on CDC guidelines and the letter from our corporate quality testing or examining specimens. organization the minimum percent ethanol required for decontamination is 60. This Standard is not met as evidenced by: Heat inactivation is a desirable method for ensuring that the Based on direct observation, interviews with infection risk associated with of SARS-CoV-2 clinical samples is as low as possible. Validation studies carried out laboratory staff on December 8 and 9, 2020, prior the beginning of testing included LoD studies with both heat inactivated and non-heat inactivated samples (see validation report sent to LFS at 1:55pm PST on October the review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, 24th). There was no performance impact on heat random review of patient test records covering inactivation. 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 ΙĎ PROVIDER'S PLAN OF CORRECTION COMPLETION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PRETIX (EACH CORRECTIVE ACTION SHOULD BE DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5401 D5401 Continued from page 26 Continued From page 27 determined that the laboratory failed to ensure Clinical performance in asymptomatic people: Per version 7 the procedure manuals for the Perkin Elmer New (06Jan2021) of The PerkinElmer* New Coronavirus Nucleic Acid Detection Kit IFU, the intended use for the kit is Coronavirus NucleicAcid Detection Kit Real Time intended for: ...the qualitative detection of nucleic acid from Polymerase Chain Reaction (RT-PCR) in vitro SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare diagnostic test were established and followed by provider (HCP), and anterior nasal swab specimens the laboratory staff. 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 Findings included: infection. The CDPH Branch Laboratory is using this kit within the The laboratory failed to establish and follow written P/P in all phases of clinical testing for Thermocycler Parameters: The correct collection temperature is 65oC. A universal .trf file containing the PCR Perkin Elmer New Coronavirus Nucleic Acid thermocycling conditions is generated by the PCR Janus program at the time a 384-well plate is set-up. The .trf file is Detection Kit RT-PCR in vitro diagnostic test imported to the AJ thermocycler. This file is correct. Records utilizing Chemagic 360 for the isolation of the viral from the PCR output files for the 60 randomly chosen nucleic acids followed by the RT-PCR assay on 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 Analytik Jena Thermal Cycler, when it started testing patient samples on 11/02/2020. error was corrected in v2 (approved 26Jan 2021). See sections 5401, 5411, 5417, 5423, 5791 for more details. The following are the accession numbers of (5401/5415/5433/5791) We acknowledge that labeling of the 60 randomly reviewed patient test records some reagents was incomplete and are working to improve compliance. Non-compliance in reagent labeling and covering the period from 11/22/2020 to completion of instrument logs has been noted (QER-20-014, 12/08/2020, wherein the laboratory started QER-20-015, QER-20-017, QER-20-036 and CAPA-20-007) performing SARS-CoV-2 tests and reported and corrective action has been initiated. Supervisors and managers were instructed to review good documentation results, but failed to ensure policies and practices Instrument forms have been updated to make clear procedures were established and followed by appropriate documentation for a shift when instrument is laboratory staff. See sections 5401, 5415, 5433, 5479 for more details. Accession Number D5401 Please see responses to findings for D5403, D5407, D5411, D5415, D5417, D5423, and D5433 below.

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D5401	declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 4. The Laboratory I (February 12, 2021 apm) the laboratory fa and procedures were followed by laborator 5. Details of the read and procedures are early 12/2020 to 12	poratory's annual testing the laboratory director attory reported 20 SARS-CoV-2 test resected approximately 2:00 iled to ensure policies e established and	r on sults	D5401				
D5403	D5403). PROCEDURE MANUCFR(s): 493.1251(b) The procedure manuwhen applicable to the	al must include the follo	owing	D5403			29Mar2021	
	(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 TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5403 D5403 Continued From page 29 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 CDPH and rejection as described in §493.1242. Branch Laboratory project the laboratory team provided feedback to the state of California on the collection (2) Microscopic examination, including process and media. Specifically, the team outlined the the detection of inadequately prepared process for administering the nasal swab sample, the contents of the collection kit, packaging, infectious agents (3) Step-by-step performance of the procedure. identification (UN3373) label, storage at room including test calculations and interpretation of temperature, and shipping timeline. This information was then collated into the laboratory's Specimen Collection, Storage and Shipping (CA-CLSRV-SOP-002) SOP and the (4) Preparation of slides, solutions, calibrators, Testing Taskforce Playbook and website for the processes controls, reagents, stains, and other materials at the collection sites. (https://testing.covid19.ca.gov/ used in testina. valencia-branch-laboratory/#howtopartner) (5) Calibration and calibration verification procedures. Instructions for obtaining sample kits (via Color Genomic (6) The reportable range for test results for for CDPH Branch Laboratory), collection and shipping of the test system as established or verified in samples is provided to collection sites set up by the Testing Task Force. (7) Control procedures. (8) Corrective action to take when calibration or Specimen collection (D5311 and D5403 parts a- £ Please control results fail to meet the laboratory's note, Color Genomics provides COVID-19 testing through its own laboratory. Color assembles and criteria for acceptability. distributes collection kits on the processes and methods (9) Limitations in the test methodology, including developed in their laboratory. These activities are interfering substances. completely separate from the CDPH Branch Laboratory (10) Reference intervals (normal values). activities and have no bearing on the CDPH laboratory. (11) Imminently life-threatening test results. Therefore, it is inappropriate to compare information on or panic or alert values. the Color website with procedures at the CDPH Branch (12) Pertinent literature references. Laboratory and described in laboratory procedure CA-CLSRV-SOP-002. (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,

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		1	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
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ratheout de to accept approximate approxim	e period from 11/22 at of 60 patient test betermined that the la include the followir courate and reliable Specimen co opropriate technique Specimen la ame or unique ident Proper stora ansportation Specimen a sposition And a sposition The laboratory fa anual that met all the arr Perkin Elmer New etection (RT-PCR) in illizing Chemagic 36 aucleic acids follower allytik Jena Therma During the on-sit and 9, 2020, we note allow: Staff interviews Perkin Elmer Emetual) Staff interviews Perkin Elmer Emetual)	cient test records cover 2/2020 to 12/08/2020, for records reviewed, it was aboratory's procedure in grequirements to ensite test results: collection using the end containers abeling, including patientifier, and specimen so age, preservation, and acceptability, rejection acceptability, rejection and acceptability, rejection acceptab	or 60 as failed ure nt urce and edure ents Acid he viral y on hber 8 these gh "f"	D5403	As it relates to testing that occurs at the CI Laboratory the state of California has cont two purposes: sample kit distribution and 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-SOP-ACC-001 incorrectly (viral transport media) as a generic term. To corrected 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 8.5 followed. Procedure and process are designed to matelectronic order to the sample tube received Use of MTM (5403 – a, c, e) The validation assay (approved by the Laboratory Directors submitted to LFS on 24Oct2020) was perform MTM. Rejection Criteria (5403 -f) The CA-ACC in effect at time of survey did not delineate rejection criteria. See Attachment 4, 6, and 8 for additional in the process and the survey did not delineate rejection criteria.	racted for testing site ranch sed of a land on card for in absorbent anch a Color I Attestation rimeStore use of MTM. used VTM This has been eedia); dure are Color 3.3 would be tch the d. In of this or and ormed using C-SOP-002 e all of the	

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	,	05D21974	16	B. WING		02/17	7/2021
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST.	ATE, ZIP CODE		
	RANCH LABORATOR	Υ	28454 L	IVINGSTO	NAVE		
			VALEN	CIA, CA 913	355		
(X4) ID	SUMMARY S	TATEMENT OF DEFICIENCIES	3	ID	PROVIDER'S PLAN OF CORRECTI	ON	(X5)
PREFIX TAG		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	EGULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)		COMPLETION DATE
D5403	Continued From pag	je 31		D5403	Continued from page 31		
	- Compatancim	on collection using			(1) Immediate Corrective Action:		
	 c. Correct speciments the appropriate technique 					_	
	containers	mique and			 Through cooperation with Color Gethe CDPH Branch Lab, a method to 		
	001100111010				data from electronic order in the for	m of a	
	(1) Based on intervie	ew with the laboratory s	taff		requisition was established. The Lab and the Quality Assurance Team rec		
	on 12/08/2020, the la	aboratory only process			training that allows them to effective	ly and	
	samples collected in	MolecularTransport			efficiently access the electronic requi includes the complete information for		
	Media (MTM).				individual patients.		
	(2) Review of FDA I	FUA IFU for PE New			 CA-ACC-SOP-001 revised (v4) and approved by Lab Director on 09Feb2021. 		
		Acid Detection Kit state	d the		Accessioning Samples, whi	ich	
		t Media (VTM) (Effecti			incorrectly stated VTM (vi	ral	
		vised 09/16/2020 and			transport media) as a gene been corrected to the MTN		
		vas no information prov	vided		(molecular transport medi	a); See	
	regarding the use of	MTM in the IFU.			Section 5.1 of version 4.1 a 09Feb2021 by Lab Director		
		boratory's P/P (Policy# 2, Title Specimen Colle			Clarified cancellation proc handling of misrouted sam		
	Storage and Shipping		,		o Added specimen rejection		
		d that CDPH Branch L	ab		a maximum 72 hour windo specimen collection to Col		
	Coordinates with CO				approval and receipt at CD	PH Branch	
	specimen collection	and submission.			Laboratory. See Section 8 this is NOT due to specime	en stability,	
					but based on decision by C	CHHS to	
	(4) Review of COLO				balance clinical utility with stability. Note that this pa	rticular	
	specimen requiremen				criteria has changed again been extended to < 96 hou	and has	
	UTM media transpor	L.			time of collection (v6.0, ap	proved by	
	(5) The laboratory fa	ailed to specify and incl	ude in		Lab Director on 24Mar202	.1	
		edures, the use of MTM			One more revision (5.0, ap		
					Lab Director on 26Feb202 the rejection "no bar code	on sample	
	d. Specimen labeli	ng, including patien	t		or bag" (Section 8.3.2.2.) w code UNSAT3 – "sample t		
	name or unique ide	ntifier, and specimer	1		unlabeled". The Unsatisfac	ctory	
	source				(rejected) Sample table fro User Manual (CA-COMP-		
		tory tour on 12/08/202			was added to the SOP (Sec		
		a.m., the laboratory st				=	
		anch Lab has been wo					
		ertified laboratory to he in ordering the test for					
	l ·	n ordering the test for h Covid-19 infections. I					
		with the patient sample					

	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
		05D21974	16	B. WING				
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE VALENCIA, CA 91355					
(X4) ID PREFIX TAG				REGULATORY TAG (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued from page 32				
D5403	only a "paper manife i. Total nu ii. Site poi iii. Trackin iv. collectiv sample v. Site nar vi. Site add (2) Review of the la CA-CLSRV-SOP-00: Storage and Shippin indicated the elemen electronic manifest, s i. Trackin ii. Manife iii. Date of iv. Site nav. Site add vi. Site poi (name, phone numbe vii. Total ii (3) The laboratory fa included complete in patients, such as patidentifier, and specin e. Proper storage and transportation (1) Based on intervi on 12/08/2020, the la samples at room terr seven days. (2) Review of FDA	st" indicating the followers imber of samples receive the followers of samples received the followers of contact growing company number and the followers of samples of sample collection are iddress ont of contact growing and such as: growing company and numbers the followers of sample collection are iddress ont of contact growing and samples of samples ided to ensure the policity formation for individual tient name or unique then source.	ction, /2020)	D5403	Continued from page 32 Created a new SOP, PreAnalytical Q (CA-ACC-SOP-003 v1), approved by Director on 24Feb2021 to capture pralready in use defining current pract tracking internal samples and clearly the process in place of accepting sam received only through Color Genom D5391 for specific details). There is c type of collection device and media (is used for clinical lab testing of SAR To determine if any delayed samples from collection time~) had been received by the laboratory (~1.6 mill conducted (28Oct2020 to 11Feb2021) 129 specimens received me hours (7 days) post collectitime were identified. To determine potential im these samples, the manufact MTM sample collection tu Longhorn Vaccines and DLLC provided data from m studies that demonstrated stability of RNA in MTM to days, room temperature, at collection. (Refer to MTM Letter from Color in Attact Only 1 specimen received (08Dec2020) more than 82 days) post collection date/t (05Nov2020) was identified with a report date of 11Dec However due to aging of the order, Optum Serve made to 'incomplete' the order at the patient to retest with 2 collection on 09Nov2020 (D-2627446715) and a repull Nov2020. Both samples negative. Due to the delay, an addition lookback was taken 11Feb2021 15Mar2021. An additional 20 servecived >96 hours post-collect identified (19/20 within 7 days the 8th day). After discussion we this was unexpected and CDPF Laboratory will implement the cut-off instead (anticipated 07 Acceptance).	(>7 days eived and mples ion) was). ore than 168 on date/ pact on cturer of the bes, aagnostics, ultiple extended up to 30 iter Attestation nment7) 0 hours (30 ime d and tested :2020. the initial the decision and notified and corted result tested nal to amples ion were and 1 on with Color, I Branch automated		

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMB			(X3) DATE SURVEY COMPLETED			
		05D21974	16	B. WNG		02/17/2021		
CDPH BRANCH LABORATORY 28454			28454 Li	DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL RE OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE COMPLETION		
D5403	D5403 Continued From page 33 use of VTM, stored at 2-8 degrees Celsius for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens should be stored at -70 degrees Celsius (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021). (3) Review of the laboratory's P/P (Policy# CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) indicated that CDPH Branch Lab Coordinates with COLOR laboratory for specimen collection and submission. (4) Review of COLOR website for specimen requirements indicated VTM or UTM media transport should be refrigerated at 2-8 degrees Celsius prior to and during transport within 24 hours. If the specimen is to be submitted >24 hours post collection, specimens should be freeze at -20 degrees Celsius or below, and then ship on dry ice. (5) Review of the laboratory's P/P (Policy# CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) stated under storage shipping and transport that specimens collected in MTM are stable at 2-25 degrees Celsius (room temperature) for 7 days. "Manufacturer's instruction for storage temperature storage and stability should be followed." (6) Review of the manufacturer's FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit stated the use of VTM, stored at 2-8 degrees Celsius for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens should be stored at -70 degrees Celsius (Effective Date 03/20/2020, Revised		ting or te ction, 2020) tates tion en ees 24	DEFICIENCY) (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 as all pertinent patient information is obtained in electronic format, the correct specimen collection device/MTM was used for all testing, manufacturer of MTM had demonstrated stability of samples in MTM 30 days after collection, and the one patient whose sample was tested outside of demonstrated stability, was retested only 4 days after the initial specimen was collected. (3) Preventative Measures: • Lab Director, Technical & General Superviso and Quality staff to continue with timely document review following Document Management procedures and making revision and edits when errors or changes in process a identified. • An automated process to reject samples >96 hours old is being implemented in LIMC (anticipated 07Apr2021). For further details see D5391.		r d there vatient t, the as used for onstrated ollection, d outside of days after Supervisors, timely timely timel to the process are optes >96		
			ction, /2020) t that -25 ays. A IFU ction rees		Supervisors to document performin compliance with correct assigns unsatisfactory specimens during months, 12 month and annual cobservation and record reviews. Operations Manager and Leadership continue to summarize and monitor unsatisfactory specimen rates to evalutrends; daily volume and quality metrodelivered to COLOR, and CDPH teadetermine any changes in supply markits and/or potential issues at the colling Quality staff conduct monthly audit Receipt Cancellations (FY2021 Audito confirm that samples with delayed documented as unsatisfactory and a by the Accessioning staff.	nent of g specified 6 competency team to team to team to team to teate for ic report ms to tagement of tection sites. s of Delayed lit Schedule) d receipt are		

(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 1D (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) D5403 D5403 Continued From page 34 Continued from page 34 09/16/2020 and 01/12/2021). See Attachments 4, 6, and 7 (7) The laboratory failed to specify and include in ACC-SOP-001 Specimen Accessioning its policies and procedures, the use of MTM. • MTM/Longhorn Stability Study ACC-SOP-003 PreAnalytical QA Specimen acceptability, rejection • Read Acknowledgement - CA-ACC-SOP-001 Specimen Accessioning and disposition 2021 Audit Schedule - Delayed Receipt Cancellation Report (1) Review of the laboratory's P/P (Policy # • Data for > 7 days CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) indicated that CDPH Branch Lab Coordinates with COLOR laboratory for specimen collection and submission. (2) Review of COLOR website for specimen rejection indicated the following: i. insufficient, incompatible transport media. ii. Dry swabs that arrive >56 hours after collection iii. Improperly capped or labeled tubes iv. Swabs inverted in collection tubes (i.e. swab bud facing up) v.Missing physician order vi. Incomplete or missing patient information (3) Review of the laboratory's P/P (Policy # CA-ACC-SOP-00, Title Accessioning, Effective Date 12/05/2020) stated only the following rejection criteria: i. Broken/Damaged/QNS ii. No barcode (4) The laboratory failed to include in its policies and procedures, rejection criteria using use of MTM.

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2197416				02/17/2021	
		******		B. WING		02/11/2021	
	ROVIDER OR SUPPLIER		STREET ADDRE				
CDPH BF	RANCH LABORATOR	Y		VINGSTO			
			VALENC	IA, CA 913	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 CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE COMPLETION DATE	
D5403	Continued From pag	e 35		D5403	Finding 2		
D5403	2. Based on direct laboratory staff on Dereview of policies and (QC) and quality assurandom review of pat the period from 11/22 out of 60 patient test determined that the late include the step-by procedure, including interpretation of result interpretation of result interpretation of result interpretation of test laboratory failed to procedure for test interpretation of test laboratory staff intervidate analysis and interpretation of test laboratory staff intervidate analysis and interpretation of test laboratory at the quality metrics (incurves generated from at remote locations between the personnel for test resinvalid, or inconclusive turn-around-time from reporting of the test capproved policy and proceed with accurate test results. c. The following are the 60 randomly revise covering the period from 12/08/2020, wherein	observation, interviews becember 8 and 9, 2020 If procedures, quality of grance (QA) records, ient test records cover 1/2020 to 12/08/2020, for records reviewed, it was aboratory's procedure for test calculations, and test calculations, and results utilized by the iewed performing onsignment of the PCR test be analy CLIA qualified testing and the PCR test be analy CLIA qualified testing and the procedure on how to be remote reporting of part of the accession number of the accession number of the laboratory perform the laboratory perform the laboratory perform	ing or 60 as failed the litrat litrat litrat litrat an artient ars of ds	D5403	1. For the purposes of data analysis, the statuse a (1) secure data repository and (2) a Pet LIMS web based application. 2. Both of these are hosted within the Perkin network 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 reranalysis were trained and qualified to do so a. EV – Trained in data analysis and delegar responsibilities of a General Supervisor b. MN – CLS trained in data analysis 5. CMS has made an exception to allow patother healthcare professionals to work remethe pandemic. CAP concurred with this exception to allow patother healthcare professionals to work remethe pandemic. The ending of the processing. To manage this evolving field, a on-site Laboratory Director, who is directly day-to-day laboratory operations and resulhas been hired so that decisions regarding of interpretation area now made in a timely meansultation of CDPH Leadership, the Test Taskforce and other professionals as appropriate that the ending of the professionals as appropriated that the ending of the professionals as appropriated that analysts may not analyze data reference and the professionals as appropriated that analysts may not analyze data reference and the professionals and those awaition onboarding/orientation that remote	rkinElmer motely is inElmer ssued and system tioned mote ted the hologist and otely during teption. ding the best issues did of sample full-time, involved in t reporting lata anner, with ing priate. Lab tec2020 motely. dl ng analysis	
	SARS-CoV-2 tests at	nd reported results, but step-by-step performan	t		was no longer a possibility; employm contingent upon on site analysis.		

