		(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE		. ,		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING			
-	ROV DER OR SUPPLIER		STREET ADDR		,		
CDPH BF	ANCH LABORATOR	Ŷ		VINGSTON			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULAT OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D3000		performs nonwaived te		D3000			
	must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).						
	(a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that						
	performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2						
	manner, and at such the Secretary may p	cretary in such form an timing and frequency, rescribe. met as evidenced by:					
	the Condition for FA0 was not met as mand	rein, it was determined CILITY ADMINISTRATI dated by CLIA in Subpa	ON				
	Findings included:	of FederalRegulation.					
	1. 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 (See D3003).						
	2. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials (See D3011).		al,				
	test requisitions of al						
LABORATORY	-	I patients tested for	SSIGNATURE		TITLE	(X	(6) DATE

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.

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI			CONSTRUCTION	(X3) DATE S COMPL	
		05D21974	16	B. WING		02	/17/2021
AME OF PI	ROV DER OR SUPPLIER		STREET ADD	RESS, CITY, STATE	, ZIP CODE		
DPH BF	RANCH LABORATOR	Y	28454	LIVINGSTON A	VE		
			VALEN	ICIA, CA 91355	5		
(X4) ID	SUMMARY S	TATEMENT OF DEFICIENCIES	6	ID	PROVIDER'S PLAN C	FCORRECTION	(X5)
PREFIX	(EACH DEFICIENCY MUS	ST BE PRECEDED BY FULL RE DENTIFYING INFORMATION)		PREFIX TAG	(EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE THE APPROPRIATE	COMPLETIO DATE
D3000	Continued From page	ge 1		D3000			
		SARS-CoV-2, for at least two years (See D3027).					
	original test reports of	led to retain records of of all patients tested for east two years (See D3					
D3003	FACILITIES CFR(s): 493.1101(a)	)(2)		D3003			
	and maintained to er patient specimens, er reagents, materials, This Standard is not Based on interview w December 8, 2020, r procedures (P/P) for and FDA EUA IFU for Coronavirus Nucleic review of test record 11/22/2020 to 12/08/ test records reviewer laboratory failed to e patient specimens, er reagents, materials, laboratory's COVID-	Acid Detection Kit, ran s covering the period fr 2020, for 60 out of 60 pa d, it was determined that insure that contamination equipment, instruments, and supplies for the 19 Reverse herase Chain Reaction	zed. on Plan dom om atient at the on of				
	1. Decontamination I	Protocol					
	10:00 a.m., the labor	ratory tour at approximatory staff stated the us ontaminate the working for accessioning heat	se of				

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMB		<b>、</b> ,	E CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING		02/	17/2021
	OV DER OR SUPPLIER	Ŷ	28454 L	RESS, CITY, STAT IVINGSTON A CIA, CA 9135	AVE		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES       ID       PROVIDER'S PLAN OF CORRECTION         (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)       PREFIX       (EACH CORRECTIVE ACTION SHOULD BE TAG         CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       DEFICIENCY)				(X5) COMPLETION DATE		
D3003	b. Review of the la procedures (Policy # Quality Managemen 11/01/2020) stated of humidity monitoring monitoring. The labor protocols to ensure to and documentation of decontamination. c. Review of the la procedures for access decapping, sample to (Policy # CA-ACC-S for SARS-CoV-2 Sat 12/05/2020; CA-EXT Inactivation of Viral S Date 11/18/2020; CA Decapping and Bato Effective Date 12/03 Title: Sample Transf Effective Date 12/03 Title: Viral RNA DNA Chemagic 360-D, Eff stated under Section Safety that, "while litt virus, the comparabl SARS-CoV and MEF 2019-nCoV may like disinfectants includir general surface disir Hydrogen Peroxide, Phenolic compounds manufacturer's recor containing Guaniding bleach, therefore not agents in CDPH Bra	aboratory's policies and CA-QM-SOP-001, Title t Plan, Effective Date only the temperature an for environmental and so paratory failed to have wr the performance, freque of environmental aboratory's policies and aboratory's policies and sisioning, heat inactivati ransfer, extraction, and SOP-001, Title: Accessin mples, Effective Date T-SOP-001, Title: Heat Swab Samples, Effective A-EXT-SOP-002, Title: h Preparation for Janus /2020; CA-EXT-SOP-002 er Using the Janus G3, /2020; CA-EXT-SOP-004 A Extraction Using the fective Date 11/03/2020 6.0 Occupational Healt the is known about this is e genetic characteristic RS-CoV suggest that ly be susceptible to ng Sodium Hypochlorited ifection, 75% ethanol, 0 Quarternary Ammoniur s, if used according to mmendations. VTM e may produce cyanide t recommended as clear	e: d safety itten ency, on, PCR oning e s G3, D3, D4, D) h and novel with s for 0.5% n, and with ning	D3003	290211	If continuation she	et Page 3 of 123

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	PLE CONSTRUCTION	· · ·	(X3) DATE SURVEY COMPLETED	
		05D2197416 B. WING 02/17/2		7/2021				
_	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST. LIVINGSTOM ICIA, CA 913	NAVE			
(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 CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
D3003	<ul> <li>which disinfectant is Branch Lab.</li> <li>(2) At the time of the December 8, and 9, using Molecular Tran Viral Transport Media also using 70% ethal any of the disinfectar Hydrogen Peroxide, Phenolic compounds</li> <li>(3) The laboratory fa documentation and w 70% ethanol was suf environmental contar</li> <li>d. Review of the la Instructions for Use ( Coronavirus Nucleic Date 03/20/2020, Re 01/12/2021 for version Warnings and Preca centrifuge tubes and disposed into a wast Sodium Hypochlorite operation, the work a instrument surface sis freshly prepared 10% solution, and then cle pure water. Finally, to working surfaces for</li> <li>(1) The laboratory fa containing a 10% So for discarded centrifu laboratory failed to si</li> </ul>	being used at the CDP e on-site survey on 2020, the laboratory was port Media (MTM), no a (VTM). The laborator nol as a disinfectant, an its (75% ethanol, 0.5% Quaternary ammonium s) specified in its proced ailed to provide <i>r</i> ritten protocol to ensur- ficient to minimize mination. boratory's FDA EUA IFU) for Perkin Elmer I Acid Detection Kit (Effe- vised 09/16/2020 and on 7.0) stated under utions #10 that, "Sterile filter-tips should be e bin containing a 10% solution. After the area surface and the hould be disinfected with o Sodium Hypochlorite eaned with 75% Ethano urn on UV light to disin	as ot y was nd not n, and dure. e that New ective e th a ol or fect ution	D3003				

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	F OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,		(X3) DATE COMF	SURVEY LETED
		05D21974	16	B. WING		Q	2/17/2021
CDPH BRANCH LABORATORY 284				RESS, CITY, ST. LIVINGSTON CIA, CA 91:	AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF (EACH CORRECTIVE ACT CROSS-REFERENCED TO T DEFICIENC	ION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D3003	<ul> <li>(2) The laboratory fa protocol for work are disinfectants, and the</li> <li>2. Decontamination Testing Process</li> <li>a. During the labor 2020 at approximatel was observed to have Solution in dispensin expiration date.</li> <li>(1) Lot # 267015, Ex dispensing bottles)</li> <li>(2) Lot # A10012002 12/07/2020 (2 disper</li> <li>b. Review of the la procedures (Policy # Quality Management 11/01/2020) stated the should be used in testindicated expiration of the following art the 60 randomly revicovering the period f 12/08/2020, wherein SARS-CoV-2 tests a failed to ensure contact.</li> </ul>	iled to provide written a, and instrument surfa e use of UV light. In Solution in the atory tour on December y 10: 30 a.m., the labor e four 70% Ethanol Clea g bottles beyond its piration Date: 12/03/20 B, Expiration Date: nsing bottles) boratory's policies and CA-QM-SOP-001, Titl t Plan, Effective Date nat reagents and chemic sting process within the date. e the accession number ewed patient test recor rom 11/22/2020 to the laboratory perform nd reported results, bu amination of patient nt, instruments, reager	er 8, atory aning 20 (2 e: cals eir ers of ds ed t	D3003			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
	05D2197416 B. WING 02/1		7/2021				
NAME OF PROV DER OR SU CDPH BRANCH LAB		Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913			
	CIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	.D BE	(X5) COMPLETION DATE
declaration 12/16/2020 approximat from 11/02/ 5. The La 12, 2021 at laboratory to patient spe reagents, n D3011 FACILITIES CFR(s): 49 Safety proc	I on the lat signed by the labo tely 430,00 /2020 to 12 aboratory t approxin failed to e ecimens, e naterials, a S 03.1101(d) cedures m	poratory's annual testin y the laboratory directo ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed (Febr nately 2:00 pm) the nsure contamination of quipment, instruments, and supplies was minim	r on sults uary ized.	D3003			