(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 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PRETIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5403 Continued From page 36 D5403 Continued from page 36 procedure, including test calculations, and interpretation of results. (2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or Accession Number recommended patient action (retesting), and there would not be patient harm. (3) Preventative Action: A request to remove VPN access software from analyst computers was placed with the IT group by the project manager on 11 Mar 2020 and completed on 13 Mar 2020 by the IT group. (4) Monitoring Mechanism: A request to query for remote release of records made on 26Feb2021 could not be completed due to complexity. Removal of VPN access removes the need to monitor. As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es). d. 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.

	IENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED				
		05D2197416			16	B. WING	30		02/17/2021	
	ROVIDER OR SUPP RANCH LABO		Y		28454 LI	DDRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355				
(X4) ID PREFIX TAG	(EACH DEFICI	ENCY MUS		DEFICIENCIES DED BY FULL REFORMATION)		1D PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE	
D5403	e. The Lab (February 12 pm) the labo the step-by-s procedure, including tes results. 3. Based of laboratory st review of pol (QC) and qu random reviet the period fro out of 60 pat determined t to include co reference int Findings incl a. Review Coronavirus Date 03/20/2 01/12/2021) kit with valid i. SARS-Col iii SARS-Col iii Invalid iic (VIC/HEX) ≤ 40 /	poratory I 2, 2021 a pratory fa step performs at calcula on direct raff on De licies and ality assi ew of pat om 11/22 tient test that the li mplete a tervals (n luded: of the F Nucleic 2020, Re indicated quality of /-2 Detect N(FAM), OF Both target Undetermin Both target Undetermin	Director aff t approxim iled to ensi- promance of tions, and if observation ecember 8 d procedure urance (QA ient test re /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 cted F1ab ROX) 5 ned or > 42 s ≤ 42 targets ≤ 42 and or > 42	ately 2:00 ure include Interpretation In, interviews and 9, 2020 es, quality co I) records, cords cover I2/08/2020, fo viewed, it was I procedure f ent informatio es). FU for PE Ne Istion Kit (Effe Istion Kit	ewith control ing or 60 as failed on on ew ective or the etation t Detected tected tected specimen tested from or recollected	D5403	Finding 3 There is scientific and clinical debate regard interpretation of high Ct values. Due to disamong Laboratory Directors, the procedure analysis was not approved in a timely mann Although not approved, a consistent methor interpretation was used (see Analysis Time 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 laboroperations and result reporting has been hid 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, ref change in interpretation from the IF 11Dec2020 – 25Jan2021 – high Ct va < 42) were interpreted as inconclusive 25Jan2021 – present were interpreted presumptive positive – high Ct value 42) (1) Immediate Corrective Action: The s in question were resulted as per SOP (see Expression of the action with the communication checklist (CA-FM-001, approved by Lab Director on 09M the data analysis team includes a written approval. shift to shift communication checklist (CA-FM-001, approved by Lab Director on 09M the data analysis team includes a written cof the most recent updated version of the arreporting SO (CA-RPT-SOP-002). (4) Monitoring Mechanism: Monthly and data integrity are performed as stipulated in audit schedule by the Quality organization. February audit (see attachment 4) confirmer results matched the current SOP and proce the time. See Attachment 9, Attachment 10, Analyst communication checklist (CA-RPT-FM-00 and proce the time.	cussion e used in eused in her. hod of line below). les in place ge this ry Director, ratory red so that a now made DPH or ere reported e) Ct cutoff ed on Ct electing a U ulues (> 37 - re d as es (> 37 - < - pecimens 05800). DP or ector, Dr. A daily -RPT- lar2021) for infirmation nalysis and dits for a the 2021 The ed that the ss 100% of		

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA 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 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX (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) D5403 Continued From page 38 D5403 If the result for a specimen is SARS-CoV-2 RNA not detected, the Ct value of the internal control must be ≤ 40, otherwise the result of that specimen is invalid: If the result for a specimen is SARS-CoV-2 RNA not detected, the Ct value of the internal control must be ≤ 40, otherwise the result of that specimen is invalid; b. At the time of inspection on 12/08/2020, the laboratory failed to provide an approved policy and procedure for test calculations, and interpretation of test results utilized by the laboratory staff interviewed performing onsite data analysis and interpretation, and reference intervals (normal values). 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 complete and consistent information on reference intervals (normal values). Accession Number

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION 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 1D PROVIDER'S PLAN OF CORRECTION (X4) 1D COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5403 Continued From page 39 D5403 d. 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. e. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to ensure include complete and consistent information on reference intervals (normal values). 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, itwas determined that the laboratory failed to have

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING	B. WNG 02/17		
CDPH BRANCH LABORATORY 2845				SS, CITY, ST. VINGSTON IA, CA 913	NAVE		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)			(X5) COMPLETION DATE
D5403	policies and procedu Reporting. Findings included: a. At the time of ins 9, 2020, and until Fel laboratory failed to pel and procedure for Inf Reporting. b. The following are the 60 randomly reviectovering the period for 12/08/2020, wherein SARS-CoV-2 tests a failed to provide police	pection on December 8 bruary 12, 2021, the rovide an approved polectious Diseases the accession number away patient test record 11/22/2020 to the laboratory performent reported results, busies to ensure it complies Reporting required laboratory r	and icy ers of ds ed t	D5403	Test results from CDPH Branch laboratory been transmitted to CalREDIE since 28Oct Color Genomics transmits all CoVID test r California's standalone Covid reporting (C database which is then transmitted to CalR The quality management plan (QMP-CA-S Section 6.1.1.1 approved 01Nov2020) state results of positive infectious disease are rep CDPH, but it did not specify the detail requision finding. (1) Immediate Corrective Action: Laborocedure CA-RPT-SOP-004 was created to policies and procedures for Infectious Disease Reporting specified in the contract between PerkinElmer. (2) Patient Impact: Patient results have been transferred to CalREDIE and CalOES per their contract with PerkinElmer; therefon change in diagnosis, treatment, or recondition (retesting), and there would in patient action (retesting), and there would in patient harm. (3) Preventative Measure: All future ver RPT-SOP-004 will specify how requirement Infectious Disease Reporting are met. (4) Monitoring Mechanism: Transmiss CalREDIE and CalOES is monitored by CoAPI response codes.	202; results to CRS) EDIE. SOP-001, d that rorted to rested in rested in capture ase Color and consistently by Color ore, there is nmended not be rsions of CA- ts for ion to	

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416	B. WING		02/17/2021	
NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY	28454	RESS, CITY, STA LIVINGSTON ICIA, CA 913	IAVE		
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c. Based on the laboratory's a declaration signed by the labora 12/16/2020, the laboratory repor approximately 430,000 SARS-Co from 11/02/2020 to 12/16/2020. d. The Laboratory Director affi 12, 2021 at approximately 2:10 laboratory failed to provide policic complied with Infectious Disease required by local, state, and feder procedures and changes in procedures and proc	tory director on ted bV-2 test results rmed (February om) the es to ensure it exporting eral authorities. cedures must be the current lenced by: n, interviews with 9, and 16, 2020,	D5403		29Mar2021	

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:						(3) DATE SURVEY COMPLETED		
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		05D2197416			B. WING		02/17	7/2021	
	ROVIDER OR SUPPL	R SUPPLIER STREET			SS, CITY, ST	ATE, ZIP CODE			
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(X4) ID	SUMMARY STATEMENT OF DEFICIENCIES			3	ID	PROVIDER'S PLAN OF CORRECTI	ON	(X5)	
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D5407	Continued Fr	om page 42			D5407	Finding 1			
	control (QC) a	and quality assur	ance (QA) red	cords,		1			
	random review	w of patient test	ecords cover	ing		Findings a-f	1: .1 1 .		
	the period from	m 12/04/2020 to	12/10/2020, f	or 32		There is scientific and clinical debate regard interpretation of high Ct values. Due to disc			
	out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure			as		among Laboratory Directors, the procedure			
						analysis was not approved in a timely mann			
		for reporting inc				Although not approved, a consistent methor interpretation was used (see Analysis Timel	od of		
	using the Perkin Elmer New Coronavirus Nucleic					All reports issues did match the analysis rul			
		n Kit Real Time F		hain		at the time of sample processing. To manag	ge this		
	,	-PCR) in vitro dia	•			evolving field, a full-time, on-site Laborator who is directly involved in day-to-day laborator			
	approved, signed, and dated by the laboratory			ory		operations and result reporting has been his			
	director.					decisions regarding data interpretation area	now made		
	Cindings inclu	ما ـ ما ،				in a timely manner, with consultation of CI	OPH		
	Findings inclu	dea:		Leadership, the Testing Taskforce and other professionals as appropriate.					
	a During th	e first day of the	on cito incoo	otion		Please refer to the Analysis Timeline.			
		e instituay of the), we interviewed		Suon		• 28Oct2020 – 11Nov2020 – results were	reported as		
		senior operation		and		per the IFU (cutoff < 42 as positive)			
		the laboratory's		iii d		• 11Nov2020 – 11Dec2020 – a lower Ct c			
		and corrective ac		the		was set for positive results based on Ct observed during validation, reflecting a			
		ber of inconclus				interpretation from the IFU	change in		
			vo panom roc	uno.		• 11Dec2020 – 25Jan2021 – high Ct value	es (> 37 -<		
	b. We review	wed the Instruction	ons for Use (I	FU)		42) were interpreted as inconclusive25Jan2021 – present were interpreted a			
		ency Use Authori		/		presumptive positive – high Ct values (
		dopted test meth		mer		(1) Immediate Corrective Action: The			
	New Coronavi	irus Nucleic Acid	Detection Kit	The		in question were resulted as per SOP (see I			
		and Interpretatio				(2) Patient Impact: See D5800.			
		sults" section sho		-		(3) Preventive Action : No revision to SC)D or		
	the expected	results for the kit	with valid pos	sitive		process is placed into use until the Lab Dir			
	and negative	control.				Rosendorff, has provided written approval	. A daily		
						shift to shift communication checklist (CA			
	Cycle	e threshold	Result Interpre	tation		FM-001, approved by Lab Director on 09N the data analysis team includes a written co			
	IC (VIC/HEX)	N(FAM), ORF1ab ROX)				of the most recent updated version of the a			
	< 40	Both targets	SARS-CoV-2 No	Detected		reporting SOP (CA-RPT-SOP-002).			
		Undetermined or > 42 _. Both targets ≤ 42	SARS-CoV-2 Del	·····		(4) Monitoring Mechanism: Monthly a			
		One of the targets < 42	······································			data integrity are performed as stipulated i			
	J					audit schedule by the Quality organization			
	>40 or	Both targets	Invalid result, needs to be re-			audits initiated on 26Feb2021 (10 samples) and 11Mar2021(25 samples) confirmed that reported			
		Undetermined or > 42	re-extraction o	181		results matched the current SOP 100% of t	•		
			from patient fo	r test.					
						See Attachment 9 and Attachment 10			

(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 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 TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) Continued From page 43 D5407 c. In order to compare how the laboratory was calculating and interpreting patient results, we also asked the laboratory on December 8, 2020, to provide the LIMC Laboratory Information System (LIS) and its policy and procedure for interpretation of patient specimen results. (i) A policy and procedure signed by the laboratory was not available on December 8, 2020. (ii) Neither an unsigned policy and procedure was available on December 8, 2020. Further interviews with the laboratory director on 12/08/2020, indicated there was a possibility that patient test results were reported in error as a result of incorrect data analysis and interpretation. The following day on 12/09/2020, we conducted random sampling of an additional 32 patient test records with specimens collected during the first week December until 12/08/2020. On December 16, 2020, we went back on-site at the laboratory to retrieve the additional patient test records. We also asked the laboratory to send via e-mail, the requested records and its policy and procedure for interpretation of patient specimen results.

	OF DEFICIENCI CORRECTION	NT					(X 3) DATE SURVEY COMPLETED		
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D5407	Continued	From page	44		D5407	Finding 1		5,	
	g. The policy and procedure sent via e-mail on Dec. 16, 2020 showed the following: (i) An annotation on the top portion of document indicated, "Effective Starting 10/29/2020" the document version history: (ii) It was an Initial document, Version 1.0, with an effective date of December 13, 2020.			on		Findings g-k			
						Contrary to Laboratory Director affirmatic Specification and Acceptance Testing form signed.	ns were		
						LIMC documentation: Provided. Please no following:	te the		
				rith		-Both the User Specification and the User forms signed by both Laboratory Director -The effective date 29Oct2020 is the date to form (template) was effective	s is provided.		
(iii) The Software Name was identified as LIMC, version 1.2				Delayed procedure approval: This timeline difficulty in coming to a scientific and clin consensus on how low viral load (high Ct	ical value –				
	h. The Detailed User Requirements Specifications section of the document, showed the following policy for interpretation of patient specimen results.			specifically > 37 - < 42) results should be in Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were r per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cu was set for positive results based on Ct val-	eported as toff (<37)				
	Reinffrement Number		Description			during validation, reflecting a change in in from the IFU • 11Dec2020 – 25Jan2021 – high Ct values	-		
	Update analysis rule for the new SOP: "Not Detected" Ct cutoff changed from 37 to 42 in WAMond ROX >37 and <=42 will be called "Not Detected". IC Failure samples (HEX=0 or >40) will be released as "Invalid". No changes on controls and "Detected" rules			were interpreted as inconclusive • 25Jan2021 – present were interpreted as positive – high Ct values (> 37 - < 42)	presumptive				
i. 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. j. There was no indication that this document identified as User Requirement Specifications				See Attachment 9, Attachment 10, and Attachment 11					

STATEMENT	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C	LIA	(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVE			
AND PLAN O	ND PLAN OF CORRECTION IDENTIFICATION NUMBER:			A. BUILDING	·	COMPLETED	
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D5407	Continued From pag	e 45		D5407	(1) Immediate Corrective Action:		
		ersion 1.0, was approv	ved,		The specimens in question were resulted as	per SOP	1
					(see D5800).		
	k. 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 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 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			 (2) Patient Impact: See D5800. (3) Preventative Action: No revision to SC process is placed into use until the Lab Dire Rosendorff, has provided written approval. shift to shift communication checklist (CA-FM-001, approved by Lab Director on 09M completed by the data analysis team, includ written confirmation of the most recent upversion of the analysis and reporting SO (CSOP-002). (4) Monitoring Mechanism: Monthly aud integrity are performed as stipulated in the schedule by the Quality organization. Tracinitiated on 26Feb2021 (10 samples) and 11Mar2021(25 samples) confirmed that represults matched the current SOP 100% of the same content of the same content of the current same current same content of the current same content of the current same content of the current same current same current same content of the current same cu	ctor, Dr. A daily RPT- ar2021), es a lated A-RPT- its for data 2021 audit er audits		
		d by the RT-PCR assa	y on				
	Analytik Jena Therm	ai Cycler.			Finding 2		
	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:		roved, for the		The VBL Playbook has been in use by a since the laboratory opened and w document control and approved for the Laboratory Director on 07Dec2021. CA-CLSRV-SOP-002 was used in draf prior to Laboratory Director approval or Please see D5407 finding 1 regarding dela of procedures.	as moved to use by In addition, t version 07Dec2020.	
	in the collection sites specimen collection,	ortation, processing, refe	٦,		Test results are transmitted to from the L thorough the Color Platform to both Call CalOES. CalREDIE transmits results to C county public health authorities and feder health authorities as required by law.	REDIE and alifornia	

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBER			LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
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					-			
D5401	ii. Step-by-step per including test calcular results. (1). Onsite Data Ana (2). Remote Data Ariii. Reference Interior. Infectious Disease b. The following at the 60 randomly revice covering the period 12/08/2020, wherein SARS-CoV-2 tests at the following at th	rformance of the procedutions, and interpretationallysis halysis vals (normal values) ases Reporting re the accession numbriewed patient test recording the laboratory performand reported results, but but test P/P, approved, si	ers of rds ned	D5407	Continued from page 46: 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 netword secured behind a firewall. This infrastruct configuration eliminates the ability for ind access the site and file repository from an elocation on a general internet connection. transferred to the location of the remote (c person. The only method to access the syst is through a secured VPN tunnel using a P issued 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 experien analyst is the same and no separate trainin procedure is used. Remote analysis is no lo See also D6082. (1) Immediate Corrective Action: Sign Out Manager was instructed by Director, Haleh Farzanmehr, on 10I analysts may not analyze data remot Human Resources informed potentic candidates and those awaiting onbot orientation that remote analysis was possibility; employment contingent analysis In addition to be being stipulated in between Color Genomics and PKI, tinfectious disease reporting has been Post-analytical QA Process (CA-RP' (2) Preventative Action: No policy or proplaced into use until Dr. Rosendorff has sig Lab Director, Dr. Rosendorff, there is no cidiagnosis, treatment, or recommended pat (retesting), and there would not be patient	ory and (2) a Both of these k and are ure ividuals to external Data is never offsite) ems remotely erkinElmer issued laptop. stem being d internal IT ce of the g or onger allowed. The Lab Dec2020 that ely. al qualified arding/ no longer a upon on site the contract the process for a detailed in T-SOP-004). The cedure is gned off. Per thange in ient action		

	F OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
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	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 d. The Laboratory II 12, 2021 at approxim laboratory failed to propose instructions to step-by-step test calcinterpretation of resul Infectious Disease Restate, and federal aut TEST SYSTEMS, ECINSTRUMENTS, RECINSTRUMENTS, RECINSTRU	poratory's annual testing the laboratory director after a control of the laboratory director at the laboratory reported of SARS-CoV-2 test result of the laborate policies to ensure clients, accurate clients, accurate clients, accurate clients, and it complied with the porting required by local horities. PUIPMENT, AGENT Se selected by the laborate performed following the control of the laboratory's sections and in a manner within the laboratory's sections for each test sys §493.1253.	ervals, atory.	D5407	Continued from page 47 (3) Preventative Action: A request to r VPN access software from analyst compute placed with the IT group by the project mather on 11Mar2020 and completed on 13Mar202 the IT group. (4) Monitoring Mechanism: Monthly internal audits are performed by the LIMC and Color Genomics. Additionally, at the beginning of each shift, data analysts confir version of the reporting SOP that is in use. See Attachment 16. D5411 Finding 1a: The laboratory has an Amplicon Contamin Prevention Plan, CA-SAFE-POL-019 v 1.0, by Lab Director, in effect at time of inspectiplan describes the measures put in place to contamination that included laboratory desconstruction of air lock doors, environment with separate HVAC systems, unidirections flow, secure PCR plate transport, use of PPI defined gowning/degowning procedures, dequipment and consumables in each room, resistant pipette tips, dedicated refrigerators separate reagents and samples, and asceptic techniques all of work areas and equipment observation made at time of inspection statlab use of 70% ethanol did not match the EU procedure (see section 5.7.2). Additionally, Safety statement was included in the technic (listed in the findings) that contradicted the approved practice and the Laboratory Qual Management Plan (approved by the director effect at time of inspection (CA-QM-SOP-Ceffective 12OCT 2020) did not provide the environmental prevention and decontamin initiatives outlined in the Amplicon Contamination; the decontamination; the decontamination; the decontamination prevention instructions do not impact perfective 120 detection kit provided possible actions preventing contamination; the decontamination; the decontamination instruction instructions do not impact perfective 120 detection kit provided possible actions prevention instructions do not impact perfective 120 detection kit provided possible actions prevention instructions do not impact perfective 120 detection kit provided possible actions prevention instructions do not impact perfective 120	admin admin admin ation approved on. This prevent sign and tal controls al sample E with edicated aerosol- s/freezers to c cleaning The ed that the UA and our a default cal SOPS e current ity or and in 001 va robust ation mination KI nucelic s for ation	29Mar2021	

	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				S	(X3) DATE SURVEY COMPLETED	
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D5411	control (QC) and quarandom review of pathe period from 11/22 out of 60 patient test determined that the last followed the adopted subsequent revisions changes made in the procedures. Findings included: 1. Review of the last specification studies, (IFU) for Perkin Elmer Acid Detection Kit, ar procedures available inspection, the laborate following: a. Decontamination Fig. Review of the laborate of 12/20/2020, Re 01/12/2021) stated up precautions #7 that, "filter-tips should be dicontaining a 10% Soc After the operation, the instrument surface streshly prepared 10% solution, and then cled pure water. Finally, to working surfaces for it. Based on direct of it. Based on direct of it.	lity assurance (QA) redicent test records coverient test records reviewed, it was aboratory failed to ensure FDA EUA IFU, the stothe EUA IFU, and laboratory's policies and laboratory's policies and during the on-site atory failed to provide the Protocol Tratory's FDA EUA IFU) for Perkin Elmer Nacid Detection Kit (Effectived 09/16/2020 and ander warnings and Sterile centrifuge tubes a sposed into a waste bidium Hypochlorite soluties work area surface and induction of UV light to disinfect with 75% Ethanolum on UV light to disinfect in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020, the laboratory is provided in the servation and interview in 12/08/2020 in the laboratory is provided in the servation and interview in 12/08/2020 in the laboratory is provided in the servation and interview in 12/08/2020 in the laboratory is provided in the servation and interview in 12/08/2020 in the laboratory is provided in the servation and interview in 12/08/2020 in the	ing for 60 fas for 60	D5411	Continued from page 48 characteristics of the test and it is the Laborat Director who determines the contamination prevention and decontamination procedures used at the Laboratory. Use of UV light to dis work surface area and the instruments is not by the Laboratory Director and therefore not in the contamination prevention plan. Based on CDC guidelines and the letter from corporate quality organization the minimum ethanol required for decontamination is 60. (1)Immediate Corrective Action: • Reviewed and updated the Quality Maras stipulated in the above summary. • Reviewed and updated all technical and to reflect the practices currently in user stipulated in the validation related to 7 nonuse of UV light and bleach. Refer to 1 for updated SOPs and further discuss Findings 1 and 2. (2) Patient Impact: Per Lab Director, Dr. Ros is no change in diagnosis, treatment, or repatient action (retesting) as the change in of ethanol and nonuse of UV and bleach as decontamination measures would not caus harm. (3) Preventative Measures: • Lab Director, Technical & General Sup Quality staff to continue with timely doreview following Document Manageme and making revisions and edits when enchanges in process are identified. • Performing employees were given immate documents at time of director approximates of the inspection process, a post inspection conducted by the quality staff, is added to the inspection process, a post inspection conducted by the quality staff, is added to the inspection process, a post inspection conducted by the quality staff, is added to 4 Audit Schedule at a time to be determined Director (3 and/or 6 months post inspection dentified findings with corresponding corpreventative and monitoring activities are determine if findings have been resolved and being monitored effectively. Any items detout of compliance will move into the QER, needed, CAPA process(es). See Attachment 1 The use of 70% EtOH meets the standard set a finactivation is an effective method to inactivation of the post of the pro	to be infect the approved included approved included a our percent agement Plan I Safety SOPS and/or 10% ethanol, to Attachment ion in D3003 acendorff, there commended concentration are patient acceptance of the patient accept	

(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 ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX. PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5411 Continued From page 49 D5411 Finding 1b: Heat inactivation is a desirable method for ensuring that the infection risk associated with SARS-CoV-2 clincial samples is as low as possible. Validation studies carried out prior to the beginning of testing included LoD decontamination solution. iii Due to safety concerns with using 10% studies with both heat inactivated and non-heat Sodium Hypochlorite solution with VTM, the inactivated samples (see validation report sent to LFS at 1:55pm PST on 24Oct2020). There was no performance laboratory used ethanol. impact on heat inactivation. iv. However, contrary to the specified ethanol (1) Immediate Corrective Action: The validation report concentration in the IFU, the laboratory, used that included the heat inactivation process was sent to 70% ethanol, and not 75% ethanol. LFS on 24OCT2020 at 1:55pm PST (2) Patient Impact: Per Lab Director, Dr. Rosendorff, as the validation was performed before the start of testing v. The laboratory failed to follow there is no change in the diagnosis, treatment, or recommended patient action (retesting), and there manufacturer's instructions specified in the IFU. would not be patient harm. (3) Preventative Measure: The quality organization will provide validation material to the inspection staff. vi. The laboratory also failed to provide (4) Monitoring Mechanism: On a yearly interval the performance specification studies showing 70% quality organization ensures the validation study ethanol is an effective decontaminant instead of information is effectively and efficiently found and provided. 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. Finding 1c: Storage condition: The long term storage -94--75oC is intended for post-testing storage. This is not a change to the method described in the IFU and has no impact on b. Heat Inactivation of Swab Samples the performance of the assay. Review of the laboratory's FDA EUA (1) Immediate corrective action: The stability of (1) Immediate corrective action: The stability of extracted RNA at -84 - -76oC was researched. Multiple sources indicate that RNA is stable at this temperature for at least one year (1. Technical Bulletin #159: Working with RNA, ThermoFisher.com [Accessed 10Mar2021]; 2. https://www.bioline.com/rna-hints-and-tips [Accessed 10Mar2021])
(2) Patient Impact: Per Lab Director, Dr. Rosendorff there is no charge in the diagnosis treatment or 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) did not include the heat inactivation procedures for swab samples. there is no change in the diagnosis, treatment, or Review of the laboratory's policies and recommended patient action (retesting), and there procedures (Policy # CA-EXT-SOP-001 Heat would not be patient harm. (3) Preventative action: Any change in material storage Inactivation of Viral Swab Samples) indicated temperature will be researched before a change is the following: implemented. (4) Monitoring mechanism: As a follow-up to the inspection process, a post inspection audit, conducted ii.a. Use of oven to 70 degrees Celsius by the quality staff, is added to the FY2021 Audit ii.b. Pre-cool centrifuge to 20 degrees Celsius Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings iii.c. The use of centrifuge at 1200 RPM with corresponding corrective, preventative and for 1 minute monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es).

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				IA, CA 91	355		
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PREFIX		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG			IPLETION DATE
D5411	Continued From pag	e 50		D5411	Finding 1d		
55411	 iii. The laboratory failed to provide performance specification studies for the heat inactivation of swab samples. c. Storage Conditions for nasopharyngeal, oropharyngeal, and anterior nasal swabs (Extracted RNA) i. Review of the laboratory's FDA EUA 				Thermocycler Parameters: The correct coll temperature is 65oC. A universal .trf file corpCR thermocycling conditions is generated Janus program at the time a 384-well plate. The .trf file is imported to the AJ thermocy is correct. Records from the PCR output firandomly chosen samples demonstrate that temperature is being used (LFS Response C Parameters). Appendix A of CA-PCR-SOP contained a typographical error. This error corrected in v2 (approved 26Jan2021).	ntaining the l by the PCR is set-up. cler. This file les for the 60 t the correct cycling -002v1 was	
	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 that, "Nasopharyngeal, oropharyngeal, and anterior nasal swabs with the extracted nucleic acids should be stored at -25 to -15 degrees Celsius. ii. Review of the laboratory's policies and procedures (Title CA-EXT-SOP-004 Title Viral RNA/DNA Extraction Using the Chemagic 360, Effective Date 11/03/2020 stated that, "Extracted		h the 25 to		(1) Immediate Corrective Action: CA-PCR-SOP-002 was updated and approved by the Lab Director on 26Jan2021 to correct the omitted step and the typographical error. (2) Patient Impact: Referencing the look back above, 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 Measure: To reduce typographical errors and improve technical accuracy, the Lab Director has directed that a Technical Supervisor will conduct a secondary review of all technical (ACC, EXT, PCR, RPT and SAF) documents prior to approval request to the Lab Director.		
		be stored at -84 to -76			(4) Monitoring Mechanism: The lab performed this time and there have been no changes to thermocycler parameters since the validationare expected for an established method that	o the n; and none is in control	
	iii. The laboratory failed to follow manufacturer's instructions specified in the IFU. iv. The laboratory failed to provide performance specification studies showing the basis for changing the storage conditions requirement for extracted nucleic acids.		ance		and performing well. There is not one specific monitoring mechanism. However, As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). A confirmation that thermocycler parameters in Appendix A of the technical SOP have not changed without a concomitant validation is an item on this audit plan.		
	d. Thermal Cycler Parameters i. 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		ctive		Finding 1e: Delayed procedure approval: Please refer to Timeline. This timeline reflects the difficult to a scientific and clinical consensus on how load (high Ct value - specifically >36-<42) r be interpreted. Due to discussion among Laboratory Direct procedure used in analysis was not approve	y in coming value viral esults should cors, the	
	set-ups:				manner. Although not approved, a consiste interpretation was used (see Analysis Timel		

(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 (X5) SUMMARY STATEMENT OF DEFICIENCIES (X4) 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) Continued From page 51 D5411 • 28Oct2020 - 11Nov2020 - results were reported as per the IFU Step Temperature Time # of Cycles 11Nov2020 - 11Dec2020 - lower Ct cutoff 1 37 degrees Celsius 2 minutes was set for positive results based on Ct value 2 50 degrees Celsius 5 minutes observed during validation, reflecting a 42 degrees Celsius 35 minutes change in interpretation from the IFU 94 degrees Celsius 10 minutes 1 11Dec2020 - present - high Ct values (>37 -5 94 degrees Celsius 10 seconds <42) were interpreted as inconclusive 55 degrees Celsius 15 seconds 45 65 degrees Celsius 45 seconds 11Dec2020-25Jan2021 or presumptive positive (25Jan2021 -present) *Collect fluorescence signal during the final 65 degrees Celsius step Due to scientific discussion and disagreement, a final laboratory procedure was not approved by the laboratory directors until 08Dec2020. Additional Review of the laboratory's policies and versions were requested with delayed approval over procedures (Policy # CA-PCR-SOP-002, Title the next week. Although the protocol in use should SARS-CoV-2-RT-PCR Using the Analytic, have been approved prior to use, mitigating Effective Date 11/04/2020) stated the following circumstances to note include: thermal cycler parameters: -Data analysts were trained using the draft protocol, which remained available to them -Changes in the interpretation of results were **Temperature** Time # of Cycles Step handled in LIMC, not determined by data analysts 25 degrees Not -An active discussion was held with 2 minutes 1 indicated Celsius CDPH directors to bring the 50 degrees 15 Not interpretation to resolution. See: 2 Celsius indicated minutes o 01Dec2020 Email CDPH Approval of v1 o 08Dec2020_Email Final SOP Definitions for v1 for 95 degrees Not 2 minutes 3 Doc Control Celsius indicated o 11Dec2020 Email Changes to Ct Not 95 degrees 4 3 seconds Reporting Celsius indicated o 14Dec2020 Email Changes to Ct 60 degrees 30 Not 5 Reporting (v2) Celsius seconds indicated o 16Dec2020 Email Changes to Ct Reporting (v3.1)

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AMME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (K4) ID REPRIX TAG (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) D5411 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 1 25 degrees Celsius 2 minutes 1 2 50 degrees Celsius 3 95 degrees Celsius 3 95 degrees Celsius 4 95 degrees Celsius 5 60 degrees Celsius 5 60 degrees Celsius 5 60 degrees Celsius 7 Collect fluorescence signal during the final 60 degrees Celsius step STREET ADDRESS. CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE VALENCIA, CA 91355 DPROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) Deviation from IFU outcomes: The clinical significance of high Ct values is a subject of scientific debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or no Ct values: - Negative (no virus detected) - Inconclusive / presumptive positive (high Ct value 37 - 42) - Positive (virus detected with Ct value <37) Note that is a post-analytical interpretative decision. This is not a change to the method described in the IFU and has no impact on the performance of the assay. (1) Immediate Corrective Action: A full-time, on-site Laboratory operations and result reporting. Decisions regarding data interpretation are now made in a timely manner. Interpretation are now made in a timely manner. Interpretation of Ct values has been vetted by Dr. Rosendorff, the CDPH Leadership and the Testing Task Force	AND PLAN C	OF CORRECTION	IDENTIFICATION NUMBER:		A. BUILDING		COMPLETED	
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PREFIX TAG (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) D5411 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 15 minutes 1 3 95 degrees Celsius 3 seconds 1 5 60 degrees Celsius 3 oseconds 45 **Collect fluorescence signal during the final 60 degrees Celsius step iv. The instruction is PLU outcomes: The clinical significance of high Ct values is a subject of scientific debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or no Ct values: - Negative (no virus detected) - Inconclusive / presumptive positive (high Ct value 37 - 42) - Positive (virus detected with Ct value < 37) Note that is a post-analytical interpretative decision. This is not a change to the method described in the IFU and has no impact on the performance of the assay. (1) Immediate Corrective Action: A full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting. Decisions regarding data interpretation are a now made in a timely manner. Interpretation are a now made in a timely manner. Interpretation are a now made in a timely manner. Interpretation of Ct values has been vetted by Dr. Rosendorff, the CDPH Leadership and the Testing Task Force				VALENC	IA, CA 913	355		
high Ct values is a subject of scientific debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or no Ct values: 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 45 **Collect fluorescence signal during the final 60 degrees Celsius step high Ct values is a subject of scientific debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or no Ct values: - Negative (no virus detected) - Inconclusive / presumptive positive (high Ct value 37) Note that is a post-analytical interpretative decision. This is not a change to the method described in the IFU and has no impact on the performance of the assay. (1) Immediate Corrective Action: A full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting. Decisions regarding data interpretation area now made in a timely manner. Interpretation of Ct values has been vetted by Dr. Rosendorff, the CDPH Leadership and the Testing Task Force	PREFIX	(EACH DEFICIENCY MUST	T BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	DBE COMPLETION	
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 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 i.b. SARS-CoV-2 Detected	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 7 the instruction to during the final 60 despecified in laborator (ii) and d (iii) is not the IFU, which indicasignal during the final 60 despecified in laborator (ii) and d (iii) is not the IFU, which indicasignal during the final 60 despecified in laborator final following the final 60 despecified in laborator final following the final 60 despecified in laborator final fina	re policies and procedum T-PCR Using the Analy 11/04/2020, indicated to lers dated 10/27/2020. Time # of Cyrius 2 minutes 1 ins 15 minutes 1 ins 2 minutes 1 ins 3 seconds 1 ins 30 seconds 45	cles 60 signal in d ion in ce tep." t ler w ctive the	D5411	high Ct values is a subject of scientific debate. IFU gives only a positive or negative interpreta decision was made to interpret high Ct values of from negative or no Ct values: - Negative (no virus detected) - Inconclusive / presumptive positive (high C 37 - < 42) - Positive (virus detected with Ct value < 37) N post-analytical interpretative decision. This is report to the method described in the IFU and has no the performance of the assay. (1) Immediate Corrective Action: A full-time Laboratory Director, who is directly involved i laboratory operations and result reporting. Deregarding data interpretation area now made in manner. Interpretation of Ct values has been v Rosendorff, the CDPH Leadership and the Tes Force (2) Patient Impact: Based on the lookback from 28, 2020 to December 11, 2020, there were 8,75 with results of IC Dropout that were reported with the SOP that was in effect by written approprise CDPH lab directors. Results were correctly inconclusive pursuant to the lab SOP. Howeve and the policies and procedures were communate finalized in a revised SOP until December indicating these samples would now be considered also D5800. Additionally, per Lab Director Dr. Rosendorff, change in definition would not be a change in treatment, or recommended patient action (retithere would not be patient harm. A memorandum was provided to Color Genor OptumServe for the samples mentioned. They receipt.	Although the tion, the differently It value Ote that is a loot a change impact on It, on-site in day-to-day cisions in a timely etted by Dr. ting Task Im October 16 samples consistent oval from reported as ir, the IFU v5 icated but 13, 2020 ered Invalid. Ithe future diagnosis, esting), and inics and confirmed Ited into use	

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D5411	Continued From pag	e 53		D5411	Continued from page 53				
	Director on 12/08/202 laboratory should be ii.a.SARS-Coi.b.SARS-Coii.b.SARS-Coii.c.Inconclusii.d.Invalid iii. At the time of insp 12/09/2020, the laborated interpretation inconclusive result. 2. The following are the 60 randomly reviectovering the period fr 12/08/2020, wherein SARS-CoV-2 tests at failed to establish its	w with the Laboratory 20 and 12/09/2020, the reporting the following: 6V-2 Not Detected 6V-2 Detecte	and the ude ers of ds ed toostic		(4)Monitoring Mechanism: Recent vers 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 forwar quality review. An audit was conducted 10 randomly selected samples from Janu integrity between LIMC and Color was of 10 samples via a routine tracer audit per 26Feb2021. An audit of an additional 25 be performed beginning 11Mar2021. Finding 2-4: Please see findings 1a - 1e and the second sec	le and data integrity indom samples d as part of 26Feb2021 on ary 2021. Data confirmed for formed samples will			

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							×*
	2 Passal on the lab						
	declaration signed by 12/16/2020, the labor	00 SARS-CoV-2 test res	r on				
	12, 2021 at approxim laboratory's failure to instructions specified director also affirmed performance specific modification of the profibal EUA IFU. The la affirmed the laboratory	follow manufacturer's in the IFU. The labora the absence of ation studies to support occdure not indicated in aboratory director also ry failed to establish its	tory t the				
D5415		nostic test P/P that incl a" through "1e", above.		D5415			29Mar2021
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
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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 quarandom review of palthe period from 11/22 out of 60 patient test determined that the I labeled the reagents Findingsincluded: 1. Review of the laprocedures (Policy # Labeling of Reagents Date 12/09/2020) states on labeling reagents: a. Name of the readed. Name of the period of the period. Date of preparate	ge 55 a culture media, control of materials, and other riate, must be labeled to ge a significant, titer, streng ents. Expiration dates, mation required for property of the procedures of the	per use. Ality ords, ing or 60 as ure it		Finding 1-5: We acknowledge that labeling of some rea incomplete and are working to improve of Supervisors and managers were instructed refamiliarize the staff with proper procedulabeling reagents. Monitoring of labeling (1) Immediate Corrective Action: Proced reviewed with staff and all technical staff hassigned reading by the MediaLab Admin LABGEN-SOP-002 (Labeling of Reagents and acknowledge the changes to this docu 31Mar2021. (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: Implemented a supervisor checklist and shift to shift comband-off; one of the action items for each supervisor to walk the floor and check reapproper labeling and expiration dates. This awareness and allows for timely correction needed. (4) Monitoring Mechanism: Each month 2021 Audit Schedule) a walk-though audit quality staff, confirms (or corrects) that all bench-tops and in refrigerated spaces mee labeling and expiration date requirements. conducted 25Feb2021 and reported 01Mars.	ompliance. I to		
	d. Date of preparation, filtered, or reconstituted by the laboratory (if applicable) e. Storage conditions (e.g., temperature, exposure to light, etc. as specified by the manufacturer f. Any relevant biohazard or chemical hazard information							