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974		B. WING			17/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	L RESS, CITY, ST LIVINGSTOI CIA, CA 91;	NAVE	I	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATOR' OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	IOULD BE	(X5) COMPLETION DATE
D301 <sup>-</sup>	from physical, chemi electrical hazards, ar This Standard is not Based on interview v December 8, 2020, r procedures (P/P) for Plan, random review the period from 11/22 out of 60 patient test determined that the I safety procedures to physical, chemical, b biohazardous materia Findings included: 1. During the labor 2020 at approximate staff stated that COV process is performed one Class II Type A2 safely working with n or potentially contam biohazardous materia sterility of the materia 2. During the labora 2020, the laboratory laboratory personnel Cabinet. 3. Review of the la procedures (Policy # General Facilities Sa 12/07/2020) failed to laboratory personnel ensure safety and mi	cal, biochemical, and nd biohazardous mater met as evidenced by: vith laboratory staff on eview of policies and General Facilities Safe of test records coverin 2/2020 to 12/08/2020, for records reviewed, it we aboratory failed to obs ensure protection from iochemical, and als. atory tour on December ly 11:00 a.m., the labor 'ID-19 sample transfer I by one testing person Biosafety Cabinet (BSC naterials contaminated inated with infectious of als and for maintaining	ety ng or 60 as erve n er 8, ratory per C) for with or r 9, bety Title: te f C to rs of	D3011			

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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	
		05D21974 <sup>-</sup>	16	B. WING		02/1	7/2021	
	OV DER OR SUPPLIER	RY	28454	DRESS, CITY, STA LIVINGSTON ICIA, CA 913	AVE	·		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MU	STATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL RE DENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN (EACH CORRECTIVE A CROSS-REFERENCED T DEFICIE	CTION SHOULD BE O THE APPROPRIATE	(X5) COMPLETION DATE	
D3011	SARS-CoV-2 tests a to observe safety pro	from 11/22/2020 to the laboratory performe and reported results but pocedures to ensure prote ical, biochemical, and	failed	D3011				
	5. Based on the la	boratory's annual testing	9					
State 2567					Z9Q211	If continuation shee	et Page 8 of 123	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17/2021	
CDPH BRANCH LABORATORY 2845			28454 L	ESS, CITY, ST. IVINGSTON CIA, CA 913			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR( DEFICIENCY)	LD BE COMPLETION	
D3011 D3027	declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 unti 6. The Laboratory f 12, 2021 at approxim laboratory failed to ob ensure protection fro biochemical, and bio RETENTION REQUI	y the laboratory directo ratory reported 00 SARS-CoV-2 test re I 12/16/2020. Director affirmed (Febr hately 2:00 pm) the oserve safety procedure m physical, chemical, hazardous materials. REMENTS	esults uary	D3011 D3027			
	<ul> <li>CFR(s): 493.1105(a)(1)</li> <li>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.</li> <li>This Standard is not met as evidenced by: Based on interviews with staff and the laboratory director on December 8, 2020, the absence of test requisitions, and random review of test records covering the period from 11/22/2020 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 requisitions for SARS-CoV-2 patient testing.</li> <li>Findings included:</li> <li>1. The laboratory performed SARS-CoV-2</li> </ul>						
	<ul> <li>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.</li> <li>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</li> </ul>						

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		· · /	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING		02/ <sup>.</sup>	17/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913			
(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 C (EACH CORRECTIVE ACTIC CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
D3027	<ul> <li>generate a test requi</li> <li>3. During the initial California clinical lab requested the laborat test requisition that wi 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.</li> <li>4. There was no ma a test requisition was There was also no ma requisitions were retations.</li> <li>5. The following and the 10 randomly revision covering the period for 12/08/2020, wherein SARS-CoV-2 tests a</li> </ul>	sition for each patient stages of its application oratory license, we tory to submit an exam <i>i</i> ll be used. A test requ veral requirements to b iboratory license. On ratory submitted a "est Order Requisition_ on- Example Only v.3." y submitted an example e used, the laboratory l a test requisition for each sechanism in place to es s generated for each p hechanism to ensure the ained by the laboratory. e the accession number ewed patient test recor	pple iisition e met, Covid Even e had had had had es sure atient. hat test ers of ds ed failed	D3027			

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	F OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		, ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING		02/ <sup>,</sup>	17/2021
	ROV DER OR SUPPLIER	Y	28454	RESS, CITY, ST LIVINGSTOI	NAVE		
(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 CORF (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AI DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D3027 D3041	<ol> <li>Based on the lat declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12</li> <li>The laboratory di affirmed December 8 11:00 a.m. that the lat records of test reque</li> </ol>	ooratory's annual testin the laboratory director ratory reported 00 SARS-CoV-2 test res 2/16/2020. Frector and testing person to 2020 at approximately boratory failed to retain sts.	r on sults onnel ly	D3027 D3041			
D3041	CFR(s): 493.1105(a) Test reports. Retain of of the original report and corrected reports date of reporting. (i) In addition, retain in as specified in 21 CF (ii) and pathology tes after the date of repor This Standard is not Based on email comu- laboratory director on original test reports, a covering the period fi 12/04/2020, for 10 ou reviewed, it was dete failed to retain record SARS-CoV-2 patient Findings included: 1. The laboratory p RT-PCR laboratory of direct detection of SA patient samples, and generated through C	(6) or be able to retrieve a (including final, prelimi s) at least 2 years after mmunohematology rep (R 606.160(d) t reports for at least 10 rting. met as evidenced by: munication with the 12/24/2020, the absen and review of test reco rom 12/02/2020 to ut of 10 patient test reco rom 12/02/2020 to ut of 10 patient test reco rom testing. erformed SARS-CoV-2 leveloped test (LDT) for ARS-CoV-2 virus RNA the final test reports w	nary, the orts years uce of rds ords tory ts for 2 or the from	D3041			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		. ,	PLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17		
	E OF PROV DER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE							
CDPH BI	RANCH LABORATOR	Y		LIVINGSTON CIA, CA 913				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
D3041	<ul> <li>SARS-CoV-2 but she laboratory process e</li> <li>CDPH Branch la Laboratory about the which amended report 12/07/2020.</li> <li>CDPH Branch Lat the test results for S/provide the original to 12/04/2020 and ame</li> <li>The following and the period from 12/02/2020 and ame</li> <li>The following and the period from 12/02/2020 and ame</li> <li>The following and the period from 12/02/2020 and ame</li> <li>Based on the laboratory for a signed by 12/16/2020, the laboratory about the laboratory about the period from 12/02/2020 to 12/27. The laboratory of 2021 at approximate</li> </ul>	build have been invalid rror on 12/04/2020. aboratory informed Colu- test results reported in orts were issued on aboratory has access we ARS-CoV-2 but failed to est results reported on inded on 12/07/2020. e the accession number ent test records coverin 2/2020 to 12/04/2020, ry performed SARS-Co- soults but failed to provious or each patient tested.	or error /ith o ers of ng oV-2 ide // sults ary 12,	D3041				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION G	(X3) DATE SU COMPLE	
	05D2197416			B. WING		02/1	7/2021
-	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI ICIA, CA 91			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	ULD BE	(X5) COMPLETION DATE
D3041	Continued From pag reports.	je 12		D3041			
D5300				D5300			
	must meet the applic requirements in §§49 unless HHS approve Appendix C of the St (CMS Pub. 7), that p testing. The laborato evaluate the overall of systems and correct specified in §493.122 subspecialty of testin This Condition is not Based on the numbe deficiencies cited her the Condition for PRE not met as mandated Title 42 of the Code of Findings included: 1. The laboratory fail requisitions for SARS D5301). 2. The laboratory fail requisitions included accurate reporting of 3. The laboratory faile and procedures for s handling were follow 4. The laboratory faill the date and time of	quality of the preanalyti identified problems as i9 for each specialty ar g performed. met as evidenced by: r and severity of the rein, it was determined ANALYTIC SYSTEMS by CLIA in Subpart K of FederalRegulation. ed to ensure it retained S-CoV-2 patient testing ed to ensure test necessary information f test results (See D5305 ed to ensure written pol pecimen submission a ed (See D5311). ed to ensure it docume	n(s) ed in lity ic nd that was of d test l(See for 5). icies nd				