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2. Durapprofound prope a. Eb. Mc. Mp 3. The 60 covering 12/08 SARS ensur	with the followerly: Elution Buffer x Magnetic Buffer Milli Q Water x 3 erson, date pre The following are orandomly revising the period following the period following are S-CoV-2 tests as	pe 56 Dry tour on 12/08/2020 a.m., the laboratory waining reagents not labeled 1- No initial of the person x1 - No initial of the person x1 - No expiration date, initipared, storage conditions at the accession number ewed patient test record of 11/22/2020 to the laboratory performent reported results but a labeled as required.	on reson iial of the n.	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 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 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 TEST SYSTEMS, EQUIPMENT, D5417 29Mar2021 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 ID (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 Continued From page 58 Finding 1-5 expiration dates. We acknowledge the failure to discard some of the ethanol reagent bottles that were in use past their Findings included: expiration; 2 bottles 5 days past expiration and 2 bottles 1 day past expiration date. During the laboratory tour on 12/08/2020 at See D3003 for additional details approximately 10:30 am., the laboratory was observed to have four 70% Ethanol Cleaning (1) Immediate Corrective Action: See D3003 Finding Solution in dispensing bottles beyond its expiration date. **(2) Patient Impact:** See D3003 Finding 2, 3, 4, 5 a.1. Lot # 267015, ExpirationDate: (3) Preventative Measure: See D3003 Finding 2, 3, 4, 5 12/03/2020 (2 dispensing bottles) (4) Monitoring Mechanism: See D3003 Finding 2, 3, 4, a.2. Lot # A10012002B, ExpirationDate: 12/07/2020 (2 dispensing bottles) 2. Review of the laboratories policies and procedures (Policy # CA-QM-SOP-001, title Quality Management Plan, Effective Date 11/01/2020) stated that reagents and chemicals should be used in testing process within their indicated expiration date. 3. 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 ensure reagents were not used past the expiration dates. Accession Number

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLI/ IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
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4 dd 1 a a fi	leclaration signed by 12/16/2020, the labor approximately 430,00 rom 11/02/2020 to 12	ooratory's annual testing the laboratory director ratory reported 00 SARS-CoV-2 test res	r on sults	D5417	Continued from page 59 (1)			
1 la o d	12, 2021 at approximate aboratory failed to media fits 70% Ethanol clear lecontamination process.	ately 2:10 pm) the onitor the expiration da aning solution utilized in the dure.	ates n					
E a	PERFORMANCE CFR(s): 493.1253(b)(Each laboratory that i	modifies an FDA-cleare , or introduces a test s	ed or	D5423			29Mar2021	

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CL AND PLAN OF CORRECTION IDENTIFICATION NUMBER				G	(X3) DATE SURVEY COMPLETED			
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	ROVIDER OR SUPPLIER RANCH LABORATOR	Y	28454 LI	ADDRESS, CITY, STATE, ZIP CODE 54 LIVINGSTON AVE LENCIA, CA 91355				
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D5423	(including methods of standardized methods of standardized methods procedures), or uses performance specific the manufacturer mutest results, establish performance specific performance charact (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sens (2)(iv) Analytical sens (2)(iv) Analytical specisubstances. (2)(v) Reportable ran system. (2)(vi) Reference interequired for test performance for test performance of the laboratory staff on Dereview of the laboratory staff on Dereview of the laborator EUA IFU Perkin Elme Acid Detection Kit Reaction (RT-PCR) processed (P/P), quality control (QA) records, random records covering the 12/08/2020, for 60 our reviewed, it was determined to establish and specifications prior to results. Findings included: 1. Review of the laborators of the laboratory staff on Dereviewed, it was determined to establish and specifications prior to results.	eveloped in-house and is such as text book a test system in which ations are not provided st, before reporting path for each test system thations for the following eristics, as applicable: sitivity. cificity to include interference of test results for the following eristics, as applicable: sitivity. cificity to include interference of test results for the formance characteristic formance characteristic formance. The following eristics in the following eristics and values). The following eristics in the following eristics and proceed by: The following eristics in the following eristics and procedures of the following eristics and procedures (QC) and quality assure the following eristics and procedures (QC) and quality assure the following eristics and procedures (QC) and quality assure the following eristics and procedures (QC) and quality assure the following eristics and procedures (QC) and quality assure the following eristics and procedures (QC) and quality assure the following eristics and procedures (QC) and quality assure the following eristics are the following eristics and the following eristics are the following eristics.	a by ident he string e test string e test string oved acleic hain string ance or ords or	D5423	Finding 1a Clinical performance in asymptomatic peoversion 7 (06Jan2021) of The PerkinElmer' Coronavirus Nucleic Acid Detection Kit III intended use for the kit is intended for:tl qualitative detection of nucleic acid from S in human oropharyngeal swab and nasoph swab specimens collected by a healthcare p (HCP), and anterior nasal swab specimens an HCP or self-collected under the supervi HCP from any individual, including indivi without symptoms or other reasons to sust 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 Nucletection Kit may be used to test asymptotindividuals, although performance has not demonstrated in an asymptomatic populat assay has been shown to exhibit high sensit tested with the FDA reference panel. 7. Use of the PerkinElmer New Coronavirus Acid Detection Kit in a general, asymptom screening population is intended to be used an infection control plan, that may include preventative measures, such as a predefine testing plan or directed testing of high-risk Negative results should not be treated as do not preclude current or future infection through community transmission or other Negative results must be considered in the an individual's recent exposures, history, a of clinical signs and symptoms consistent valued to the considered of the perkinElmer New Corona Nucleic Acid Detection Kit; however, perfor this specimen type has not been determined 1. Immediate Corrective Action: Recurrent IFU (version 6) to confirm asymptomatic individual is appropared treatment, or recommended patier (retesting), and there would not be	New EU, the ne ARS-CoV-2 aryngeal provider collected by sion of an duals spect skit within leic Acid matic been ion. This tivity when has Nucleic atic d as part of additional d serial individuals. Efinitive and cobtained exposures. context of and presence with r the rovider can wirus mance with the viewed that use in riate. Or. liagnosis, at action		

(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 CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5423 D5423 Continued From page 61 3. Preventative Action: The laboratory will verify the current version of the IFU as part of the Quality Management Review process (at least current policies and procedures, the laboratory failed every quarter) to determine if any changes that to provide documentation of established performance impact our current method have been made. specifications for the performance characteristics listed in "a." through "f." as follows: 4. Monitoring Mechanism: As a follow-up to the inspection process, a post inspection audit, a. Clinical Performance Evaluation for conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined specimens collected from asymptomatic by Lab Director (3 and/or 6 months post individuals. inspection). All identified findings with corresponding corrective, preventative and i. Review of the laboratory's FDA EUA and IFU for monitoring activities are evaluated to determine if findings have been resolved and/or are being Perkin Elmer New Coronavirus Nucleic Acid monitored effectively. Any items determined to be Detection Kit (01/12/2021) stated under the out of compliance will move into the QER, and if product authorization that, "Your product is a test needed, CAPA process(es). for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal and nasopharyngeal swab specimens collected by a HCP and anterior nasal swab specimens Finding 1b: collected by a HCP or self- collected under the The laboratory has an Amplicon Contamination supervision of a HCP from ANY INDIVIDUAL, Prevention Plan (CA-SAFE-POL-019 v 1.0, approved including without symptoms or other reasons to by Lab Director, in effect at time of inspection. This suspect COVID-19 infection." plan describes the measures put in place to prevent contamination that included laboratory design and ii. Review of the same EUA and IFU for Perkin construction of air lock doors, environmental controls Elmer New Coronavirus Nucleic Acid Detection with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with Kit (01/12/2021) also stated that, "Perkin Elmer defined gowning/degowning procedures, dedicated MUST further evaluate the clinical performance equipment and consumables in each room, aerosolfrom ASYMPTOMATIC individuals in an FDA resistant pipette tips, dedicated refrigerators/freezers to agreed upon post authorization clinical evaluation separate reagents and samples, and asceptic cleaning study within 30 calendar days of the date of this techniques all of work areas and equipment. The letter. Labeling updates must be made after observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our submission to FDA." procedure (See Section 5.7.2). Additionally, a default It was also stated under the kit limitations that, Safety statement was included in the technical SOPS "nasal swab specimens self-collected under the (listed in the findings) that contradicted the current supervision of or collected by a healthcare approved practice and the Laboratory Quality provider performance has not been determined." Management Plan (approved by the director and in effect at time of inspection (CA-QM-SOP-001 va iii. The laboratory must provide its protocol and effective 01NOV2020) did not provide the robust environmental prevention and decontamination clinical performance evaluation from initiatives outlined in the Amplicon Contamination asymptomatic individuals, as stated by the Prevention Plan. **FDA**

(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 PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5423 D5423 Continued From page 62 Continued from page 62 under the "Conditions of Authorization." The FDA EUA instructions for use of the PKI nucelic Acid detection kit provided possible actions for v. The laboratory must provide the performance preventing contamination; The decontamination prevention instructions do not impact the evaluation for nasal swab specimens performance characteristics of the test and it is the self-collected under the supervision of or Laboratory Director who determines the collected by a healthcare provider. contamination prevention and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work surface area and the Decontamination Protocol instruments is not approved by the Laboratory Director and therefore not included in the contamination prevention plan. i. Review of the laboratory's FDA EUA Instructions for (1)Immediate Corrective Action: Use (IFU) for Perkin Elmer New Coronavirus Nucleic Updated all technical protocols to reflect the Acid Detection Kit (Effective Date 03/20/2020, Revised current disinfectant in use, 70% Ethanol and 09/16/2020 and 01/12/2021) stated under warnings remove the (See Attachment X for list of and precautions #7 that, "Sterile centrifuge tubes and documents, approval date). AS 70% was already filter-tips should be disposed into a waste bin the disinfectant used in the lab, re-training was not required. containing a 10% Sodium Hypochlorite solution. After Updated the Quality Management Plan (CAthe operation, the work area surface and the instrument QM_SOP-001, Sections 6.3.4.7, 6.5.1, 6.8.1, surface should be disinfected with a freshly prepared approved by Lab Director and effective 01Mar2021) to reflect contamination prevention 10% Sodium Hypochlorite solution, and then cleaned and monitoring that is in place, following with 75% Ethanol or pure water. Finally, turn on UV current Amplicon Contamination Prevention light to disinfect working surfaces for 30 minutes." Plan (SAFE-POL-019., v1.1, approved by Lab Director and effective 14Dec202). Staff were assigned to read and acknowledge the changes ii. Based on direct observation and interview with to this document. the laboratory staff on 12/08/2020, the laboratory (2) Patient Impact: Per Lab Director Dr. Rosendorff, was utilizing 70% Ethanol as their general there is no change in diagnosis, treatment, or recommended patient action (retesting), and there decontamination solution. would not be patient harm. Appropriate quality control reactions are helpful in determining whether contamination has occurred. A patient iii Due to safety concerns in using 10% Sodium lookback (from 28OCT2020 to 08DEC2020) and a Hypochlorite solution with VTM, the laboratory patient lookforward (09DEC2020 to 28FEB2021) was conducted to review all positive and negative used ethanol. controls to look for the presence of viral targets that could indicate contamination. There was no iv. However, contrary to the specified evidence of contamination as values were well below 2% threshold. (See Attachment 1) The trend ethanol concentration in the IFU, the downward noted is due to a software change laboratory used 70% ethanol, and not 75% allowing for color compensation and better resolution and not attributable to EtOH or % of ethanol. EtOH used. Per Dr. Rosendorff, the current Lab v. The laboratory failed to follow Director, there is no contamination of patient manufacturer's instructions specified in the IFU. samples or test results. vi. The laboratory also failed to provide performance specification

studies showing 70% ethanol is an

effective

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(X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X5) PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC IDENTIFYING INFORMATION) TAG OR LSC IDENTIFYING INFORMATION) TAG (X5) COMPLETIC DATE (X6) PREFIX TAG (EACH CORRECTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	PREFIX (EACH D	
decontaminant instead of 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. c. Heat inactivation of Swab Samples i. 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 O9/16/2020 and 01/12/2021) did not include the heat inactivation procedures (Policy & CA-EXT-SOP-001 Heat Inactivation of Viral Swab Samples. iii. Review of the laboratory's policies and procedures (Policy & CA-EXT-SOP-101 Heat Inactivation of Viral Swab Samples indicated the following: iii. A Use of oven to 70 degrees Celsius iii. The laboratory failed to provide studies about the heat inactivation of swab samples. d. Storage Conditions for nasopharyngeal, and anterior nasal swabs (Extracted RNA) i. Review of the laboratory's PDA 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 that, "Nasopharyngeal, oropharyngeal, and anterior nasal swabs (Extracted RNA) i. Review of the laboratory's PDA 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 that, "Nasopharyngeal, oropharyngeal, and anterior nasal swabs with the extracted nucleic acids should be stored at -25 to -15 degrees Celsius. ii. Review of the laboratory's policies and procedures (Title CA-EXT-SOP-004 Title Viral	i. Revisitable and the second and th	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION PROVIDER/SUPPL IDENTIFICATIONN		(X) PROVIDER/SUPPLIER/CI IDENTIFICATIONNUMBE	/CLIA		(X2) MULTIPLE CONSTRUCTION A. BUILDING		EY .	
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D5423	RNA/DNA Extraction Effective Date 11/03/ nucleic acids should it degrees Celsius for lo iii. The laboratory fails specification studies conditions requireme acids. e. Thermal Cycler f i. Review of the lat Instructions for Use (Coronavirus Nucleic / Date 03/20/2020, Re 01/12/2021) stated th set-ups: Step Temperature 1 37 degrees Celsi 2 50 degrees Celsi 3 42 degrees Celsi 4 94 degrees Celsi 5 94 degrees Celsi 5 94 degrees Celsi 65 degrees Celsi 8 *Collect fluorescence degrees Celsius step ii. Review of the lat procedures (Policy # SARS-CoV-2-RT-PC	Using the Chemagic 3t 2020 stated that, "Extra be stored at -84 to -76 ang term storage." ed to provide performant to support the storage into support the support the storage into support the support the storage into support the suppor	lew stive ster stees	D5423	Finding 1d See D5411 finding 1b for additional infor (1) Immediate Corrective Action: See D 1b (2) Patient Impact: See D5411 finding 1b (3) Preventative Measure: See D5411 fin (4) Monitoring Mechanism: See D5411 fin Finding 1e: Thermocycler Parameters: The correct of temperature is 650°C. A universal strf file the PCR thermocycling conditions is gen PCR Janus program at the time a 384-we up. The strf file is imported to the AJ then This file is correct. Records from the PC for the 60 randomly chosen samples dem the correct temperature is being used (LF Cycling Parameters). Appendix A of CA-SOP-002v1 contained a typographical errors as updated and approved 26Jan2021 (1) Immediate Corrective Action: CA-F was updated and approved by the Lab Di 26Jan2021 to correct the omitted step and typographical error. (2) Patient Impact: Referencing the look per Lab Director, Dr. Rosendorff, there is diagnosis, treatment, or recommended pretesting), and there would not be patier (3) Preventative Measure: To reduce typerrors and improve technical accuracy, thas directed that a Technical Supervisor vsecondary review of all technical (ACC, and SAF) documents prior to approval relab Director. (4) Monitoring Mechanism: The lab per at this time and there have been no chan thermocycler parameters since the valida are expected for an established method the and performing well. There is not one spenonitoring mechanism. However, As a finspection process, a post inspection and by the quality staff, is added to the FY202 Schedule at a time to be determined by Land/or 6 months post inspection). A con thermocycler parameters in Appendix A SOP have not changed without a concomis an item on this audit plan. Finding If: Delayed procedure approval: Please refer Timeline. This timeline reflects the diffic to a scientific and clinical consensus on load (high Ct value – specifically/Refer to <42 results should be interpreted.	ding 1b collection containing erated by the ll plate is set- mocycler. R output files constrate that SR Response PCR- ror. This error collection d the lback above, so change in atient action attient action tharm. cographical he Lab Director will conduct a EXT, PCR, RPT equest to the forms one test ges to the tion; and none hat is in control hecific collow-up to the it, conducted l' Audit ab Director (3 firmation that of the technical hitant validation to the Analysis hulty in coming how low viral		

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DE 422	Continued From page 65				_	D5423					
D3423	D5423 Continued From page 65					D3425	Timeline. Due to discussion among Labora	tory			
	Step	Temperature	Time	# of Cycle	s		Directors, the procedure used in analysis w approved in a timely manner. Although no	as not t approved, a			
		25 degrees					consistent method of interpretation was use				
	1	Celsius	2 minutes	Not indicate	ted		Analysis Timeline below).				
		50 degrees					• 28Oct2020 – 11Nov2020 – results w	ere reported			
	2	Celsius	15 minutes	Not indicat	ted		as per the IFU • 11Nov2020 – 11Dec2020 – a lower	Ct cutoff was			
		95 degrees					set for positive results based on Ct v	alue			
	3	Celsius	2 minutes	Not indicat	ted		observed during validation, reflecting in interpretation from the IFU				
				i i			• 11Dec2020 – 25Jan2021 – high Ct v < 42) were interpreted as inconclusi	h Ct values (> 37 -			
	4	95 degrees Celsius	3 seconds	Not indicate	ted		 25Jan2021 – present – high Ct value 	es (> 37 - <			
				<u> </u>			42) were interpreted as presumptive	positive			
	5 60 degrees 30 seconds Not indicated			ted		Due to scientific discussion and disagreen					
	Celsius						laboratory procedure was not approved by				
							laboratory directors until 08Dec2020. Add versions were requested with delayed appr				
	iii. Review o	f the same p	olicies and pro	cedures			next week. Although the protocol in use should have				
			CR Using the				been approved prior to use, mitigating circ	umstances to			
	Jena, Effect	ive Date 11/0	04/2020, indica	ated the			Data analysts were trained using the draft protocol, which remained available to them Changes in the interpretation of results were handled in LIMC, not determined by data				
	following the	ermal cyclers	dated 10/27/2	2020.							
		mperature		of Cycles							
		ees Celsius ees Celsius	2 minutes 15 minutes	1							
		ees Celsius	2 minutes	1			analysts				
	_	ees Celsius	3 seconds	1			- An active discussion was held with CDP to bring the interpretation to resolution. S				
	_	ees Celsius	30 seconds	45			o 01Dec2020 Email CDPH Approval of v				
	3						o 08Dec2020_Email Final SOP Definition				
		-	mal during the	final 60			Doc Control				
	degrees Ce	Isius step					o 11Dec2020 Email Changes to Ct Report				
	i The insta	II	Hant Burner				o 14Dec2020 Email Changes to Ct Report o 16Dec2020 Email Changes to Ct Report				
			liect fluorescer degrees Celsi								
	-	-	rocedures ide	•			Deviation from IFU outcomes: The clinica				
			ame as the ins				significance of high Ct values is a subject of debate. Although the IFU gives only a pos				
			ed "Collect fluc				debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or				
			degrees Cels								
							no Ct values: - Negative (no virus detected)				
			o provide perfo				Negative (no virus detected) Inconclusive / presumptive positive (high	n Ct value			
			upport the abo				-> 37 - < 42)				
	described change in thermo cyclerparameters.						- Positive (virus detected with Ct value < 3	37)			

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
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NAME OF P	ROVIDER OR SUPPLIER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Υ	28454 LI	VINGSTO	NAVE		
			VALENC	IA, CA 91	355		
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D5423	Continued From page 66			D5423	Continued from page 66		
	f. Interpretation of Te				Note that is a post-analytical interpretative. This is not a change to the method described as a change to the change to the method described as a change to the c	oed in the	
	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:				IFU and has no impact on the performance assay.		
					(1) Immediate Corrective Action: A full- Laboratory Director, who is directly invol	ved in day-	
	i.a. SARS-Co	V-2 Not Detected			to-day laboratory operations and result re Decisions regarding data interpretation as		
	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:				in a timely manner. Interpretation of Ct v	alues has	
					been vetted by Dr. Rosendorff, the CDPH and the Testing Task Force	Leadership	
					(2) Patient Impact: Based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by		
	ii a SARS-C	oV-2 Not Detected			written approval from the CDPH lab direct	ctors. Results	
		oV-2 Not Detected			were correctly reported as inconclusive pu		
	ii.c. Inconclu				lab SOP. However, the IFU v5 and the pol procedures were communicated but not fi		
	ii.d. Invalid				revised SOP until December 13, 2020 indi	cating these	
		ed "inconclusive" to the le time of inspection on		è	samples would now be considered Invalid D5800.	. See also	
		/2020, the laboratory fa				lauff tha	
	provide performance s	pecification studies for	updated		Additionally, per Lab Director Dr. Roseno future change in definition would not be a		
	interpretation of test re	sults.			diagnosis, treatment, or recommended pa	tient action	
	2. The following are	e the accession number	rs of		(retesting), and there would not be patien	t harm.	
		ewed patient test record	ds		A memorandum was provided to Color G		
	covering the period fr				OptumServe for the samples mentioned. To confirmed receipt.	Гћеу	
		the laboratory modified e IFU of the SARS-Co\			confirmed receipt.		
		orted results, but failed					
	demonstrate it establ						
	specifications for the performance						
		erated in "1 a. through t					
	the procedure, test ca	-by-step performance of)I				
	interpretation of result						
	Accession Number						

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:) DATE SURVEY COMPLETED	
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D5423	3. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 4. The Laboratory E 12, 2021 at approximately to proapplicable performance.	oratory's annual testing the laboratory director atory reported 0 SARS-CoV-2 test resi/16/2020. Director affirmed (Februately 2:10 pm) the ovide documentation for the specification studies	on ults uary r the		(3) Preventative Action: No revision to SO is placed into use until the Lab Director, D Rosendorff, has provided written approval checklist is being completed at shift change Analyst staff and verified by the Sign Out M (4) Monitoring Mechanism: Recent versic RPT-SOP-002 (v4, v5, and v6) were made approved in a timely manner. To ensure abetween LIMC and Color, check of 10 randis performed each month going forward as quality review. An audit was conducted 26 10 randomly selected samples from Januar integrity between LIMC and Color was con 10 samples via a routine tracer audit perfor 26Feb2021. An audit of an additional 25 sabe performed beginning 11Mar2021. Finding 2-4: Please see responses to Findings 1a - 1f ab See Attachment 9	r. A daily by the Data Manager. ons of CA- and ata integrity dom samples part of Feb2021 on y 2021. Data affirmed for emed mples will		
D5433	IVIAIN I ENANCE AND	FUNCTION CHECKS		D5433			29Mar2021	

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED A. BUILDING _ IDENTIFICATIONNUMBER: 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 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 (X3) DATE SURVEY STATEMENT OF DEFICIENCIES 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 DATE (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION 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. CA-DC-SOP-002 (Good Documentation Practices) did not annotate every day of laboratory was re-assigned for all Managers, Supervisors, and operation. technical to re-read. 2. Instrument forms have been updated to make clear appropriate documentation for a shift when Centrifuge SN # JBR20K009, not annotated instrument is not in use (see centrifuge log as on 12/02/2020, 12/03/2020, 12/04/2020, and example). 12/05/2020. See Attachment 2 (1) Immediate Corrective Action: 3. The following are the accession numbers of • See CAPA-20-007 the 60 randomly reviewed patient test records • Procedures referenced in CAPA-20-007 have covering the period from 11/22/2020 to been reviewed with staff and all technical staff 12/08/2020, wherein the laboratory failed to have been reassigned reading by the MediaLab Admin of CA-DC-SOP-002 (Good ensure the established maintenance protocol Documentation Practices) with acknowledgment were performed and documented. expected by 31Mar2021. (2) Patient Impact: Per Lab Director, Dr. Rosendorff, Accession Number there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. (3) Preventative Action: Supervisors have checklists that include daily review of instrument logs for compliance with GDP and documentation of maintenance are now in use. (4) Monitoring Mechanism: In addition to the daily supervisor review of equipment maintenance logs, a monthly walk-through audit reviewing all equipment logs is conducted by the quality staff (see FY2021 audit schedule).

(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 (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 TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5433 Continued From page 70 D5433 D5791 Finding 1a - 1d, 2-4: Appendix A - The Quality Management Plan has been revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 ver. 2.0 approved by Lab Director and effective 01Mar2021. The Amplicon Contamination Prevention Plan, CA-Based on the laboratory's annual testing SAFE-POL-019 v 1.0, approved by the Lab Director declaration signed by the laboratory director on was in effect in affect at the time of inspection and 12/16/2020, the laboratory reported specifies the use of 70% EtOH. The observation made approximately 430,000 SARS-CoV-2 test results at the time of inspection stated that the lab use of 70% from 11/02/2020 to 12/16/2020. ethanol did not match the EUA procedure; however, the instructions for use were meant to be possible actions and do not impact the performance The Laboratory Director affirmed characteristics of the assay. Based on CDC guidelines (February 12, 2021 at approximately 2:10 pm) and the letter from our corporate quality organization the laboratory failed to ensure centrifuge the minimum percent ethanol required for maintenance was performed and documented. decontamination is 60. Heat inactivation was included in the validation studies submitted to LFS at D5791 ANALYTIC SYSTEMS QUALITY ASSESSMENT D5791 29Mar2021 1:55pm PST on 24Oct2020. The storage of extracted CFR(s): 493.1289(a)(c) RNA at -84 - -76oC is a post-test process that does not impact the performance of the assay. The (a) The laboratory must establish and follow thermocycler parameters have been the same as written policies and procedures for an ongoing described in the IFU for all tests performed, despite a typographical error in CA-PCR-SOP-002 (corrected mechanism to monitor, assess, and when 26Jan2021). indicated, correct problems identified in the Delayed procedure approval: Please refer to the analytic systems specified in Analysis Timeline. This timeline reflects the §§493.1251 through493.1283. difficulty in coming to a scientific and clinical (c) The laboratory must document all analytic consensus on how low viral load systems assessment activities. (high Ct value - specifically > 37 - < 42) results should be interpreted. Please refer to the Analysis Timeline. This Standard is not met as evidenced by: Based on direct observation, interviews with • 28Oct2020 - 11Nov2020 - results were laboratory staff on December 8 and 9, 2020, reported as per the IFU (cutoff < 42 as positive) review of policies and procedures (P/P), quality • 11Nov2020 – 11Dec2020 – a lower Ct cutoff control (QC) and quality assurance (QA) records. (<37) was set for positive results based on Ct random review of patient test records covering value observed during validation, reflecting a the period from 11/22/2020 to 12/08/2020, for 60 change in interpretation from the IFU • 11Dec2020 - 25Jan2021 - high Ct values (> 37 out of 60 patient test records reviewed, it was -< 42) were interpreted as inconclusive determined that the laboratory failed to establish • 25Jan2021 - present were interpreted as and follow written policies and procedures for an presumptive positive - high Ct values (> 37 - < ongoing mechanism to monitor, assess, and 42) when indicated, correct problems identified in the

	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIES DELAN OF CORRECTION IDENTIFICATION NUM				PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page analytic systems spethrough 493.1254. Findings included: 1. Review of the laprocedures (Policy # Management Plan, Einclude an ongoing indocument quality issee. a. The laboratory famanuals for the Perk Nucleic Acid Detection (RT-were established, aviaboratory staff (See) b. The laboratory famanuals for Perkin Eincleic Acid Detection (RT-utilizing Chemagic 36 nucleic acids followed Analytik Jena Therm	boratory's policies and CA-QM-SOP-001, Quaffective 11/01/2020) fail nechanism to perform cues regarding the following the Real Time Polym PCR) in vitro diagnostic ailable, and followed by D5401). Tailed to ensure the proceding the procedin	led to or ving: edure irus erase o test / the edure erase o test eviral y on	D5791	Due to scientific discussion and disagreer final laboratory procedure was not appro laboratory directors until 08Dec2020. Ad versions were requested with delayed app the next week. Although the protocol in thave been approved prior to use, mitigaticircumstances to note include: - Data analysts were trained using the draprotocol, which remained available to the Changes in the interpretation of results handled in LIMC, not determined by dat An active discussion was held with CDPI directors to bring the interpretation to resee: o 01Dec2020 Email CDPH Approval of vo 08Dec2020_Email Final SOP Definition for Doc Control o 11Dec2020 Email Changes to Ct Report o 14Dec2020 Email Changes to Ct Report 16Dec2020 Em	ment, a ved by the ditional voroval over use should ng aft em were a a analysts - H solution. It ins for v1 ting ting (v2) o ng (v3.1) n Plan, e Lab of tOH. The m stated atch the is for use not impact iauy. Based ir ium ation is 60. idation on A at -84 -
	- (b)(14) (See D5403 c. The laboratory for procedure manuals of Coronavirus Nucleic. Polymerase Chain R diagnostic test utilizing isolation of the viral of RT-PCR assay on All were approved, signal Laboratory Director (d. The laboratory for adopted FDA EUA IF	ated Time tro e y the ycler, rrent		-76oC is a post-test process that does not performance of the assay. The thermocyc parameters have been the same as describ IFU for all tests performed, despite a type error in CA-PCR-SOP-002 (corrected 26 See Attachment 9 for additional information of the seed of the process of the proc	impact the ler bed in the organical fan2021). Sition D5403, se see D5401, found D5403, do not be see D5407, found D5403, f	

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laboratory's policies D5411). e. The laboratory reagents as required for the laboratory decontamination so RT-PCR have not expected for the laboratory verified, and docum specification chara approved SARS-Contamination for the laboratory established mainted centrifuges were presented for the laboratory of the laboratory established mainted centrifuges were presented for the laboratory of the laboratory o	d changes made in the and procedures (See failed to ensure it labeled (See D5415). If alled to ensure it monitority in the exceeded the expiration failed to ensure it established to ensure it established the performance exercistics for its modified by-2 RT-PCR (See D542) failed to ensure the	ored oV-2 date ished, FDA 23).	D5791	Finding 1e - 1f, 2-4: See Attachment 2 and D5415 and D5417: summary, expired reagents, such as the 70 were only expired by a few days. Since the concern of aging EtOH is evaporation and over 60% EtOH is effective, the risk posed Corrective actions are being taken. (1) Immediate Corrective Action: Please and D5417 (2) Patient Impact: Please see D5415 and (3) Preventative Action: Please see D5415. (4) Monitoring Mechanism: Please see D5417. Findings 1g, 2-4. See Attachment 13 and D5423: Summary: The laboratory is using this kit limits of the intended use. (1) Immediate Corrective Action: Please (2) Patient Impact: Please see D5423. (3) Preventative Action: Please see D5423. (4) Monitoring Mechanism: Please see D5 Findings 1h, 2-4: See Attachment 2 and D5433: Summary: In summary, issues with mainta are primarily good documentation practic properly completing logs when an instrun use. A corrective action plan is in place. (1) Immediate Corrective Action: Please (2) Patient Impact: Please see D5433. (3) Preventative Action: Please see D5433. (4) Monitoring Mechanism: Please see D5433.	% EtOH, main I CDC states is low. see D5415 D5417 5 and D5417 5415 and within the see D5423. 8. 5423. enance logs e and nent is not in see D5433.		

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D5791	3. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12. 4. The Laboratory In 12, 2021 at approximately 12, 2021 at approx	poratory's annual testing the laboratory director atory reported 00 SARS-CoV-2 test rese/16/2020. Director affirmed (Februately 2:10 pm) the naure there was an ong	on sults uary	D5791				
D5800	indicated, correct pro systems. POSTANALYTIC SYS			D5800			8Mar2021	
	must meet the applica	performs nonwaived te able postanalytic syster .1291 unless HHS app	ms					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(A1) PROVIDER/SUPPLIER/CLIA		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
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D5800	a procedure specified Operations Manual (Gequivalent quality test monitor and evaluate postanalytic systems problems as specified specialty and subspecialty an	d in Appendix C of the CMS Pub. 7) that provisiting. The laboratory may 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 citined that the condition is was not met as mand if of Title 42 of the Code curately and reliably pecific data from the potential of the control of th	des Just The Indiana I	D5800	(5801/5805/5807/5809/5821) In regard to the in question (D5801), we have verified that the samples were handled in accordance with the operating procedure (SOP) in place on Dece (CA-SOP-RPT-002). Based on the input fror laboratory directors', it was determined that IC dropout were better characterized as Invo. (19) and the negative samples with high Ct v better characterized as inconclusive (13). The classification was implemented via the onsite directors' discretion on December 11, 2020. During the results were manual reported and staff were CDPH lab directors until the LIMC changes implemented. On December 13, 2020, a LIM implemented into production to automated calculation thereby reducing any manual intended at 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 in the sum of the color patient report values for N and ORF1ab. The CT values have removed and are no longer present on the Color of December 16, 2020. A memorandum was provided to Color GenoptumServe for the samples mentioned. The receipt. Please refer to the Analysis Timeline. 280ct2020 – 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 a interpretation from the IFU 11Dec2020 – 25Jan2021 – high Ct value (25Jan2021 – present – high Ct values (were interpreted as presumptive positive results based on Ct observed during validation, reflecting a interpretation from the IFU 11Dec2020 – 25Jan2021 – high Ct value (25Jan2021 – present – high Ct values (were interpreted as presumptive positive results based on Ct observed during validation, reflecting a interpreted as presumptive positive values (were interpreted as presumptive positive results based on Ct observed during validation, reflecting a interpreted as presumptive positive positive results based on Ct observed during validatio	e e standard mber 10, 2020 in the CDPH results with lid results alues were is change in e CDPH lab with the SOP se two days, trained by the were C update was result code ervention by Detected was e (Not the green there as well. showed CT re been polor report omics and results and results are confirmed e. e reported as cutoff (<37) value in change in es (> 37 - < 42) we reports in iginal results. Laboratory is the status Leadership, the tation is to	

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA 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 (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) Continued From page 75 **D5800** Continued from page 75 D5800 a. Staff "superuser" training The laboratory failed to ensure it promptly b. Improvement to Janus Reformatter and Chemagic notified and issued corrected reports to the c. Evidence provided at on-site inspection as part of authorized person or individual using the test CAPA-20-002 Both the LIMC User Specification and the User results and maintained duplicates of the original Acceptance forms were signed by both Laboratory report (See D5821) Directors is provided. The effective date 29Oct2020 is the date the blank form (template) was effective. In summary, there is scientific and clinical debate 7. The laboratory failed to establish and follow regarding the best interpretation of high Ct values. All written policies and procedures for an ongoing 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 Director, who is mechanism to monitor, assess, and when indicated, correct problems identified in the directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions postanalytic systems (See D5891) regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the D5801 TEST REPORT 29Mar2021 Testing Taskforce CFR(s): 493.1291(a) The below details are for D5801, D5805, D5807, The laboratory must have an adequate manual or In regard to the 32 samples in question (D5801), we electronic system(s) in place to ensure test have verified that the samples were handled in results and other patient-specific data are accordance with the standard operating procedure accurately and reliably sent from the point of data (SOP) in place on December 10, 2020 (CA-SOP RPT-002). Based on the input from the CDPH entry (whether interfaced or entered manually) to laboratory directors', it was determined that results final report destination, in a timely manner. This with IC dropout were better characterized as Invalid includes the following: results (19) and the negative samples with high Ct values (37-42) were better characterized as (a)(1) Results reported from calculated data. inconclusive (13). This change in classification was (a)(2) Results and patient-specific data implemented verbally via the onsite CDPH lab electronically reported to network or interfaced directors' discretion on December 11, 2020 with the SOP approved on December 13, 2020. During these systems. two days, results were manual reported and staff were (a)(3) Manually transcribed or electronically trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a transmitted results and patient-specific LIMC update was implemented to automate result information reported directly or upon receipt from code calculation thereby reducing any manual intervention by the data analyst staff. It was observed outside referral laboratories, satellite or that the LIMC result of Not Detected was listed on the point-of-care testing locations. Color patient report as Negative (Not Detected). This This Standard is not met as evidenced by: has been changed so that in the green banner (Not Detected) has also been placed there as well. It was Based on direct observation, interviews with observed that the Color patient report showed CT values for N and ORF1ab. The CT values have been laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality removed and are no longer present on the Color report as of December 16, 2020. A memorandum was control (QC) and quality assurance (QA) records, provided to Color Genomics and OptumServe for the random review of patient test records covering 32 samples mentioned. They confirmed receipt. The the period from 12/04/2020 to 12/10/2020, for 32 original report and letter of correction for the 19 samples with a change in terminology was provided to out of 32 patient test records reviewed, it was Dr. Pan. determined that the laboratory failed to ensure

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES A. BUILDING COMPLETED AND PLAN OF CORRECTION 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 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY D5801 Continued From page 76 Continued from page 76 the electronic system(s) it used accurately and Please refer to the Analysis Timeline. reliably transmitted patient-specific data, from the • 28Oct2020 - 11Nov2020 - results were point of data entry to final report destination. reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 - 11Dec2020 - a lower Ct cutoff Findings included: (<37) was set for positive results based on Ct value observed during validation, reflecting a The laboratory subcontracts the preanalytic change in interpretation from the IFU and postanalytic phases of testing to an outside 11Dec2020 - 25Jan2021 - high Ct values (> 37 entity, COLOR. -< 42) were interpreted as inconclusive • 25Jan2021 - present were interpreted as The following 13 final patient test reports presumptive positive - high Ct values (> 37 - < emailed by the laboratory on 01/06/2021 were reported as "Negative" for SARS-CoV-2. The laboratory maintains duplicate original reports in addition to issuing amended reports with original a. The laboratory LIMC LIS report sent by the results. laboratory to the examiners via e-mail on 12/22/2020 showed a result of "Not Detected" for Test results are transmitted to from the LIMS API thorough the Color Platform to both CalREDIE and SARS-CoV-2. CalOES. CalREDIE transmits results to California county public health authorities and federal public b. The final test result generated by COLOR health authorities as required by law. showed a final result of "Negative" (1) Immediate Corrective Action: The specimens in question were resulted as per SOP. A look forward LIMIC from December 13, 2020 to December 31, 2020 NOT DETECTED **Final Test Report** Report verified that all samples were reported per SOP Not Detected Negative for SARS-CoV-2 versions 2 and 3.1. The CT values were removed from the Color patient report on December 16, 2020. Not Detected Negative for SARS-CoV-2 (2) Patient Impact: Based on the lookback from Not Detected Negative for SARS-CoV-2 October 28, 2020 to December 11, 2020, there were Not Detected Negative for SARS-CoV-2 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by Not Detected Negative for SARS-CoV-2 written approval from the CDPH lab directors. Results Not Detected Negative for SARS-CoV-2 were correctly reported as inconclusive pursuant to the lab SOP. However, the IFU v5 and the policies and Not Detected Negative for SARS-CoV-2 procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these Not Detected Negative for SARS-CoV-2 samples would now be considered Invalid. For this Not Detected Negative for SARS-CoV-2 reason a memorandum was provided to the public healthcare providers responsible for receiving results Not Detected Negative for SARS-CoV-2 explaining the change in interpretation to remain on Not Detected Negative for SARS-CoV-2 file in the event that these 19 patients contacted them to explain any questions regarding their results. Of Not Detected Negative for SARS-CoV-2 the 19 samples reported as invalid, 14 patients were retested (74%) per Color and all tested negative. Not Detected Negative for SARS-CoV-2

(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 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) 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 and review of the 32 patient test records obtained action (retesting). 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.