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			X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, STA IVINGSTON CIA, CA 913	AVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	_D BE	(X5) COMPLETION DATE	
D5300	Continued From pag	je 13		D5300				
	written policies and p mechanism to monito	ed to ensure it establis procedures for an ongo or, assess, and when oblems identified in the See D5391).						
D5301				D5301				
	request for patient te person. This Standard is not Based on interviews the laboratory director absence of written por for retaining test requirequisitions for each review of test records 11/02/2020 to 12/08// test records reviewed laboratory failed to re- for SARS-CoV-2 patient Findings included: 1. The laboratory por RT-PCR laboratory of direct detection of S// patient samples under Health Officer. 2. Although the labor prescribing order for a the state from the Sta authorized person; th generate a test required 3. During the initial	have a written or electristing from an authorized met as evidenced by: with testing personnel or on December 8, 2020 blicies and procedures uisitions, the absence of patient tested, and ran is covering the period fr 2020, for 10 out of 10 pa d, it was determined that etain records of test records ent testing.	and 0, the (P/P) of test dom om atient at the quests 2 or the from e nket thin					

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( )			X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17/20	21
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	ESS, CITY, ST VINGSTON XIA, CA 913			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE CC	(X5) DMPLETION DATE
D5301	<ul> <li>laboratory to submit a that will be used. A term several requiremareceiving 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 s no mechanism in pla requisition was gene</li> <li>5. The following are the 10 randomly revia covering the period fit 12/08/2020, wherein SARS-CoV-2 tests at to provide test requisit</li> <li>Accession Number</li> <li>6. Based on the laboratory is a several requisition signed by 12/16/2020, the laboratory is a several several signed by 12/16/2020, the laboratory is a several sev</li></ul>	an example test requises est requisition is only or ents to be met, prior to y license. On 10/20/202 tted a documented title on Covid 19 Sample e Only v.3." Even thoug an example requisition pratory had not been uisition for each patien ailed to provide a writte standing orders. There ce to ensure a test rated for each patient. e the accession number ewed patient test recor rom 11/02/2020 to the laboratory perform and reported results but titions for each patient test titions for each patient test titions for each patient test operatory's annual testin / the laboratory directo ratory reported 00 SARS-CoV-2 test rest	ne of 20, d, gh the n that t. en was ers of ds ed failed ested.	D5301			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI		. ,	CONSTRUCTION	(X3) DATE S COMPL	
		05D21974	16	B. WING	02	/17/2021	
	OV DER OR SUPPLIER	Υ Υ	28454 I	RESS, CITY, STATE LIVINGSTON A CIA, CA 91355	VE	·	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	STATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL RE DENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETIC DATE
D5301	Continued From page	ge 15		D5301			
	affirmed (December 11:00 a.m.) that the	lirector and testing perso 8, 2020 at approximate laboratory did not have patient or policies to ado	ely test				
D5305	TEST REQUEST CFR(s): 493.1241(c	)		D5305			
	<ul> <li>solicits the following</li> <li>(1) The name and an identifiers of the authitest and, if appropriation for using the test rest address of the labor specimen, including person to enable the threatening laborator values.</li> <li>(2) The patient's name (3) The sex and age (4) The test(s) to be (5) The source of the when appropriate.</li> <li>(6) The date and, if a collection.</li> <li>(7) For Pap smears, period, and indication a previous abnormal (8) Any additional improvement including interpretation threatening interpretation threatening interpretation threatening interpretation threatening interpretation threatening interpretation threatening interpretation of the standard is not basence of written period in the standard is not basence of written period is the standard is not basence of written perio</li></ul>	ddress or other suitable orized person requestin ate, the individual respo- sults, or the name and atory submitting the , as applicable, a contact e reporting of imminently ry results or panic or all ne or unique patient iden or date of birth of the pa- performed. e specimen, uppropriate, time of spect the patient's last mension n of whether the patient report, treatment, or bio formation relevant and of reporting of results,	ig the nsible ct y life ert itifier. itient. trual t had opsy. ate d the he P/P) red				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/17	02/17/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI CIA, CA 91				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
D5305	<ul> <li>each patient tested, a records covering the 12/08/2020, for 10 ou reviewed, it was dete failed to ensure test in necessary informatio test results for COVII Transcriptase-Polym (RT-PCR).</li> <li>Findings included:</li> <li>1. The laboratory u diagnostic laboratory direct detection of SA patient samples. It ut isolation of the viral in RT-PCR assay on An</li> <li>2. During the laboration approximately 10:00 stated that CDPH Bra with another CLIA ce healthcare providers patients diagnosed w infections. It was obs patient sample was of indicating the total nu received, site point o company number, co collected, site name</li> <li>3. The laboratory fa requisitions for each which included inform and address of the a the test, patient's nar age, date of birth, test of specimen, date an</li> </ul>	and random review of t period from 11/22/202 ut of 10 patient test rec ermined that the laboral requisitions included n for accurate reporting D-19 Reverse erase Chain Reaction tilized SARS-CoV-2RT developed test (LDT) ARS-CoV-2 virus RNA ilizes Chemagic 360 for bucleic acids followed to halytik Jena Thermal C atory tour on 12/08/202 a.m., the laboratory sta anch Lab has been work rified laboratory to hel in ordering the test for <i>i</i> th possible Covid-19 erved that along with to only a "paper manifest" umber of samples f contact, tracking illective date for sample	0 to ords tory g of -PCR forthe from or the by the ycler. 20 at aff king p he he e e e ad me esting sex, urce d any	D5305				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416 B. WING 0			02/1	02/17/2021			
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913	AVE			
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRC DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D5305	<ul> <li>to ensure accurate a reporting of results.</li> <li>4. The following are the 10 randomly revice covering the period for 12/08/2020, wherein reported SARS-CoV-results, but failed to p which included inform accurate test result result result result result result and the comparison of the second second</li></ul>	nd timely testing and the accession numbe ewed patient test recor- rom 11/02/2020 to the laboratory tested a -2 RT-PCR patient test provide test requisitions nation necessary for eporting.	rds and s s s	D5305				
	affirmed December 8 11:00 am, that the lal	irector and testing pers 3, 2020 at approximate boratory did not have to luded necessary inform ilts reporting.	ly est					
D5311	SPECIMEN SUBMIS REFERRAL CFR(s): 493.1242(a)	SSION, HANDLING, AN	ND	D5311				
	The laboratory must	establish and follow w	ritten					