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING _ COMPLETED 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 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION 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) D5801 Continued From page 78 D5801 Reported as Inconclusive but should be reported as Invalid. 4. The laboratory failed to show the electronically transmitted results between its LIMC LIS, and the outside entity subcontracted by the laboratory, were periodically verified for accuracy. 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 2:10 pm) that the electronic system(s) used by the laboratory, accurately and reliably transmitted

(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 ID (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREEIX 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 29Mar2021 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

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D5805	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 to its clients. a. In an e-mail communication with the laboratory director on 01/12/2021, the examiners asked if corrected reports were issued for the affected patients. The laboratory director indicated that reports were not amended to provide the correct interpretation of results because COLOR did not have the current system				D5805			
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	3. 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.		r on					
D 5807	4. The Laboratory (01/12/2021 at approting through email comm failed to ensure its tecorrect interpretation TEST REPORT CFR(s): 493.1291(d)	eximately 1 unication the est results parts for SARS-	1:58 a.m.) nat the labor provided the	atory	D5807	See response started in D5801		29Mar2021
	Pertinent "reference as determined by the tests, must be availa who ordered the test individual responsible	e laboratory ble to the a s and, if ap	performing authorized pe pplicable, the	the erson				

(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 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5807 Continued From page 82 D5807 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 its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results. Findings included: 1. Based on review of patient test reports for SARS-CoV-2, the laboratory indicated under the test result and specific genes cycle threshold (Ct) value, "To learn more about the technical details of the test, please see the test methodology and limitation section." 2. Review of the test reports methodology and limitation section did not indicate how the laboratory determined its results (Positive, Negative, Inconclusive, and Invalid). The report also indicated its reference, "Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, 2019-nCOv-PCR AUS Instructions for Use (IFU)." Review of Perkin Elmer New Coronavirus Nucleic Acid Detection Kit FDA Approved EUA IFU for PE New Coronavirus Nucleic Acid (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) indicated only the interpretation for the following: a. Detected b. Not Detected c. Invalid

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D5807	Review of the update for analysis and report (last final version on following interpretation). a. Detected b. Not Detected c. Inconclusive d. Invalid 3. Random patient from 12/04/2020 to 1 tested and reported patient test results we ensure its accurate redetermined by the last results and reported of the state of	ed policies and procedularing of SARS-CoV-2 A 12/16/2020) indicated forms sampling covering the procedular court of 32 out of 32 SARS-Court of 32 out of 32 SARS-Court of the laboratory failed and out of 32 out of 32 SARS-Court of the laboratory were available on, or individual responsibility.	oeriod ory CoV-2 ed to e for sible	D5807			

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED A. BUILDING IDENTIFICATION NUMBER: 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 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** 29Mar2021 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

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50000	laboratory director reported on 12/10/	on 01/12/202	1, and revie	w of patients				
	a. Results were "Negative" but she "Inconclusive"							
	b. Results were "but should have							
	The laborato their clients regard of results. The lab subcontractor, fai because the curre of issuing correct.	ling change ir oratory's outs ed to issue co nt system it u	n the interpre side entity orrected rep	tation				
	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 it updated their clients regarding changed in the interpretation of results.							
	a. Below are ter "Negative", but the been "Inconclusive	e correct resu	were reporte ult should ha	ed as ve				
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	b. Below are te	et reculte that	were renorts	ac he					
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D5809	Continued From pag 4. Based on the lab 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 interpretation of relaboratory failed to is: TEST REPORT CFR(s): 493.1291(h) When the laboratory results within its estal laboratory must deter of the patient test(s) in the appropriate individuality. This Standard is not represent the patient design. This Standard is not represent the patient design.	e 87 coratory's annual testing the laboratory director atory reported to SARS-CoV-2 test rest/16/2020. Director affirmed a.m.) through email the laboratory failed to blients regarding change esults because the sue corrected reports. cannot report patient testing the part of the laboratory failed to blients regarding change esults because the sue corrected reports.	g on aults est e gency notify les ality	D5809	Finding 1-5: 1. The only client of the CDPH Branch Labothe State of California. The laboratory report of samples to the Testing Test Force, CDPH and Dr. Pan nightly (see VBL Updates). 2. Per the laboratory contract with the state, expectation is to meet the 48hr TAT in 95% (1) Immediate Corrective Action: The daily report is sent by the CDPH Branch Laborator manager to key stakeholders. A review of date emails shows that this summary was given the each day from 4Dec2020 – 10Dec2020. Due mission and scope of testing performed, our Task Force, Dr. Pan and the State of Californ not requested a list of individual barcodes exhours. (2) Patient Impact: Our TAT time for Nove December averaged 37.39 hours which is with 24-48 hour target with continued trend tower TAT. Per Lab Director Dr. Rosendorff, there change in diagnosis, treatment, or recomme patient action (retesting), and there would repatient harm. (3) Preventative Action: The routine daily oby the project manager allows the provider a stakeholders to monitor sample status. (4) Monitoring Mechanism: The daily sum generated each day and emailed by the project of the key stakeholders. This report is stored.	pratory is the status Leadership, the of cases. y status ory project willy update to the client to the relients, the min have exceeding 48 tember and thin the ards faster e is no ended not be the many is ect manager if by the	29Mar2021	
	Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002, Title Specimen Collection, Storage, and Shipping, Effective Date 12/07/2020) stated, "The turnaround time (TAT) for the results is within 24-				laboratory. Turnaround time is monitored as indicated in the Quality Management Plan (CA-QM-SOP-001). This process has been added to the Post-analytical QA Process (CA-RPT-SOP-004). See Attachment 14			

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	48 hours."						
	2. Based on email	communication with					
		or on 01/08/2021, that					
	the laboratory start of	counting for TAT when					
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	3. Random patient	sampling covering the	period				
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	tested and reported	5 out of 32 SARS-CoV	-2				- 1
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		d Received Reported	Result				
	Accession # Collected D-6195896854 12/04/202		Inconclusive				1
	D-6195255010 12/04/202		Inconchisive Inconchisive				- 1
	D-6199026441 12/04/202 D-6192530811 12/04/202		Inconclusive				
	D-4669414825 12/04/202	0 12/05/2020 12/10/2020	Inconclusive				
	4. Based on the la	aboratory's annual testi	ng				
	declaration signed b	by the laboratory directory	or on				
	12/16/2020, the lab	oratory reported					
-	approximately 430,0	000 SARS-CoV-2 test re	sults				
	from 11/02/2020 to 1	12/16/2020.					
	The Laboratory	Director affirmed					
	(February 12, 2021	at approximately 2:10	pm)				
	that the laboratory f	failed to ensure it					
		in reporting patient test					
	results.						
				D5821	See response started in D5801		29Mar2021
D5821	TEST REPORT			D3021			
	CFR(s): 493.1291(l	k)					
	OFN(3). 433. 128 ((TAIL TO SEE THE SECOND		
	Mhon orrors in the	reported patient test re	sults				
	are detected the la	aboratory must do the					
	following:	wordtory must do alo					
	Tollowing.						
		m.					

1. 1		, ,	1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
05D219			16	B. WING		02/17/29	021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE			
	CDPH BRANCH LABORATORY 284			VINGSTO				
0511151				IA, CA 91				
	0						(X5)	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	FATEMENT 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)	DBE	COMPLETION DATE	
D5821	Continued From pag	e 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 a Based on direct obse and procedures, qual assurance (QA) reconducted with the lallaboratory 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 failer. a. Notification and Is Reports	the authorized person if applicable, the indiv of reporting errors. If reports promptly to the dering the test and, if dual using the test resurates of the original report. The tas evidenced by: arvation, review of policity control (QC) and quids, and interviews	idual e lts. ort, as ies ies iality it is to test inal					
	laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, "Not detected" but should have been "Inconclusive," and "Inconclusive" but should have been true "Invalid. " The laboratory failed to ensure it notified and issued amended reports to the individual using the test results.							

					(V2) MI II TII	PLE CONSTRUCTION		
		' '				G	(X3) DATE SU COMPLET	
	## PH BRANCH LABORATORY ## SUMMARY STATEMENT OF DEFICIENCIES ## (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) ## D5821 Continued From page 90 ## 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 Corr				33 22.			
		16	B. WNG		02/1	7/2021		
NAME OF PR		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE				
CDPH BF		LIVINGSTO	N AVE					
		ICIA, CA 91	355					
(VA) ID	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID	PROVIDER'S PLAN OF CO	ODDECTION	(X5)		
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TAG	Continued From page 90			TAG	CROSS-REFERENCED TO THE		DATE	
						DEFICIENCY)		
D5821	, •			D5821				
	ii Random patient	samplinge	overing the r	nerind				
	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		s.		.*.			
			rpretation					
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			PATRICIA PROGRAMMA PROGRAM					
			£					
			lusive					
		Negative	Inconc	lusive				
		Negative	Inconc	lusive				
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		Negative	Inconc	lusive				
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STATEMENT	OF DEFICIENCIES	(X1) PROVIDE	ER/SUPPLIER/CL	.lA	(X2) MULTIP	LE CONSTRUCTION	(X3) DATE SU	IRVEY
	F CORRECTION	ORRECTION IDENTIFICATIONNUMBER: 05D2197416 DER OR SUPPLIER STREET ICH LABORATORY 284		A. BUILDING		COMPLE	TED	
			_					
	ME OF PROVIDER OR SUPPLIER STREE PH BRANCH LABORATORY 28 VA (4) ID SUMMARY STATEMENT OF DEFICIENCIES REFLX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATOR)	6	B. WING		02/1	7/2021		
NAME OF PR	DPH BRANCH LABORATORY 284 VAL (X4) ID SUMMARY STATEMENT OF DEFICIENCIES		STREET ADDI	RESS, CITY, STA	ATE, ZIP CODE			
CDPH BF	RANCH LABORATO	RY		28454 L	LIVINGSTON	I AVE		
				VALEN	CIA, CA 913	155		
(X4) ID	SUMMARY	STATEMENT OF	DEFICIENCIES		ID			(X5) COMPLETION
PREFIX	(EACH DEFICIENCY MU	JST BE PRECED	ED BY FULL REC	SULATORY	PREFIX			COMPLETION DATE
TAG	OR LSC I	DENTIFYING IN	-ORMATION)		TAG			
D5004	0	0.4			D5004			1
D5821	Continued From pa	ige 91			D5821			
	INICONICI INDIC	December 1	Comment lands	1				
	INCONCLUSIVE	Reported	Correct Interp					
	******	nconclusive nconclusive	Invali Invali					
	******	nconclusive	Invali					
	******	nconclusive	Inval	***************************************				
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	******	nconclusive	Invali					
	******	nconclusive	Invali					
	,	nconclusive	Invali					
		nconclusive	Invali	d				
	1			10				
	b. Maintain duplic	ates of the o	riginal report					
	i. Based on revie	w of nationts	tost roserds					
	i. Based on revie emailed by the labor							
	the laboratory throu							
	reports on 12/07/20							
	results on 12/04/20							
	original report.							
	ii. The following 10 out of 10SARS-CoV-2							
	patient test results v	were amende	ed:					
	*							

	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416				` '	LE CONSTRUCTION	(X3) DATE SUR COMPLETE	
41					B. WING		02/17	//2021
	ROVIDER OR SUPPLIER	RY			SS, CITY, STA	ITE, ZIP CODE		
				VALENC	IA, CA 913	55		
(X4) ID PREFIX TAG	(EACH DEFICIENCY ML	STATEMENT OF DEFICI ST BE PRECEDED BY F DENTIFYING INFORMAT	ULL REGULA	TORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE.	(X5) COMPLETION DATE
D5821	Continued From pa	ge 92			D5821			
	Accession #	Original Report	Amende	ed be				
	Accession #	12/04/2020	12/07/20	020				
		Detected	*				6	
		Detected	*					
		Detected	*					
		Not Detected	*	*******				
	Detected * Detected * Detected *							
	Leteded							
	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			rocess				

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/O			PLE CONSTRUCTION 3	(X3) DATE SUI COMPLET	
		16	B. WING _		02/1	7/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDRE	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Y	28454 LI	VINGSTO	N AVE		
			VALENC	IA, CA 91	355		
(X4) ID	SUMMARY ST	TATEMENT OF DEFICIENCIES	5	ID	PROVIDER'S PLAN OF CORRECTION	ON	(X5)
PREFIX TAG		T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	GULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROF DEFICIENCY)		COMPLETION DATE
	Continued From pag	e 93					
D5891	POSTANALYTIC SYS	STEWS QUALITY		D5891	Finding 1a		29Mar2021
	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.				The inconclusive rate for this assay in the inconclusive rate for this assay in the same and the same are same as a same are same as a same are same are same as a same are same a		
					monitored daily. Summaries are sen		
			itton		Testing Task Force daily. Currently,		
			itteri		inconclusive samples include only the internal control failures (invalid) or		
					that were unsatisfactory for testing.		
	CFR(s): 493.1299(a) 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. 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 control (QC) and quality assurance (QA) records,			current rate has been consistently			
				~0.5%. Several factors contribute to	this		
	indicated, correct problems identified in the postanalytic systems specified in §493.1291. This Standard is not met as evidenced by: 1. Based on direct observation, interviews wit laboratory staff on December 8, 9, and 16, 2020 review of policies and procedures (P/P), quality				including:		
					a. Staff "superuser" training b. Improvement to Janus Ref	ormatter	
			with			and Chemagic protocols	
					c. Evidence provided at on-site		
					inspection		
					as part of CAPA-20-002		
		ient test records coveri			(1) I 1: C A CADA		
		//2020 to 12/10/2020, f			(1) Immediate Corrective Action: CAPA-provided at on-site inspection provides the		
		records reviewed, it wa			corrective actions that were taken. Including		
	determined that the la	aboratory failed to ensu	ıre		the internal control from 5ul to 20ul per re-		
	there was a mechanis	sm to periodically verify	/		allowed by the EUA, updating instrument p		
		sults sent to interfaced			and providing additional training for staff.		
		specific data for SARS	-		increasing the internal control from 5ul to reaction, as allowed by the EUA, updating it		
	CoV-2.				protocols and providing additional training		
	Findings included:				(2) Patient Impact: Per Lab Director Dr. R there is no change in diagnosis, treatment,	osendorff,	
	a. Prior to the sche	duled on-site inspection	n,		recommended patient action (retesting).		
	Laboratory Field Serv	vices (LFS) sent an e-n	nail		(3) Preventative Action: Since the immedi	ate	
	communication on No	ovember 13, 2020, who	erein		corrective actions were effective process im no further preventative action is needed. IC		
	we informed the labor	atory that we will be loc	king		rate is included on the daily report to allow		
	into the report of incre	eased number of			for trends.		
		est results, published in			(4) Monitoring Mechanism: Recent versio		
		mber 10, 2020. Below	is the		RPT-SOP-002 (v4, v5, and v6) were made a approved in a timely manner. A daily report		
	excerpt of the e-mail	communication:			inconclusive and invalid samples is shared Testing Task Force, OptumServe, and CDI	with the	
	"Please refer to the following media report:				. The quality organization is responsible for review and signoff of future SOPs.		
	https://www.newswee	ek.com/spike-bad-test-	result				
		n-covid-19-testing-lab-co					
	es-amid-tighter-restric	_					

	OF DEFICIENCIES OF CORRECTION	3		R/SUPPLIER/C CATIONNUMBE			PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
				05D21974	16	B. WING		02/17	7/2021
	ROVIDER OR SUPP RANCH LABO		Y			SS, CITY, ST. VINGSTOI IA, CA 91	N AVE 355		(VE)
(X4) ID PREFIX TAG	(EACH DEFICIE	ENCY MUS				ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT' (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5891	LFS expects fi * Evaluation of during the affiliook-back. * How the lab correspondin * What is the * How the lab action. Is it the b. During the first purpose of the Emergent laboratory's and the Emergent laboratory's and the expected and negative services.	ull document of report fected to be identified a correction of is month of the first of the firs	mentation of the particular to the period. It is the problem of the protection	ests results Patient em and the corrective n-site insper aboratory personnel, a cumented on regarding e patient res for Use (IFU on of the d, Perkin Eli petection Ki of Patient ved a table with valid pos Result Interpr SARS-CoV-2 No SARS-CoV-2 De SARS-CoV-2 De Invalid result, needs to be re re-extraction of	etation et Detected estected	D5891	Finding 1b-m LIMC v1.0 was validated and accepted by the Director on 27Oct2020 (note that 28Aug20 the PerkinElmer form used to document the was effective). This validation included acculing the perkinElmer form used to document the was effective). This validation included acculing the control of the perkinElmer form used to document the was effective). This validation included acculing the control of the perkinElmer form used to document the was effective). This validation and LIMC Operational Quality updated LIMC version 1.2 was approved by Laboratory Director on 13Dec2020 and (not form, called CA-COMP-FM-003, is a form acceptance testing and was approved on 28 CDPH Branch Laboratory form). The data validation of "inconclusive" at C values bethe validation of	19 is the date e validation eptance of on fication. The of the ote that the used for user Oct2020 as a showing tween 37 and approval of signatures ecimens in forward from C k from here were that were in effect by ctors. Results tresuant to the icies and nalized in a cating these. For this he public ving results remain on facted them esults. Of the swere	
		1		from patient f	græst.		Additionally, per Lab Director Dr. Rosen- future change in definition would not be diagnosis, treatment, or recommended pa (retesting), and there would not be patien	a change in atient action	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE		1 '	PLE CONSTRUCTION G	(X3) DATE SUR COMPLETE	
		16	B. WING		02/17	7/2021	
	ROVIDER OR SUPPLIER	Υ		ESS, CITY, ST. IVINGSTON	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 CORRECTION (EACH CORRECTIVEACTION SHOUL) CROSS-REFERENCED TO THE APPROPRIATE OF THE APPRO	D BE	(X5) COMPLETION DATE
D5891	d. In order to composite calculating and interpretation asked the lat 2020, to provide the System (LIS) and its interpretation of paties. a. A policy and procest laboratory was not as 2020. b. Neither an unsigned available on December 1 2/08/2020, indicated that patient test result a result of incorrect dinterpretation. f. The following date conducted random sapatient test records with during the first week Equation of the patient test records. In the laboratory to send via records and its policy interpretation of paties. h. The policy and process of the process of the policy and	are how the laboratory of preting patient results, boratory on December LIMC Laboratory Inform policy and procedure for specimen results. Induction of the procedure of the specimen results. Induction of the procedure of the p	8, nation or	D5891	(3) Preventative Action: No revision to 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. Daily updates will continue to be to clients and key stakeholders including CCDPH Leadership, Dr. Erica Pan, Optum Color. (4) Monitoring Mechanism: Monthly at integrity are performed as stipulated in the schedule by the Quality organization. A 23 Tracer audit of 10 samples confirmed that matched the current SOP 100% of the time of an additional 25 samples will be performed in a matched the current SOP 100% of the time of an additional 25 samples will be performed beginning 11Mar2021.	rector, Dr. L. A daily e by the Out e distributed CHHS, berve and ditts for data e 2021 audit 8Feb2021 the results E. An audit	

	ENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER. N OF CORRECTION IDENTIFICATIONNUM!					PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED	
			05D21974	16	B. WING _		02/17/202	1
NAME OF P	ROVIDER OR	SUPPLIER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LA	BORATOR	Υ		VINGSTO			
(X4) ID PREFIX TAG	(EACH DE	FICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTIONS HOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE COM	(X5) IPLETION DATE
D5891	Continue	ed From pag	je 96		D5891 Finding 10-p			
	an effective date of December 13, 2020. (iii) The Software Name was identified as LII version 1.2 i. The Detailed User Requirements Specifications section of the document showed the following policy for interpretation of patient specimen results. User Requirement Description					In regard to the 32 samples in question (D58 verified that thesamples were handled in account the standard operating procedure (SOP) in p December 10, 2020 (CA-SOP-RPT-002). Bas input from the CDPH laboratory directors', idetermined that results with IC dropout were characterized as Invalid results (19) and the samples with high Ct valu better characterize inconclusive (13). This change in classification implemented via the onsite CDPH lab direct on December 11, 2020 with the SOP approve December 13, 2020. During these two days, I manual reported and staff were trained by the directors until the LIMC changes were imple December 13, 2020, a LIMC update was imploreduction to automated result code calculated.	ordance with lace on ed on the t was better negative d as on was ors' discretion d on esults were e CDPH lab mented. On emented into	
						reducing any manual intervention by the dat It was observed that the LIMC result of Not l	a analyst staff. Detected was	
			of Ct cylindf changed from 37 to 42 OX > 37 and <=42 will be called elected. Ox = 40 or > 40 will be release.			listed on the Color patient report as Negative Detected). This has been changed so that in the banner (Not Detected) has also been placed to lit was observed that the Color patient report values for N and ORF1ab. The CT values have removed and are no longer present on the Color December 16, 2020. A memorandum was provided to Color General Color Color General Color Service of the Samples mentioned. The receipt. Please refer to the Analysis Timeline.	he green here as well. showed CT e been olor report as omics and y confirmed	
			ent		28Oct2020 – 11Nov2020 – results were per the IFU (cutoff < 42 as positive) 11Nov2020 – 11Dec2020 – a lower Ct of was set for positive results based on Ct observed during validation, reflecting a interpretation from the IFU 11Dec2020 – 25Jan2021 – high Ct value 42) were interpreted as inconclusive 25Jan2021 – present – high Ct values (interpreted as presumptive positive) The laboratory maintains duplicate original	value (<37) value change in es (> 37 - < > 37 - < 42) //e reports in		
			red, r.		addition to issuing amended reports with or (5815) The only client of the CDPH Branch 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 expect meet the 48hr TAT in 95% of cases	Laboratory is s the status Leadership, the ation is to		
						(5891) The inconclusive rate for this assay is daily. Summaries are sent to the Testing Tas Currently, inconclusive samples include only internal control failures (invalid) or samples unsatisfactory for testing. The current rate h consistently ~0.5%. Several factors contribut including:	k Force daily. those with that were as been	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBE		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17	/2021
	ROVIDER OR SUPPLIER	Y	28454 L	RESS, CITY, ST. IVINGSTO! 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 CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE	(X5) 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 Not Deterported as Inconclusive reported as Inconclusive whreported as "Inconclusive" whreported as "Invalid"	s, the laboratory also fast LIS to include a result is LIS to include a result in the LIS can be attended as a contract of the LIS can be attended as a contract in the LIS can be contract in the LIS can be attended as a contract in the LIS can	orted on O20.		a. Staff "superuser" training b. Improvement to Janus Reformatter and Oprotocols c. Evidence provided at on-site inspection a CAPA-20-002 Both the LIMC User Specification and the U Acceptance forms were signed by both Labo Directors is provided. The effective date 29C date the blank form (template) was effective. In summary, there is scientific and clinical d regarding the best interpretation of high Ct reports issues did match the analysis rules in time of sample processing. To manage this e a full-time, on-site Laboratory Director, who involved in day-to-day laboratory operation reporting has been hired so that decisions re interpretation area now made in a timely ma consultation of CDPH Leadership, the Testic (1) Immediate Corrective Action: The st question were resulted as per SOP. A look f December 13, 2020 to December 31, 2020 v samples were reported per SOP versions 2 a (2) Patient Impact: Based on the lookbac October 28, 2020 to December 11, 2020, the samples with results of IC Dropout that wer consistent with the SOP that was in effect to approval from the CDPH lab directors. Results were correctly reported as inconclu- to the lab SOP. However, the IFU v5 and th procedures were communicated but not fin revised SOP until December 13, 2020 indica samples would now be considered Invalid. It reason a memorandum was provided to the healthcare providers responsible for receivi explaining the change in interpretation to r in the event that these 19 patients contacted explain any questions regarding their result samples reported as invalid, 14 patients wer (74%) per Color and all tested Additionally, per Lab Director Dr. Rosendor change in definition would not be a change i reatment, or recommended patient action (i and there would not be patient harm. (3) Preventative Action: No revision to SOF placed into use until the Lab Director, Dr. Re provided written approval. A daily checklist completed at shift change by the Data Analy, verified by the Sign Out Manager. Daily upd continue to be distributed to cli	s part of ser ratory ct2020 is the ebate values. All place at the volving field, o is directly s and result garding data unner, with ng Taskforce recimens in forward from erified that all and 3.1. k from ere were 8,756 re reported y written sive pursuant e policies and alized in a atting these For this public ng results emain on file I them to s. Of the 19 e retested ff, the future n diagnosis, retesting), or process is osendorff, has is being st staff and attes will stakeholders	

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/ AND PLAN OF CORRECTION IDENTIFICATIONNUMB				PLE CONSTRUCTION G	(X3) DATE SUR COMPLET			
		05D21974	16	B. WNG _		02/1	7/2021		
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	ADDRESS, CITY, STATE, ZIP CODE					
CDPH BR	RANCH LABORATOR	Y		4 LIVINGSTON AVE ENCIA, CA 91355					
							(VE)		
(X4) ID PREFIX TAG	TAG (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 APPROI DEFICIENCY)	DBE	(X5) COMPLETION DATE		
D5891	891 Continued From page 98			D5891	Continued from page 98	1			
D5891	o. Based on the lal declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 p. The Laboratory (February 12, 2021 at the laboratory failed to periodically verify control to interfaced systems of the laboratory failed to periodically verify control to interfaced systems of the laboratory failed to periodically verify control to interfaced systems of the laboratory failed to periodically verify control 12/08/2021/16/2020 and emai 12/22/2020, 12/24/2001/12/2021, review of quality control (QC) a records, it was determined to the laboratory of the laborator	boratory's annual testing the laboratory director ratory reported to SARS-CoV-2 test results approximately 2:10 properties of ensure was a mechal calculated results, resultems, and patient spectors. ew with the laboratory to 12/09/2020 and communication on 20, 01/06/2021 and policies and proceduring quality assurance (on ined that the laboratory).	sults m) that nism lts cific es, QA)		Continued from page 98 (4) Monitoring Mechanism: As a follow-up inspection process, a post inspection audit, cethe quality staff, is added to the FY2021 Audit a time to be determined by Lab Director (3 at months post inspection). All identified findic corresponding corrective, preventative and nactivities are evaluated to determine if findin resolved and/or are being monitored effectivitiems determined to be out of compliance with QER, and if needed, CAPA process(es). A tracer studies will confirm that electronic traresults is accurate.	onducted by it Schedule at nd/or 6 ngs with nonitoring gs have been ely. Any ll move into Monthly			
	failed to establish and procedures for an one	d follow written policies	and						

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PRÉFIX PREFIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY D589 Finding 2 D5891 Continued From page 99 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 patient-specific data from the point of data entry to fi revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 report destination (See D5801). ver. 2.0 approved by Lab Director and effective 01Mar2021 The laboratory failed to ensure its test result (1) Immediate Corrective Action: Please see D5411, provided the correct interpretation for SARS-CoV-2 (See D5805). (2) Patient Impact: Please see D5411, D5800 d. The laboratory failed to ensure its accurate (3) Preventative Action: Please see D5411, D5800 reference intervals determined by the laboratory (4) Monitoring Mechanism: Please see D5411, based on LOD were available for the authorized D5800 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) 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).

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	from 12/04/2020 to 1 32 out of 32 results r laboratory tested and results, but failed to	ampling covering the period of	t for 2 going				

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declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 j. The Laboratory 12, 2021 at approxim laboratory failed to mindicated, correct propostanalytic systems D6076 LABORATORY DIRECTR(s): 493.1441 The laboratory must the qualification requith is subpart and provious and direction in account this subpart. This Condition is not on the severity of the was determined that Performing High Condition Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met. Findings included: 1. The Laboratory Director was not met.	poratory's annual testing the laboratory director attory reported 20 SARS-CoV-2 test research 216/2020. Director affirmed (Februardly 2:10 pm) that the conditor, assess, and whoblems identified in the estate of \$493.1443 and a sevidenced by: deficiencies cited here the condition Laborator applexity Testing, Laborator failed to demonstration of the postanalytic pratory failed to provide any; delegated to quality ary; delegated to quality sponsibilities which caranical supervisor, generolatory failed super	eets of een Based ein, it ries atory trate ic e or by fied n be ral	D5891	To manage the laboratory effectively, a fusite Laboratory Director, has been hired directly involved in day-to-day laborator and result reporting. The Laboratory Dir 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 contin happen only onsite at the CDPH B Laboratory • (6083) Ensure environmental condare established at the CDPH Branc laboratory are appropriate for testive (6084) Ensure testing personnel cobe safe from physical, chemical and hazards • (6093) Ensure quality control progare established continue to be main to identify failures in quality as the (6094) Ensure quality assurance achave been established continue to maintained and to identify failures as they occur • (6101) Ensure the laboratory continue the adequate number of person appropriate training to perform testically in the performance of the demonstrate competency prior (6102) Ensure the laboratory staff to demonstrate competency prior (6102) Ensure the laboratory prior (6102) Ensure the laboratory prior (6102) Ensure the laboratory prior (6103) Ensure the laboratory prior (6104) Ensure the laboratory staff (6105) Ensure the laboratory prior (6106) Ensure the laboratory prior (6107) Ensure the laboratory prior (6108) Ensure the l	who is y operations ector is an y. The e below 6 and its ues to ranch litions that h ng ntinue to d biological crams that ntained and coccur tivities that be in quality nues to onnel with sting continues	8Mar2021

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D6076	analysis and reportin taking place at a local known physical locat State and CLIA applicated appropriate for the testing personnel we chemical and biological appropriate for the testing personnel we chemical and biological and biological appropriate for the testing personnel we chemical and biological and biological appropriate for the testing personnel we chemical and biological and biological and biological appropriate for the Laboratory quality control program anintained to assure provided, and to identioccur (See D6093). 5. The Laboratory quality assurance act maintained by the labor services provided, quality as they occur for the Laboratory Diadequate number of complexity testing with supervision according. 7. The Laboratory Diadequate number of complexity staff demorporting patient test LABORATORY DIRECER(s): 493.1445(e).	g of patient test results ation outside of the lister ion of the laboratory in cations (See D6082). rector failed to ensure the cations of the laboratory asting performed (See Director failed to ensure the safe from physical, cal hazards (See D6084). Director failed to ensure the quality of services the quality of services the quality of services the quality as and to identify failures (See D6094). Prector failed to ensure the quant to identify failures (See D6094). Prector failed to ensure the quant to identify failures (See D6094). Prector failed to ensure the quant to identify failures (See D6094). Prector failed to ensure the prector failed to ensure the prector failed to ensure the presults (See D6102). ECTOR RESPONSIBIL (1)	ed and its that tare 06083). e that 4). re and they it utilized or high to provide or the prior to JITIES	D6076	Continued from page 102 (1) Immediate Corrective Action: As the n delegated Lab Director (27JAN2021), all do and processes for sample workflow (preanal analytical, and postanalytical as well as the system essentials that support them are und to determine if they are in compliance with requirements and reflect actual lab practice. Quality Management Plan underwent a maj reorganization following initial review; now deliberate review of the policies and proceds support that plan are being carefully review, that there are 243 documents, this process is To date, 153 documents (63%) have been re Media Lab, with 40 documents revised/approperture (2) Patient Impact: Based on the deficiencia under D6076 we believe that the impact to phad the potential to be significant. In particular, 4,6,5,7 could have negatively impacted the invalid/cancelled specimens, and potentially turnaround times, thereby causing a delay in identification of patients at risk of COVID at reatment. However, our TAT time for Nov December averaged 37.39 hours which is widentification of patients at risk of COVID at reatment. However, our TAT time for Nov December averaged 37.39 hours which is widentification of patients at risk of covidence and the search of laborator generated 28Oct2020 - 31Dec2020 and a prinspection lookback at results generated 01J 28Feb2021, QC values were within acceptable (see attached report (therefore we do not be these deficient practices impacted the accumpatient testing or a delay in timely treatmen (3) Preventative Action: Dr Rosendorff, Lato continue to review and approve documer understand processes in place and revise as necessary to ensure that regulatory guidelinfollowed, that quality assurance activities armeasurable and timely and the corrective acdocumented, resolved in timely manner and continue to monitor existing quality indicates.	recuments lytical, quality ler review regulatory The or a a ures that ed. Given s ongoing. viewed in roved. es listed batient care alar items e volumes of v impacted and timely ember and thin the lards faster ler ranges lieve that lacy of t. b Director, ats and he deems es are e ettions are d effective. Review/ ality Metric.	021

(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 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

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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				1. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. 2. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. a. This infrastructure configuration eliminates the ability for individuals to access the site and file repository from an external location on a general								
	Analysis)				internet connection. b. Data is never transferred to the location of the remote (offsite) person.								
	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 VALLL015 b. RR VALLL014 c. AE VALLL020 d. SM VALLL013				3. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer issued set of credentials on a PerkinElmer issued laptop. During any remote session the data and system being accessed are located on the prior mentioned internal IT systems hardware. 4. The two data analysts who performed remote analysis were trained and qualified to do so: a. EV – Trained in data analysis and delegated the responsibilities of a General Supervisor b. MN – CLS trained in data analysis 5. CMS has made an exception to allow pathologist and other healthcare professionals to work remotely during the pandemic. CAP concurred with this exception. See Attachment 10. (1) Immediate Corrective Action:								
					 SignOut Manager was instructed by Director, Helen Farzanmehr, on 10D that analysts may not analyze data re 	ec2020							
					Human Resources informed potential qualified candidates and those awaiting onboarding/orientation that remote analysis was no longer a possibility; employment contingent upon on site analysis. (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.								

(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 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (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) D6082 Continued From page 105 D6082 (3) Preventative Action: A request to remove VPN access software from analyst computers was placed with e FJ VALLL017 the IT group by the project manager on 11Mar2020 and f. MW VALLL021 completed on 13Mar2020 by the IT group. g. YZ VALLL002 (4) Monitoring Mechanism: A request to query for h. WT VALLL033 remote release of records made on 26Feb2021 could not i. MN VALLL023 be completed due to complexity. Removal of VPN access removes the need to monitor. 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

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find 1 a find 1 a a C find a temperature of the property of th	The total number of refrom 12/07/2020 to 12 g. The total number from 11/22/2020 to 11 n. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 n. The Laboratory Direction. It is personnel at analysis personnel are failed to provide documents assessment, and concelephone, as necessive apportioned to tech supervisor, and clinical analysis and remote refrom 12/07/2020 to 12	esults reported by MN 2/08/2020 was 1,974. r of results reported by /30/2020 was 13, 291. coratory's annual testing the laboratory director ratory reported 0 SARS-CoV-2 test res	g r on sults 20 at 12:15 two data ne SARS- coratory competency or by salified n be ral ne time data t results	D6082				

	EMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
		05D21974	16	B. WING		02/1	17/2021		
	RÖVIDER ÖR SUPPLIER RANCH LABORATOR	Υ	28454 L	DDRESS, CITY, STATE, ZIP CODE 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	(EACH CORRECTIVE ACTION SHOUL	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)			
D6083	CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. 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, interviews conducted with the laboratory staff on 12/08/2020 and 12/09/2020, review of 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 Director failed to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was minimized. Findings included: 1. The laboratory failed to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptore Reluments, materials, and supplies for the laboratory's COVID-19 Reverse			D6083	D6083 Finding 1: Reference D3003 for our the finding. (1) Immediate Corrective Action: See D3003 (2) Patient Impact: See D3003 (3) Preventative Measure: See D3003. Add Laboratory Director has instituted the below • Weekly quality meetings that include QERs and CAPAs • Meet with TS/GS on any type of sche • Request review (documented by sign what? He doesn't have to review QC but he is. What else does he want to as an active presence in the lab. • How is Adam coordinating his proce document review process. Should the coordinated plan wherein all docume reviewed in a timely cycle by category of employees (Director, Quality, supe Personnel documents reviethe QMP in Feb • Equipment documents reviethe QMP in April • Safety documents reviewed QMP in July • Technical documents reviet the QMP in September • Quality documents reviewed QMP in Nov (4) Monitoring Mechanism: See D3003	itionally, the witems. es a review of dule? ature) of monthly, review/sign dure/ his be a ents are by by a team ervisors): ewed against dewed against the wed against the wed against	29Mar2021		
D6084				D6084 Finding 1: Reference D3011 for our response to the finding. (1) Immediate Corrective Action: See D3011 (2) Patient Impact: See D3011 (3) Preventative Measure: See D3011 (4) Monitoring Mechanism: See D30113			29Mar2021		