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	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLI IDENTIFICATIONNUMBER			A. BUILDING	CONSTRUCTION	(X3) DATE S COMPLI	
		05D21974	16	B. WING		02	/17/2021
	ROV DER OR SUPPLIER	Y	28454	RESS, CITY, STATE LIVINGSTON A ICIA, CA 91355	VE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE A CROSS-REFERENCED TC DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5311	<ul> <li>policies and procedurif applicable:</li> <li>(1) Patient preparation</li> <li>(2) Specimen collect</li> <li>(3) Specimen labeling</li> <li>unique patient identif</li> <li>specimen source.</li> <li>(4) Specimen storag</li> <li>(5) Conditions for specimen accept</li> <li>(6) Specimen procession</li> <li>(7) Specimen accept</li> <li>(8) Specimen referrant</li> <li>This Standard is not</li> <li>Based on interviews</li> <li>December 8, 2020, r</li> <li>procedures (P/P) for</li> <li>storage, and shipping</li> <li>records covering the</li> <li>12/08/2020, for 10 or</li> <li>reviewed, it was deternant</li> <li>failed to ensure that</li> <li>procedures for specific handling were follow</li> <li>Findings included:</li> <li>1. The laboratory undiagnostic laboratory undiagnostic laboratory undisolation of the viral r</li> <li>RT-PCR assay on A</li> <li>2. Review of the lapprocedures (Policy #</li> <li>Specimen Collection</li> <li>Effective Date 12/07, "Collection kits with i packaging and shipping</li> </ul>	res for each of the follo on. ion. g, including patient nam fier and, when appropr e and preservation. ecimen transportation. ising. iability and rejection. I. met as evidenced by: with laboratory staff on eview of policies and specimen collection, g, and random review o period from 11/02/2020 ut of 10 patient test rec- ermined that the laborat written policies and men submission and ed. tilized SARS-CoV-2RT developed test (LDT) for ARS-CoV-2 virus RNA for tilizes Chemagic 360 for nucleic acids followed b nalytik Jena Thermal C boratory's policies and cA-CLSRV-SOP-002, , Storage, and Shipping	T-PCR for the from or the ycler. Title: g, n,	D5311			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
	<b>05D2197416</b> В. W			B. WING		02/17/2	2021
CDPH BRANCH LABORATORY 284			28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE
D531 <sup>-</sup>	not collected correctl results." The laboratory failed provided to all staff in procurement process a. Correct specimen the appropriate techn containers b. Specimen labeling unique identifier, and c. Proper storage and d. Proper transportat e. Specimen accepta and disposition 3. During the labor approximately 11:00 stated that they only in Molecular Transport at room temperature The laboratory coord Laboratory for specin submission to CDPH a. Review of COLO requirements only in transported at 2-8 De hours, or -20 Degree specimen is to be su	y will lead to inaccurate to provide the instruction the collection sites for s. collection using hique and , including patient name I specimen source d preservation ion ability, rejection atory tour on 12/08/202 a.m., the laboratory state process samples colle ort Media (MTM), transport , and stable for seven of linates with COLOR men collection and I Branch Lab. DR website for specime dicated VTM or UTM me egrees Celsius within 2 ss Celsius on dry ice if the bitted >24 hours. ailed to provide the clie contains the reference ments for swab	ions r their e or 20 at aff cted ported days. en edia 4 the	D5311			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		· ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021	
	V DER OR SUPPLIER	Y	28454 L	RESS, CITY, ST. LIVINGSTON CIA, CA 913				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR( DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
2 t c r r r r r r r r r r r r r r r r r r	the 10 randomly revie covering the period fr 12/08/2020, wherein reported SARS-CoV- results, but failed to e procedures for specir handling using MTM v Accession Number 5. Based on the lak declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 6. The laboratory di 12, 2021 at approxim laboratory failed to er procedures for specir handling were availal SPECIMEN SUBMIS REFERRAL CFR(s): 493.1242(b) The laboratory must it receives a specime	e the accession number ewed patient test recor- rom 11/02/2020 to the laboratory tested a -2 RT-PCR patient test ensure written policies men submission and were available and follo were available and follo boratory's annual testin / the laboratory director ratory reported 00 SARS-CoV-2 test rest 2/16/2020. irrector affirmed (Februan hately 2:00 pm) that the nsure written policies a men submission and ble and followed. iSION, HANDLING, AN document the date and	rds and and owed. owed. owed. any sults ary on sults	D5311				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/1	02/17/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. LIVINGSTON CIA, CA 913	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE	
D5313	<ul> <li>Based on interviews</li> <li>December 8, 2020, r</li> <li>and procedures (P/P</li> <li>patient test records c</li> <li>11/02/2020 to 12/08/</li> <li>test records reviewed</li> <li>laboratory failed to e</li> <li>specimen receipt in t</li> <li>specimen for SARS-</li> <li>documented.</li> <li>Findings included: <ol> <li>The laboratory u</li> <li>based diagnostic I</li> <li>(LDT) for the direct</li> <li>virus RNA from patholic content of the direct</li> <li>virus RNA from patholic content of the direct</li> <li>During the laboratory u</li> <li>stated that CDPH</li> <li>working with anoth</li> <li>to help healthcare</li> <li>test for patients potinfections. It was content on the direct on</li></ol></li></ul>	with laboratory staff or eview of available polic ), and random review of covering the period from 2020, for 10 out of 10 d, it was determined the nsure the date and time he laboratory for each CoV-2 patient testing with the laboratory developed test to detection of SARS-Cover and to the solation of the viration wed by the RT-PCR as the isolation of the viration wed by the RT-PCR as thermal Cycler. atory tour on 12/08/2020 00 a.m., the laboratory Branch Lab has been her CLIA certified labor providers in ordering to possible with Covid-19 observed that along with s only a "paper manife date for all the sample llection site. It did not and time of collection for amples. boratory's policies and of an to document the oblection for SARS-Covert and the of collection for amples.	cies of n patient at the e of vas F-PCR est oV-2 s al ssay 20 at staff atory he h the st" es or	D5313				

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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	
	05D2197416		16	B. WING		02/17/2021		
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI CIA, CA 91	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	_D BE	(X5) COMPLETION DATE	
D5313	4. The following are the 10 randomly revic covering the period fi 12/08/2020, wherein reported SARS-CoV- results, but failed to a specimen receipt wa Accession Number	e the accession numbe ewed patient test recor rom 11/02/2020 to the laboratory tested a -2 RT-PCR patient test ensure the date and tin	rds and ne of	D5313				
D5391	declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 6. The laboratory d 12, 2021 at approxim laboratory failed to el documented the date receipt. PREANALYTIC SYS ASSESSMENT CFR(s): 493.1249(a) The laboratory must policies and procedu mechanism to monito indicated, correct pro-	y the laboratory director ratory reported 20 SARS-CoV-2 test re 2/16/2020. irrector affirmed (Februan nately 2:00 pm) that the nsure the laboratory and time of specimen TEMS QUALITY establish and follow with	r on sults ary e	D5391				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		· ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. LIVINGSTON CIA, CA 91:		·		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE	
D5391	<ul> <li>through 493.1242.</li> <li>This Standard is not Based on interview v December 8, 2020, r documentation of po for Test Requisition, laboratory failed to e procedures for an or monitor, assess, and problems identified in specified at CFR 493</li> <li>Findings included:</li> <li>Review of the lap procedures (Policy # Quality Management 11/01/2020) did not i mechanism to perfor issues regarding the complete information accurate test results D5305); as well as s handling (See D5311</li> <li>The laboratory u facilities. The laborator policies and procedu accountability or trac of collection to receip a. At the time of th December 8, 2020, th Molecular Transport swab specimens, wit days at room temper</li> </ul>	met as evidenced by: vith the laboratory staff eview and the lack of licies and procedures ( it was determined that stablish written policies agoing mechanism to I when indicated, corre the preanalytic system 3.1241 through 493.124 boratory's policies and CA-QM-SOP-001, Titl t Plan, Effective Date nclude an ongoing m and document qualit lack of test requisition w necessary to ensure reporting (See D5301 pecimen submission at I and D5313). Uses off-site collection tory failed to establish res to ensure proper king of specimens from ot in the laboratory. e on-site survey on the laboratory was only to Media (MTM) to transp th a stated stability of s ature.	P/P) the s and ct ms 42. e: ty with and nd time using port even	D5391				

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/ AND PLAN OF CORRECTION IDENTIFICATIONNUMB			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/1	7/2021
	ROV DER OR SUPPLIER	Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE
D5391	<ul> <li>date and time into the will not be able to de acceptability based of days at room temper</li> <li>3. The following and the 10 randomly revie covering the period fit 12/08/2020, wherein reported SARS-CoV-results, wherein the I there was an ongoing document quality issues.</li> <li>Accession Number</li> <li>4. Based on the late declaration signed by 12/16/2020, the labor approximately 430,000 from 11/02/2020 to 12</li> <li>5. The laboratory di 12, 2021 at approximately to entre the results of the results.</li> </ul>	e laboratory, laboratory termine specimen on sample stability of se ature. e the accession number ewed patient test recor- rom 11/02/2020 to the laboratory tested a -2 RT-PCR patient test aboratory failed to ens g mechanism to perform ues in the preanalytic poratory's annual testing y the laboratory director ratory reported 00 SARS-CoV-2 test res 2/16/2020. irector affirmed (Februa- nately 2:00 pm) that the nsure they have an ong m and document quality ytic systems.	even ers of ds and ure n and and g r on sults ary going	D5391			
D5400		-		D5400			

	EMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CI			. ,	PLE CONSTRUCTION	· · /	(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/1	7/2021	
-	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, STA IVINGSTON CIA, CA 913				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR( DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5400	<ul> <li>CFR(s): 493.1250</li> <li>Each laboratory that must meet the applic requirements in §§45 unless HHS approve Appendix C of the St (CMS Pub.7), that pr testing. The laborato evaluate the overall of systems and correct specified in §493.126 subspecialty of testin</li> <li>This Condition is not Based on the number deficiencies cited her ANALYTIC SYSTEM</li> <li>Findings included:</li> <li>The laboratory fr manuals were estable followed by laboratory</li> <li>The laboratory far manuals met the req CFR 493. 1251 (b)(1)</li> <li>The laboratory far manuals were updated dated by the current D5407).</li> <li>The laboratory far adopted FDA EUA IF to the EUA, and char policies and procedu</li> </ul>	performs nonwaived te sable analytic systems 33.1251 through 493.12 s a procedure, specific ate Operations Manua ovides equivalent qual ry must monitor and quality of the analytic identified problems as 39 for each specialty and g performed. met as evidenced by: r and severity of the rein, the Condition: I was not met. ailed to ensure procedu ished, available to, and y personnel (See D540 ailed to ensure the proc uirements specified in )-(b)(14) (See D5403). ailed to ensure procedu ed, approved, signed a Laboratory Director (S ailed to ensure it follow FU, the subsequent rev nges made in the labora	283, ed in l ity nd ure d 1). edure 42 ure and see ed the <i>i</i> sions atory's	D5400				

PREFIX TAG     IEACH DEPICIENCY IN GIVE ON FORMATION)     PREFIX TAG     IEACH OCRECTORACTION CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       D5400     Continued From page 26 labeled as required (SeeD5415).     D5400       6. The laboratory failed to ensure the decontamination solution used forSARS-CoV-2 RT-PCR were not used past the labeled expiration dates (See D5417).     D5400       7. The laboratory failed to ensure it established and verified performance specifications prior to reporting patient test results using its modified FDA EUA IFU SARS-CoV-2 RT-PCR (See D5423).     The laboratory failed to the ensure the       8. The laboratory failed to the ensure the     Image: Construction of the ensure the     Image: Construction of the ensure the		NT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA OF CORRECTION IDENTIFICATIONNUMBER:			. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
CDPH BRANCH LABORATORY       28454 LIVINGSTON AVE VALENCIA, CA 91355         (X4) ID PREFIX TAG       SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)       ID PREFIX TAG       PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       (CACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)         D5400       Continued From page 26 labeled as required (SeeD5415).       D5400         6. The laboratory failed to ensure the decontamination solution used forSARS-CoV-2 RT-PCR were not used past the labeled expiration dates (See D5417).       D5400         7. The laboratory failed to ensure it established and verified performance specifications prior to reporting patient test results using its modified FDA EUA IFU SARS-CoV-2 RT-PCR (See D5423).       The laboratory failed to the ensure the         8. The laboratory failed to the ensure the       State of the ensure the       State of the ensure the		05D2197416			B. WING		02/17/2021		
PREFIX TAG     (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)     PREFIX TAG     CEACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)     COMPLETION DATE       D5400     Continued From page 26 labeled as required (SeeD5415).     D5400     D5400       6.     The laboratory failed to ensure the decontamination solution used forSARS-CoV-2 RT-PCR were not used past the labeled expiration dates (See D5417).     D5400       7.     The laboratory failed to ensure it established and verified performance specifications prior to reporting patient test results using its modified FDA EUA IFU SARS-CoV-2 RT-PCR (See D5423).     RT-PCR (See D5423).       8.     The laboratory failed to the ensure the		CDPH BRANCH LABORATORY 28454			LIVINGSTON AVE				
Iabeled as required (SeeD5415).         6. The laboratory failed to ensure the decontamination solution used forSARS-CoV-2 RT-PCR were not used past the labeled expiration dates (See D5417).         7. The laboratory failed to ensure it established and verified performance specifications prior to reporting patient test results using its modified FDA EUA IFU SARS-CoV-2 RT-PCR (See D5423).         8. The laboratory failed to the ensure the	PREFIX	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			PREFIX	(EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRC	COMPLETION		
established maintenance protocol for centrifuges were performed and documented (SeeD5433). 9. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (D5791). PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60		<ul> <li>labeled as required (</li> <li>6. The laboratory fadecontamination solu RT-PCR were not use expiration dates (See</li> <li>7. The laboratory fa and verified performative reporting patient test FDA EUA IFU SARS D5423).</li> <li>8. The laboratory fatestablished maintenative centrifuges were perf (SeeD5433).</li> <li>9. The laboratory fatestablished maintenative rechanism to monitor indicated, correct pro- analytic systems (D5)</li> <li>PROCEDURE MANIC CFR(s): 493.1251(a)</li> <li>A written proceduress and examinations per must be available to, personnel. Textbook replace the laboratory testing or examining</li> <li>This Standard is not Based on direct obsection laboratory staff on Dar control (QC) and qua- random review of patients</li> </ul>	SeeD5415). ailed to ensure the ution used forSARS-Co- sed past the labeled e D5417). ailed to ensure it establis ance specifications price results using its modif G-CoV-2 RT-PCR (See ailed to the ensure the ance protocol for formed and documented ailed to establish and for procedures for an ongo or, assess, and when oblems identified in the G791). JAL emanual for all tests, a erformed by the laborat and followed by, labor s may supplement but y's written procedures specimens. met as evidenced by: ervation, interviews witt ecember 8 and 9, 2020 d procedures (P/P), qu lity assurance (QA) rec tient test records cover	shed or to ied ed illow bing ssays, ory ratory not for h ), ality pords, ring					

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE			
		05D21974	16	B. WING		02/ <sup>,</sup>	17/2021		
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355					
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE IENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF ( (EACH CORRECTIVE ACTI CROSS-REFERENCED TO TI DEFICIENC)	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE		
D5401	determined that the I the procedure manual Coronavirus Nucleic. Polymerase Chain R diagnostic test were the laboratory staff. Findings included: 1. The laboratory fa written P/P in all pha Perkin Elmer New Co Detection Kit RT-PCI utilizing Chemagic 36 nucleic acids followe Analytik Jena Therm testing patient sampl 2. The following are the 60 randomly revis covering the period fi 12/08/2020, wherein performing SARS-Co results, but failed to a	als for the Perkin Elmer Acid Detection Kit Real Reaction (RT-PCR) in vi established and follows ailed to establish and follows ailed to establish and follows as of clinical testing for oronavirus Nucleic Acid R in vitro diagnostic tes 50 for the isolation of the d by the RT-PCR assa al Cycler, when it started les on 11/02/2020. e the accession number ewed patient test recor from 11/22/2020 to the laboratory started bV-2 tests and reported	r New Time itro ed by ollow or d st e viral y on ed rs of rds	D5401					

If continuation sheet Page 28 of 123

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CI AND PLAN OF CORRECTION IDENTIFICATIONNUMBE				(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416		16	B. WING		02/17/2021		
				RESS, CITY, ST.				
	VALE			CIA, CA 913	355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D5401	<ul> <li>declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12</li> <li>4. The Laboratory I (February 12, 2021 a pm) the laboratory fa and procedures were followed by laborator</li> <li>5. Details of the real and procedures are of D5403).</li> </ul>	poratory's annual testir y the laboratory director ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed it approximately 2:00 iled to ensure policies e established and y staff. quired elements for pole enumerated in D5403,	ron sults icies	D5401				
D5403	PROCEDURE MANU CFR(s): 493.1251(b)			D5403				
	The procedure manu when applicable to th (1) Requirements for		lowing					

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	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB	ER:	A. BUILDING	CONSTRUCTION	(X3) DATE S COMPL	
		05D21974	16	B. WING		02	/17/2021
NAME OF PF	OV DER OR SUPPLIER	-	STREET ADD	RESS, CITY, STATE	, ZIP CODE		
CDPH BR	ANCH LABORATOR	Υ Υ		LIVINGSTON A ICIA, CA 91355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	STATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL RE DENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5403	specimen collection, preservation, transport referral; and criteria and rejection as des (2) Microscopic exart the detection of inad slides. (3) Step-by-step perf including test calculat results. (4) Preparation of slit controls, reagents, st used in testing. (5) Calibration and converification procedur (6) The reportable rat the test system as end §493.1253. (7) Control procedur (8) Corrective action control results fail to criteria for acceptable (10) Reference inter (11) Imminently life-to or panic or alert value (12) Pertinent literatu (13) The laboratory's in the patient record a including, when app reporting imminently panic, or alert values (14) Description of th a test system becom This Standard is not 1. Based on direct laboratory staff on D review of policies and	labeling, storage, ortation, processing, an for specimen acceptabi cribed in §493.1242. mination, including equately prepared formance of the proced ations and interpretatio ides, solutions, calibrate stains, and other materi- calibration res. ange for test results for stablished or verified in es. to take when calibratic meet the laboratory's lifty. test methodology, inclu es. vals (normal values). threatening test results, es. ure references. s system for entering re and reporting patient re- ropriate, the protocol fo r life-threatening results s. ne course of action to ta	ility ure, n of ors, ials on or ding sults sults sults sults r, or ke if with o,	D5403			

	F OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMB		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED			
	05D2197416			B. WING		02/	02/17/2021		
	ROV DER OR SUPPLIER	Y	28454 L	DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355					
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE		
D5403	random review of pat the period from 11/22 out of 60 patient test determined that the li to include the followin accurate and reliable Specimen c appropriate technique Specimen la name or unique idem Proper stora transportation Specimen a disposition Findings included: a. The laboratory fa manual that met all th for Perkin Elmer New Detection Kit Real Tin Reaction (RT-PCR) i utilizing Chemagic 36 nucleic acids followe Analytik Jena Therma b. During the on-sit and 9, 2020, we note three sources, and a below: (1) Staff interviews (2) Perkin Elmer Em (EUA) Instructions for	tient test records cover 2/2020 to 12/08/2020, f records reviewed, it wa aboratory's procedure ing requirements to ense test results: collection using the e and containers abeling, including patie tifier, and specimen so age, preservation, and acceptability, rejection a alled to provide the proc he applicable requirem v Coronavirus Nucleic v me Polymerase Chain n vitro diagnostic test 50 for the isolation of th d by the RT-PCR assa al Cycler. te inspection on Decem ed discrepancies from re specified in "c" thou	For 60 as failed ure nt urce and eedure ents Acid he viral y on hber 8 these gh "f"	D5403					

If continuation sheet Page 31 of 123

	IT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA OF CORRECTION IDENTIFICATIONNUMBER:			. ,	PLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
	05D2197416		16	B. WING		02/1	7/2021	
	CDPH BRANCH LABORATORY 28454			L RESS, CITY, ST. LIVINGSTOI CIA, CA 913	NAVE			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APF DEFICIENCY)	ULD BE	(X5) COMPLETION DATE	
D5403	5403 Continued From page 31			D5403				
D5403	<ul> <li>c. Correct specim the appropriate teck containers</li> <li>(1) Based on intervia on 12/08/2020, the la samples collected in Media (MTM).</li> <li>(2) Review of FDA B Coronavirus Nucleic / use of Viral Transpor Date 03/20/2020, Re 01/12/2021). There v regarding the use of</li> <li>(3) Review of the lal CA-CLSRV-SOP-002 Storage and Shipping 12/07/2020) indicated Coordinates with CO specimen collection a</li> <li>(4) Review of COLC specimen requirement UTM media transport</li> <li>(5) The laboratory fa its policies and processor</li> <li>(4) Specimen labeling name or unique ide source</li> <li>(1) During the labora approximately 10:00 stated that CDPH Bra</li> </ul>	en collection using hnique and ew with the laboratory s aboratory only process Molecular Transport EUA IFU for PE New Acid Detection Kit state t Media (VTM) (Effectiv vised 09/16/2020 and vas no information prov MTM in the IFU. boratory's P/P (Policy# 2, Title Specimen Colle g, Effective Date d that CDPH Branch La LOR laboratory for and submission. DR website for nts indicated VTM or t. ailed to specify and inclu- edures, the use of MTM ng, including patient ntifier, and speciment tory tour on 12/08/2020 a.m., the laboratory sta anch Lab has been wo	d the ve vided tection, ab ude in	D5403				
	with another CLIA ce healthcare providers patients possible with	rtified laboratory to hel in ordering the test for n Covid-19 infections. I with the patient sample	p twas					

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	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			CONSTRUCTION	(X3) DATE S COMPL	
		05D2197416	<b>;</b>	B. WING		02	/17/2021
NAME OF PR	OV DER OR SUPPLIER		STREET ADDR	ESS, CITY, STATI	E, ZIP CODE		
CDPH BR	ANCH LABORATOR	RY		VINGSTON A			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MU	STATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL REGL DENTIFYING INFORMATION)	JLATORY	ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE ) THE APPROPRIATE	(X5) COMPLETIOI DATE
D5403		-		D5403			
	only a "paper manife	est" indicating the following	g:				
	<ul> <li>ii. Site po</li> <li>iii. Trackir</li> <li>iv. collecti</li> <li>sample</li> <li>v. Site na</li> <li>vi. Site ad</li> </ul> (2) Review of the la CA-CLSRV-SOP-00	dress aboratory's P/P (Policy# /2, Title Specimen Collecti ng, Effective Date 12/07/20 nts for the paper and	ion,				
	ii.Manife iii.Date d iv.Site n v.Site ad vi.Site p (name, phone numbe	ddress oint of contact					
	included complete in	ailed to ensure the policy nformation for individual tient name or unique men source.					
	e. Proper storage and transportation						
	(1) Based on interview with the laboratory staff on 12/08/2020, the laboratory would receive MTM samples at room temperature, and good for seven days.						
		EUA IFU for PE New Acid Detection Kit stated t	he				

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	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/O		. ,	PLE CONSTRUCTION G	(X3) DATE SL COMPLE	
	AN OF CORRECTION						
	05D2197416			B. WING		02/1	17/2021
	ROV DER OR SUPPLIER				ATE, ZIP CODE		
CDPH BI	RANCH LABORATOR	Y		LIVINGSTO			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AF DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D5403	<ul> <li>use of VTM, stored at to 72 hours after collest shipping is expected, stored at -70 degrees 03/20/2020, Revised 01/12/2021).</li> <li>(3) Review of the lai CA-CLSRV-SOP-002 Storage and Shipping indicated that CDPH with COLOR laborate and submission.</li> <li>(4) Review of COLO requirements indicate transport should be r Celsius prior to and chours. If the specime hours post collection freeze at -20 degrees ship on dry ice.</li> <li>(5) Review of the lai CA-CLSRV-SOP-002 Storage and Shipping stated under storage specimens collected degrees Celsius (roo "Manufacturer's instructemperature storage followed."</li> <li>(6) Review of the m for PE New Coronavi Kit stated the use of Celsius for up to 72 h delay in testing or sh specimens should be complexed.</li> </ul>	t 2-8 degrees Celsius ection. If a delay in tes specimens should be s Celsius (Effective Da 09/16/2020 and boratory's P/P (Policy# 2, Title Specimen Colle g, Effective Date12/07/ Branch Lab Coordir ory for specimen collect OR website for specime ed VTM or UTM media efrigerated at 2-8 degr during transport within in is to be submitted >2 , specimens should be s Celsius or below, and boratory's P/P (Policy# 2, Title Specimen Colle g, Effective Date 12/07 shipping and transpor in MTM are stable at 2 m temperature) for 7 d uction for storage and stability should be anufacturer's FDA EU/ irus Nucleic Acid Deter VTM, stored at 2-8 degnours after collection. If	ting or te te te tection, (2020) nates tion en ees 24 24 then then that 2-25 lays. A IFU ction grees f a	D5403			