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBE		JUN		G	(X3) DATE SURVEY COMPLETED		
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	ROVIDER OR SUPPLIER RANCH LABORATOR	Υ	28454	STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE VALENCIA, CA 91355				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	CTION (X5) ULD BE COMPLETION ROPRIATE DATE			
D6084	biological hazards. This Standard is not Based on interview of December 8, 2020, reprocedures (P/P) for Plan, and review of the period from 11/22/20 of 60 patient test recedetermined that the lensure safety procedemployees from physicand biohazardous methodical standard in the lensure safety procedemployees from physicand biohazardous methodical standard in the lensure safety procedures to ensure chemical, biochemical materials (See D301 LABORATORY DIRECFR(s): 493.1445(e) The laboratory direct quality control programaintained to assure services provided an as they occur. This Standard is not Based on direct obsection of the laboratory of the 12/08/2020 and 12/0 records covering the 12/08/2020, for 60 or reviewed, it was deto Director failed to ensure established and laboratory to assure in the safety of the same services provided and laboratory to assure safety or safety in the safety of the safet	met as evidenced by: with laboratory staff on eview of policies and General Facilities Safe est records covering th 120 to 12/08/2020, for 6 ords reviewed, it was Laboratory Director faild dures were in place to p sical, chemical, biocher aterials. ailed to observe safety protection from physic al, and biohazardous 1). ECTORRESPONSIBILI (5) for must ensure that the times are established an ethe quality of laborato d to identify failures in met as evidenced by: ervation, interviews aboratory staff on 19/2020, and review of to period from 11/22/202 ut of 60 patient test rec- ermined that the Laborator ure quality control activi	ee 60 out ed to protect mical, al, TIES ed dry quality test 0 to ords atory vities	D6084	Finding 1-8: See Attachment 9 and ID D5411 In summary, there is scientific and clini regarding the best interpretation of high reports issues did match the analysis ru the time of sample processing. To mana evolving field, a full-time, on-site Labor Director, who is directly involved in dalaboratory operations and result report hired so that decisions regarding data in area now made in a timely manner, with of CDPH Leadership, the Testing Taskf professionals as appropriate. See full responses in D5415, D5417, D5	h Ct values. All les in place at age this ratory y-to-day ing has been nterpretation h consultation force and other		

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			A. BUILDING		(X3) DATE SURVEY COMPLETED				
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D6093	Continued From page	ge 112		D6093	(1) Immediate Corrective Action: Pleas D5415, D5417, D5423, D5433.	se see D5411,			
	Findings included:				(2) Patient Impact: Please see D5411, D5423, D5433.	5415, D5417,			
	 The laboratory failed to ensure procedure manuals were established, available to, and followed by laboratory personnel (See D5401). The laboratory failed to ensure the procedure manuals met the requirements specified in 42 CFR 493. 1251 (b)(1)-(b)(14) (See D5403). 				(3) Preventative Action: Please see D54 D5417, D5423, D5433 (4) Monitoring Mechanism: Please see D5417, D5423, D5433				
	manuals were updat	failed to ensure procedo ted, approved, signed a Laboratory Director (S	and						
ē	adopted FDA EUA I	failed to ensure it follow FU, the subsequent rev nges made in the labor ures (See D5411).	visions						
	5. The laboratory flabeled as required	ailed to ensure reagent (See D5415).	s were						
В			oV-2						
	and verified perform reporting patient tes	ailed to ensure it establi ance specifications pri t results using its modit 3-CoV-2 RT-PCR (See	or to						
D6094	established mainten centrifuges were per	failed to the ensure the ance protocol for formed and document		D6094			8Mar2021		
D6094		ECTOR RESPONSIBII	LITIES	20004					

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING 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 DATE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) 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, 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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION	
A. BUILDING	

(X3) DATE SURVEY COMPLETED

05/02/1974/16

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 PRETIX 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 SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

(X5) COMPLETION

29MAR2021

D6101 Continued From page 114 CFR(s): 493.1445(e)(11)

> The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation. properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This Standard is not met as evidenced by: Based on direct observation, interviews conducted with the laboratory staff on 12/08/2020, 12/09/2020, and 12/16/2020, and review of 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 Director failed to ensure there was an adequate number of supervisors for high complexity testing, with appropriate education, training and experience in order to provide accurate and reliable test performance and reporting.

Findings included:

- 1. Analytic Testing Supervision
- Based on interview with the laboratory staff designated as Perkin Elmer Genomics GM Global Laboratory Operations who was providing supervision to the analytic testing laboratory staff, and observation of laboratory personnel on 12/16/2020, lack of training documents, lack of written delegation of duties, it was determined that there was inadequate supervision of the analytic phase of testing.
- b. Review of CMS 209, signed and dated by the Laboratory Director on 10/15/2020, did not

D6101 Finding 1-5

1. Supervisory staff onsite on 12Dec2020 included:



Note – the hiring process for much these staff were not complete at the time CMS 209 was submitted on 15Oct2020.

- 2. PerkinElmer is contracted by the state to provide testing services. The CDPH Branch Laboratory has extensive support from the wider PerkinElmer team (see org chart). There was no request for updated CMS209 to be submitted prior to the inspection; staff were being onboarded every week in anticipation of the testing demands. The Supervisory staff onsite on 16Dec2020 had not started working at the lab at the time of submission of initial application. It was the expectation, and responsibility, to provide this to the inspection team at time of inspection.
- The PerkinElmer Genomics GM Global Laboratory Operations, who is an experienced ACSPcertified molecular geneticist, does function in an advisory capacity for the laboratory (as he did on 16Dec2020); HOWEVER, he is not a laboratory supervisor and does not perform this function for the clinical laboratory staff. The GM Global Lab Ops may provide oversight and instruction for R&D / development work being done in the laboratory that is separate from clinical activities.
- The Principal Scientist Molecular and Special Diagnostic team member is not a supervisor. As part of the PerkinElmer team, this individual deployed to CDPH Branch Laboratory, submitted credentials, and completed training. She has functioned as a technologist in the analysis area. Technologists may participate in training of staff and sharing knowledge pertaining to the work being performed.
- (1) Immediate Corrective Action: An updated CMS209 with staff current as 04Dec2020 was provided to the inspection team on the first day of inspection 08Dec2020. It included all staff (general and technical supervisors, clinical consultants, and technologists) that had been hired since the initial submission date.

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB			PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED		
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			VALEN	CIA, CA 91:	355			
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D6101	Continued From pag	e 115		D6101				
	indicate the name of the interviewed general				Continued from page 115			
		providing supervision t			(2) Patient Impact: The lookback shows	c adaguata		
		atory staff on 12/16/202			supervision at the time of the inspection			
					look forward the CDPH Branch Laborat			
	2. Data Analysis Su	pervision			added more supervisors and managers t			
					testing process. Per Lab Director Dr. Ro			
		observation and intervi			there is no change in diagnosis, treatme recommended patient action (retesting),			
		aff designated as Princ			would not be patient harm.	and there		
		nd Special Diagnostics			•			
		providing supervision t			(3) Preventative Action: An Inspection V			
		cientist performing data	a		Instruction has been drafted for the CDPH Laboratory to ensure that laboratory person			
	analysis on 12/08/202		an it		understand their role in managing an effici			
		ritten delegation of dutie there was inadequate	35, IL		appropriate inspection process. This proce			
		tory personnel perform	ina		a pre-meeting, assigned roles for the day in			
	data analysis.	tory personner personn	ing		and debrief following the inspection. This			
	data arraiyoso.				was followed for the LFS on-site visit 11Mar2021 with improved outcome. As part of this process, laboratory			
	b. Review of CMS 2	209, signed and dated b	ov the		personnel are reminded to state their role i			
		n 10/15/2020, did not	,		laboratory when introduced to laboratory			
		the general supervisor		list of current personnel including Laboratory				
	interviewed providing	supervision to the dat	a	Director, Technical Supervisor, General Supervisor, as well as Mentors has been created to assist in the				
	analysis personnel.				inspection process (CA-PER-GUIDE-001)	. Initiated		
	D = = 1 == 5=4 == 1				the Roster feature of the MediaLab softwar			
		ew with the Laboratory			all personnel with their designated CLIA routilized as part of the onboarding and sepa			
		20, the Principal Scient al Diagnostics Supervis			processes, allowing rapid availability of a co			
	interviewed on 12/08/		,01		CMS209 at all times.			
		ause the person was o	nlv					
	requested to help dur		,		(4) Monitoring Mechanism: All monthly s			
		general supervisors list	ed		(FY 2021 Audit Schedule) end to end trace and wet lab walkthrough audits, conducted			
		so not available onsite.			staff, include a review of MediaLab person			
					documentation related to qualifications, tra	aining and		
	3. Random patient sampling covering the period				competency for employees involved in spec			
	from 11/22/2020 to 12/08/2020, showed the				handling, testing (reagents and equipment) reporting of samples selected for audit.	, and result		
	laboratory tested and reported 60 out of60				reporting of sumples selected for addit.			
	SARS-CoV-2 patient test results, when there was							
		on of laboratory person	inel					
	performing data analy	/sis.						
	Accession Number							

			AT) FROVIDER/SOFF LIENGLIA		PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED			
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			VALENC	ENCIA, CA 91355					
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D6101	Continued From page 116			D6101					
					· ·				
					6				
					8				
						1			
	4. Based on the lab	oratory's annual testing	9						
	declaration signed by	the laboratory director							
	12/16/2020, the labor	atory reported							
		0 SARS-CoV-2 test res	ults						
	from 11/02/2020 to 12	/16/2020.							
	5. The Laboratory D	liractor offirmed							
		.m.) the laboratory fails	ed to						
		uate number of laborat							
	personnel	passo mannoon on moonat	5						

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA ANDPLAN OF CORRECTION IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
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NAME OF PF	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE		
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			VALENC	CIA, CA 91	355		
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D6101	Continued From pag	je 117		D6101	Finding 1		
	for high complexity testing with appropriate training to provide supervision accordingly.				Findings a-f		
D6102	LABORATORY DIRE CFR(s): 493.1445(e)(DRATORY DIRECTOR RESPONSIBILITIES			There is scientific and clinical debate regarding the best interpretation of high Ct values. Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a timely manner. Although not approved, a consistent method of		29Mar2021
	The laboratory director must ensure that prior to testing patients' specimens, all personnel have				interpretation was used (see Analysis Timeli All reports issues did match the analysis rule	ne below). es in place	
		ation and experience, ate training for the type	and		at the time of sample processing. To manage evolving field, a full-time, on-site Laboratory		
		vices offered, and have			who is directly involved in day-to-day labora	atory	
		ey can perform all testi			operations and result reporting has been hird decisions regarding data interpretation area	now made	
		provide and report acc	curate		in a timely manner, with consultation of CD Leadership, the Testing Taskforce and other	PH	
	results. This Standard is not r	mot as ovidenced by:			professionals as appropriate.		
	Based on direct obse				Please refer to the Analysis Timeline. A single analysis policy was in place on 08Dec2020.	le data	
	conducted with the la				• 28Oct2020 – 11Nov2020 – results were 1	reported as	
	12/08/2020, 12/09/20)20 and 12/16/2020, ar			per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cu	stoff (<37)	
		s covering the period from			was set for positive results based on Ct v	alue	
		2020, for 60 out of 60 pa d, it was determined tha			observed during validation, reflecting a contemperation from the IFU	change in	
		ailed to ensure all labor			• 11Dec2020 – 25Jan2021 – high Ct values	s (> 37 -<	
	staff received approp		,		42) were interpreted as inconclusive25Jan2021 – present were interpreted as		
	reporting patient test	results.			presumptive positive – high Ct values (>		
	Findings included:				(1) Immediate Corrective Action: The spin question were resulted as per SOP (see D		
	Data Analysis Pe	erformed at CDPH			(2) Patient Impact: See D5800.		
	Branch Lab	monned at CDFH			(3) Preventive Action: No revision to SOI process is placed into use until the Lab Dire Rosendorff, has provided written approval.	ctor, Dr.	
		observation and intervi	ew		shift to shift communication checklist (CA-		
	with the Clinical Laboratory Scientist (CLS)				FM-001, approved by Lab Director on 09Ms the data analysis team includes a written con		
	performing data analysis on 12/08/2020, it was determined that the CLS was not updated on the				of the most recent updated version of the ar	ialysis and	
	laboratory's current data analysis policies and				reporting SOP (CA-RPT-SOP-002).	1:4 - C	
	procedures.				(4) Monitoring Mechanism: Monthly au data integrity are performed as stipulated in		
					audit schedule by the Quality organization.		
		s and procedures for d	lata		audits initiated on 26Feb2021 (10 samples) and		
	analysis, it was determined an 12/09/2	mined at the time of 2020, the laboratory has			11Mar2021(25 samples) confirmed that represults matched the current SOP 100% of the		
		iting data analysis polici			See Attachment 0 and Attachment 10	e time.	

See Attachment 9 and Attachment 10

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
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D6102	and procedures. c. The following are the 60 randomly revie covering the period from 12/08/2020, wherein reported 60 out of 60 results, but failed to 6	e the accession number ewed patient test recon	nd test aff	D6102					

(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 SLIMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACHCORRECTIVE ACTION SHOULD BE DATE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6102 Continued From page 119 D6102 D6102 - Finding 2 1. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. 2. Data Analysis Performed Outside 2. Both of these are hosted within the PerkinElmer CDPH Branch Lab (Remote Reporting) network and are secured behind a firewall. a. This infrastructure configuration eliminates the a. Based on review of test records, it was ability for individuals to access the site and file determined that the two laboratory staff who repository from an external location on a general performed data analysis from the location outside internet connection. the CDPH Branch Lab did not have training b. Data is never transferred to the location of the remote documentation on how to handle remote (offsite) person. reporting, direction and consultation electronically 3. The only method to access the systems remotely is or by telephone when the Laboratory Director and through a secured VPN tunnel using a PerkinElmer delegated personnel were not with them during issued set of credentials on a PerkinElmer issued laptop. remote data analysis. During any remote session the data and system being accessed are located on the prior mentioned internal IT b. Review of policies and procedures (Policy # systems hardware. 4. The two data analysts who performed remote analysis CA-PER-SOP-002, Title Competency were trained and qualified to do so: Assessment) failed to include training for remote reporting. a. EV - Trained in data analysis and delegated the responsibilities of a General Supervisor b. MN – CLS trained in data analysis 5. CMS has made c. Random review of test records covering the an exception to allow pathologist and other healthcare period from 11/22/2020 to 12/08/2020, the professionals to work remotely during the pandemic. laboratory tested and reported 60 out of 60 CAP concurred with this exception. SARS-CoV-2 patient test results, showed two The data analysts are trained based on the current laboratory personnel to perform data analysis version of CA-RPT-SOP-002 (v6, effective date M/D/Y) outside the location of CDPH Branch laboratory in Valencia without documented training for remote See Attachment 10. reporting. d. Below are 30 representative examples each for EV and MN, wherein data were remotely analyzed, and patient test results were released remotely

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		1	(X2) MULTIPLE CONSTRUCTION A, BUILDING		(X3) DATE SURVEY COMPLETED					
		05D219	7416	B. WING		02/1	7/2021					
NAME OF PR	OVIDER OR SUPPLIER		STREET ADI	DRESS, CITY, ST	ATE, ZIP CODE	*						
CDPH BR	ANCH LABORATOR	Υ		LIVINGSTON								
			VALE	NCIA, CA 913	355							
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC T BE PRECEDED BY FULL ENTIFYING INFORMATION	REGULATORY	ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOU	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)						
D6102	Continued From page	ge 120		D6102								
	Data Analyzed by E	V:			Continued from page 121							
	Accession Number				(1) Immediate Corrective Action:							
					(1) Immediate Corrective Action.							
			88.255.136		SignOut Manager was instructed by							
	11/22/2020 165.88.255.136 11/22/2020 165.88.255.136				Director, Helen Farzanmehr, on 10Dec2020 that analysts may not analyze data remotely.							
					that analysis may not analyze data i	chiotory.						
			88.176.91		Human Resources informed potent							
			88.176.91		candidates and those awaiting onbo orientation that remote analysis wa	oarding/						
			88.176.91 88.176.91		a possibility; employment contingent upon on							
			88.192.131		site analysis.							
		···············	88.192.131		one analysis.							
			38.192.131		(2) Patient Impact: Per Lab Director Dr.	Rosendorff,						
			38 192 131		there is no change in diagnosis, treatment							
			88.176,64		recommended patient action (retesting), and there would not be patient harm.							
	•		88.176. 6 4		(3) Preventative Action: A request to remove VPN							
			88.176.64									
		11/25/2020 165	88.176.64		access software from analyst computers w							
			88.176.64		with the IT group by the project manager 11Mar2020 and completed on 13Mar2020							
			88.176.64		group.	by the 11						
			88.176.64									
			88.176.64		(4) Monitoring Mechanism: Query perfo 26Feb2021 demonstrated no remote relea-							
			38.254.202		Removal of VPN access removes the need							
			88.254.202									
			38.254.202									
			38.254.202 DB 254.202									
			38.254.202 38.254.202									
			88.254.202									
		***************************************	38.254.202									
		······································	88.254.202									
			88.254.202									
							9					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION			(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		050	05D2197416		B. WING		02/1	17/2021	
NAME OF PR	OVIDER OR SUPPLIER			STREET ADD	RESS, CITY, ST.	ATE, ZIP CODE			
CDPH BR	ANCH LABORATOR	RY			I LIVINGSTON AVE INCIA, CA 91355				
(X4) ID	SUMMARY S	STATEMENT OF DEFI	CIENCIES	3	ID	PROVIDER'S PLAN OF COR	RECTION	(X5)	
PREFIX TAG	(EACH DEFICIENCY MUS		FULL RE		PREFIX TAG	(EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	COMPLETION DATE	
D6102	Continued From page	Market and the second s			D6102				
	Data Analyzed by MN:								
	Accession Number	Date Reported	IP.	Address					
		12/07/2020	165.8	88.254.222					
	<u></u>	12/07/2020	165.8	38.254.222					
		12/07/2020	165.8	38.254.222					
	1	12/07/2020	······	38.254.222					
		12/07/2020	······	38.254.222					
	<u> </u>	12/07/2020		38.254.222		15			
	<u> </u>	12/07/2020	165.8	8.254.222					
	<u></u>	12/07/2020	165.8	88.254.222					
			165.8	路.254.222					
			38.254.222						
	<u>,</u>	12/07/2020	165.8	38.254.222					
	1	12/07/2020	165.8	38.254.222					
	<u></u>	12/07/2020		38.254.222					
	<u></u>	12/07/2020		88.254.222					
		12/07/2020		88.254.222					
	4	12/08/2020		88.254.200					
	<u></u>	12/08/2020		88.254.200					
	<u></u>	12/08/2020		8.254.200					
	ļ	12/08/2020		88.254.200					
	<u></u>	12/08/2020		8.254.200					
	ļ	12/08/2020		88.254.200					
	<u> </u>	12/08/2020		88.254.200					
		12/08/2020		88.254.200					
		12/08/2020		88.254.200		200			
		12/08/2020		88.254.200					
	<u> </u>	12/08/2020		88.254.200					
	<u> </u>	12/08/2020		88.254.200					
	<u> </u>	12/08/2020		88.254.200					
		12/08/2020		8.254.200					
		12/08/2020	105.8	88.254.200					
	from 12/07/2020 to 1	er of results repor	,974. ted byE						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION C. BUILDING		(X3) DATE SURVEY COMPLETED		
05D2		05D21974	16	D. WING		02/	02/17/2021	
CDPH BRANCH LABORATORY 284				ADDRESS, CITY, STATE, ZIP CODE 64 LIVINGSTON AVE ENCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATO OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	(EACH CORRECTIVE AC CROSS-REFERENCED TO	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) (X COMPI		
D6102	3. Based on the la declaration signed b 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1 4. The Laboratory (12/16/2020 at 1:00 ensure the laborator)	boratory's annual testin y the laboratory director ratory reported 00 SARS-CoV-2 test res	ed to	D6102				