		(X1) PROVIDER/SUPPLIER/C		. ,		(X3) DATE SU		
AND PLAN	PLAN OF CORRECTION IDENTIFICATION NUMBE		ER:	A. BUILDING	G	COMPLET	COMFLETED	
	05D2197416			B. WING		02/1	7/2021	
NAME OF P	ROV DER OR SUPPLIER				ATE, ZIP CODE			
CDPH B	RANCH LABORATOR	Y		LIVINGSTO				
(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 CORREC (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE	
D5403	<ul> <li>09/16/2020 and 01/1</li> <li>(7) The laboratory failits policies and processing processing processing f. Specimen accessing and disposition</li> <li>(1) Review of the lab CA-CLSRV-SOP-002 Collection, Storage at 12/07/2020) indicated Coordinates with CO collection and submits</li> <li>(2) Review of COLOF specimen rejection in i. insufficien media.</li> <li>ii. Dry swab after collection iii. Improper iv. Swabs in swab bud facing up) v.Missing ph vi. Incomple patient infor</li> <li>(3) Review of the lab CA-ACC-SOP-00, Tit Date 12/05/2020) starejection criteria:</li> <li>i. Broken/Damaged/ii. No barcode</li> </ul>	2/2021). iled to specify and inclue dures, the use of MTM <b>ptability, rejection</b> ind shipping, Effective d that CDPH Branch Li- LOR laboratory for speciation. R website for indicated the following: t, incompatible transports is that arrive >56 hours ity capped or labeled tur inverted in collection tub inverted in collection	I. Date ab ecimen vrt bes es (i.e.	D5403				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	( )		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D21974	16	B. WING 02/17/2			
NAME OF PROV DER OR SUPPLIER CDPH BRANCH LABORATO	CDPH BRANCH LABORATORY 28454 VALEN				·	
PREFIX (EACH DEFICIENCY MU	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETIO	N
<ul> <li>laboratory staff on I review of policies at (QC) and quality as random review of p the period from 11/2 out of 60 patient test determined that the to include the step-procedure, including interpretation of rest.</li> <li>Findings included: <ul> <li>a. At the time of i laboratory failed to and procedure for the interpretation of test laboratory staff interdata analysis and in b. The laboratory staff interdata analysis and in b. The laboratory the quality metrics (curves generated frat remote locations personnel for test resinvalid, or inconclus turn- around-time fr reporting of the test approved policy and proceed with accuratest results.</li> <li>c. The following at the 60 randomly revision for the period 12/08/2020, wherei SARS-CoV-2 tests</li> </ul> </li> </ul>	et observation, interviews December 8 and 9, 2020 and procedures, quality of surance (QA) records, atient test records cover 22/2020 to 12/08/2020, for the records reviewed, it will laboratory's procedure by-step performance of g test calculations, and ults. Inspection on 12/08/2020 provide an approved po- est calculations, and the results utilized by the rviewed performing onsi- terpretation. also requested approva- including raw data) and om the PCR test be and by CLIA qualified testime esults of positive, negati- ive in order to shorten to on 12/21/2020 without d procedure on how to the remote reporting of pa- re the accession number viewed patient test record	o, ontrol ing or 60 as failed the 0, the licy te l that alyzed g ve, he to an atient ers of rds	D5403			

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	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		CONSTRUCTION	(X3) DATE S COMPLI	
		05D2197416	B. WING		02	17/2021
			RESS, CITY, STATE			
CDPH BR	ANCH LABORATOR		LIVINGSTON A ICIA, CA 91355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL REGULATORY ENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE AC CROSS-REFERENCED TC DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5403		test calculations, and	D5403			
	declaration signed by 12/16/2020, the labo	00 SARS-CoV-2 test results				

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	T OF DEFICIENCIE	S				. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE		
AND FLAN	OF CORRECTION	CTION IDENTIFICATION NUMBER: 05D2197416 DR SUPPLIER S LABORATORY STATEMENT OF DEFICIENCIES DEFICIENCY MUST BE PRECEDED BY FULL REGU			A. DOILDING		COMPLE	IED		
	05D2197416		16	B. WING		02/*	17/2021			
-	ROV DER OR SUP					ORESS, CITY, ST.	,			
						LIVINGSTON ICIA, CA 913				
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC IDENTIFYING INFORMATION)					ID PREFIX TAG	(EACH CORRECTIVE ACTION SH	/IDER'S PLAN OF CORRECTION CORRECTIVE ACTION SHOULD BE EFERENCED TO THE APPROPRIATE DEFICIENCY)		
D5403 Continued From page 37				D5403						
e. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to ensure include the step-by-step performance of the procedure, including test calculations, and interpretation of results.					n of					
	3. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory's procedure failed to include complete and consistent information on reference intervals (normal values).									
	Findings inc	luded:								
	a. 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) indicated the expected results for the kit with valid quality control as:									
	i. SARS-Co ii SARS-Co iii Invalid									
	IC (VIC/HEX)	N(FAM), OF	(F1ab ROX)	Result Interpr	etation					
	≤ 40 Both targets Undetermined or > 42 SARS-CoV-2 Not Detected									
	/ Both targets ≤ 42 SARS-CoV-2 Detected									
	Ans-CoV-2 Detected           /         One of the targets ≤ 42         SARS-CoV-2 Detected           /         One of the targets ≤ 42         SARS-CoV-2 Detected           >40 or         Both targets         Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.			specimen -tested from or recollected						
	/: No requireme	nt on the Ct	value.							

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2197416				PLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
			16	B. WING		<b>02/</b> 1	17/2021	
	NAME OF PROV DER OR SUPPLIER     STREET ADD       CDPH BRANCH LABORATORY     28454       VALEI							
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE API DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
D5403	<ul> <li>value of the internal contraspecimen is invalid;</li> <li>If the result for a spevalue of the internal contraspecimen is invalid;</li> <li>b. At the time of instaboratory failed to prand procedure for test laboratory staff intervention of test laboratory staff intervention, and revealues).</li> <li>c. The following at the 60 randomly revise covering the period for 12/08/2020, wherein SARS-CoV-2 tests a failed to include com</li> </ul>	cimen is SARS-CoV-2 RNA not o ol must be ≤ 40, otherwise the cimen is SARS-CoV-2 RNA not o ol must be ≤ 40, otherwise the pection on 12/08/2020 rovide an approved po st calculations, and results utilized by the viewed performing onsi ference intervals (norm re the accession numb ewed patient test recor rom 11/22/2020 to the laboratory perform nd reported results but	result of that detected, the Ct result of that , the licy te nal ers of ds ued	D5403				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	AND PLAN OF CORRECTION IDENTIFICATIONNUME 05D21974		B. WING		02/1	7/2021	
NAME OF PROV DER OR SUPPLIER CDPH BRANCH LABORATOR	łY	28454	RESS, CITY, ST. LIVINGSTOM ICIA, CA 913	NAVE			
PREFIX (EACH DEFICIENCY MU	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
<ul> <li>declaration signed to 12/16/2020, the laboratory approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory 12, 2021 at approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory 12, 2021 at approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory 12, 2021 at approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory 12, 2021 at approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory 12, 2021 at approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory 12, 2021 at approximately 430,0 from 11/02/2020 to 1</li> <li>e. The Laboratory failed to 0 and consistent inform (normal values).</li> <li>4. Based on di with laboratory staff review of policies ar (QC) and quality as random review of patheter period from 11/2 out of 60 patient test.</li> </ul>	boratory's annual testir y the laboratory directo oratory reported 00 SARS-CoV-2 test re 2/16/2020. Director affirmed (Febr	or on sults ruary e rvals iews 2020, control ring for 60 as	D5403				

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	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/*	17/2021	
	CDPH BRANCH LABORATORY 28454 VALE				ATE, ZIP CODE N AVE 355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE DENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTION CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
D5403	<ul> <li>policies and procedu Reporting.</li> <li>Findings included:</li> <li>a. At the time of ins 9, 2020, and until Fe laboratory failed to p and procedure for In Reporting.</li> <li>b. The following ar the 60 randomly revi covering the period f 12/08/2020, wherein SARS-CoV-2 tests a failed to provide polici</li> </ul>	ares for Infectious Dise spection on December & bruary 12, 2021, the rovide an approved pol fectious Diseases e the accession numbe ewed patient test recor from 11/22/2020 to the laboratory perform and reported results, bu cies to ensure it compli- ase Reporting required	8 and licy ers of rds ned t ed	D5403				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
NAME OF PROV DER OR SUPPLIER		05D21974	16	B. WING		02/17/2021	
NAME OF PROV DEF				DRESS, CITY, ST	ATE, ZIP CODE		
				LIVINGSTOI NCIA, CA 91:			
(X4) ID PREFIX (EAC TAG	CH DEFICIENCY MUS	ATEMENT 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	
D5403 Con	Continued From page 41			D5403			
C. decla 12/10 appro from d. 12, 2 labor comp requi D5407 PRO CFR Proc appro labor This 1. labor	Based on the lab aration signed by 6/2020, the labor roximately 430,00 11/02/2020 to 12 The Laboratory I 2021 at approxim ratory failed to pro- plied with Infection ired by local, state OCEDURE MANU R(s): 493.1251(d) cedures and char roved, signed, an ratory director be Standard is not r Based on direct of ratory staff on De	poratory's annual testin the laboratory directo ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed (Februately 2:10 pm) the povide policies to ensure pus Disease Reporting te, and federal authorit JAL ages in procedures must d dated by the current	r on sults uary e it ies. st be	D5407			

If continuation sheet Page 42 of 123

STATEMENT OF DEFICIENCIES		(X1) PROVIDER/SUPPLIER/CLIA				. ,	(X3) DATE SURVEY		
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION			IDENTIFICATION NUMBER:		A. BUILDING	3	COMPLI	ETED	
			)5D21974	16	B. WING		02	17/2021	
NAME OF PI	NAME OF PROV DER OR SUPPLIER STREET A				STREET ADD	DRESS, CITY, ST	ATE, ZIP CODE		
CDPH BF									
	VALE				ICIA, CA 91	355			
(X4) ID PREFIX TAG	(EACH DEFICIE	NCY MUS		BY FULL RE		ID PREFIX TAG	PROVIDER'S PLAN OF (EACH CORRECTIVE ACT CROSS-REFERENCED TO 1 DEFICIENC	TON SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5407	Continued F	Continued From page 42							
D5407	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)         7       Continued From page 42 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 the procedure for reporting inconclusive result using the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic was approved, signed, and dated by the laboratory director.         Findings included:         a.       During the first day of the on-site inspection on 12/08/2020, we interviewed laboratory directors and senior operations personnel, and requested for the laboratory's documented investigation and corrective action regarding the increased number of inconclusive patient results.         b.       We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the laboratory's adopted test method, Perkin Elmer New Coronavirus Nucleic Acid Detection Kit. The "Examination and Interpretation of Patient Specimen Results" section showed a table listing the expected results for the kit with valid positive and negative control.         Image: CV/C threshold       Result Interpretation (IC (VIC/HEX) N(FAM), ORF1ab ROX) ≤ 40         Image: Sector Showed a table listing the expected results for the kit with valid positive and negative control.					D5407			
	1	· • · · · · · · · · · · · · · · · · · ·		ARS-CoV-2 De	tected				
	/	• • • • • • • • • • • • • • • • • • • •			¢				
			In	valid result,	specimen				
		-							
	Undetermined	Undeterm			or recollected				
			tr	om patient fo	or test.				

If continuation sheet Page 43 of 123

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		· ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
	05D2197416 B. WING		02/1	02/17/2021			
CDPH BRANCH LABORATORY 2845				RESS, CITY, ST. IVINGSTON CIA, CA 913	AVE		
(X4) ID PREFIX (EAC TAG	CH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
c. In calcul also a to pro Syste interp (i) A labora 2020. (ii) N was a d. I on 12 that p a resu interp e. T condu patier during f. () on-sit patier labora	lating and interp asked the labora ovide the LIMC I em (LIS) and its oretation of patie A policy and pro- ratory was not av Neither an unsig available on Dec Further interview 2/08/2020, indica oatient test resul ult of incorrect of oretation. The following da ucted random sa nt test records v g the first week I On December 1 te at the laborat nt test records. V atory to send via rds and its policy	are how the laboratory preting patient results, tory on December 8, 20 Laboratory Information policy and procedure f ent specimen results. cedure signed by the vailable on December a ned policy and procedu	we 020, for 8, 8, Ire irector bility or as al 32 ed 020. c tional	D5407	DEFICIENCY)		

If continuation sheet Page 44 of 123

	TATEMENT OF DEFICIENCIES ND PLAN OF CORRECTION AME OF PROV DER OR SUPPLIER		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:	· /	CONSTRUCTION	(X3) DATE S COMPLI	
			05D2197416	B. WING		02	/17/2021
		SUPPLIER BORATOR	Y 28454	DRESS, CITY, STATE LIVINGSTON A NCIA, CA 9135	AVE		
(X4) ID PREFIX TAG	(EACH DE	FICIENCY MUS	TATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL REGULATORY DENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE A CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE D THE APPROPRIATE	(X5) COMPLETIC DATE
D5407	<ul> <li>g. The product of the produ</li></ul>	2020 showe annotation of t indicated, 20" the docu as an Initial ve date of I Software Na .2 Detailed Us tions section he following becimen res	or ocedure sent via e-mail on ed the following: on the top portion of "Effective Starting ument version history: document, Version 1.0, with December 13, 2020. ame was identified as LIMC, ser Requirements n of the document, g policy for interpretation of sults. Description tule for the new SOP: ed" Ct cutoff changed from 37 to 42 ROX >37 and <=42 will be called as "Inconclusive"	D5407	DEFICIEN	NCY)	
	laborator laborator specimer result cat	y's adopted y's policy fo n results, sh egory of Inc e was no inc	view of the IFU for the EUA method, and the r interpreting patient owed the laboratory added a conclusive. dication that this document				

If continuation sheet Page 45 of 123

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLI			. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
	05D2197416		16	B. WING		<b>02</b> /1	02/17/2021	
					ate, zip code N AVE 355			
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
D5407	<ul> <li>CA-COMP-FM-001 N signed, and dated by</li> <li>k. This policy and p laboratory's signature indication or verificat director affixed a digi signing and dating the</li> <li>2. Based on direct laboratory staff on Dereview of policies and (QC) and quality ass random review of patthe period from 11/22 out of 60 patient test determined that the I the updated and app signed by the current Perkin Elmer New Certain (RT-PCR) in utilizing Chemagic 36 nucleic acids followe Analytik Jena Therm</li> <li>Findings included: <ul> <li>a. At the time of instal/2/09/2020, there was signed and dated by following:</li> <li>i. Client procedure in the collection sites specimen collection,</li> </ul> </li> </ul>	Version 1.0, was approver the Laboratory Director procedure did not include e. There was also no- ion that the laboratory ital signature approving the document observation, interviewe ecember 8 and 9, 2020 d procedures, quality c urance (QA) records, tient test records cover 2/2020 to 12/08/2020, for records reviewed, it was aboratory failed to prov- roved procedure manu- t laboratory director for pronavirus Nucleic Acid me Polymerase Chain n vitro diagnostic test 50 for the isolation of the d by the RT-PCR assa al Cycler. spection on 12/08/2020 is no updated P/P, appri- the laboratory director for labeling, storage, ortation, processing, references of the isolation of the section of the store of the section of the d by the RT-PCR assa	or. le the g, s with ), ontrol ing or 60 as <i>i</i> ide ials the d e viral y on ) and oved, for the staff	D5407				

If continuation sheet Page 46 of 123

	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02	/17/2021	
	CDPH BRANCH LABORATORY		28454	RESS, CITY, ST LIVINGSTOI CIA, CA 91	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE IT BE PRECEDED BY FULL R ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN O (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE	
D5407	<ul> <li>ii. Step-by-step per including test calcula results.</li> <li>(1). Onsite Data Ana (2). Remote Data Ana (2). Remote Data Ana iii. Reference Interview. iv. Infectious Disea b. The following and the 60 randomly revi covering the period ff 12/08/2020, wherein SARS-CoV-2 tests and</li> </ul>	formance of the proced tions, and interpretations, and interpretations alysis vals (normal values) ses Reporting e the accession numbe ewed patient test recor rom 11/22/2020 to the laboratory perform nd reported results, but ated P/P, approved, sig	ers of rds ied	D5407				

If continuation sheet Page 47 of 123

	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/CLIA		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY	
AND PLAN O	OF CORRECTION	IDENTIFICATIONNUMB	ER:	A. BUILDING	3	COMPLETED	
		05D21974	16	B. WING		02/17/2021	
				RESS, CITY, ST			
CDPH BR	RANCH LABORATOR	Y					
				ICIA, CA 91		0.7	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUI CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE COMPLETIC	ON
D5407	Continued From pag	je 47		D5407			
D5411	<ul> <li>c. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,000 from 11/02/2020 to 12</li> <li>d. The Laboratory I 12, 2021 at approxim laboratory failed to pro- proper instructions to step-by-step test calco interpretation of resul Infectious Disease Re- state, and federal aut TEST SYSTEMS, EQ INSTRUMENTS, RE- CFR(s): 493.1252(a)</li> <li>Test systems must be manufacturer's instru provides test results of performance specific as determined under</li> <li>This Standard is not Based on direct obsel laboratory staff on Designed</li> </ul>	poratory's annual testin the laboratory directory ratory reported 00 SARS-CoV-2 test resons 2/16/2020. Director affirmed (Febric hately 2:10 pm) the ovide policies to ensured o clients, accurate culations, reference inter the porting required by low thorities. QUIPMENT, AGENT e selected by the laboric performed following the ictions and in a manner within the laboratory's ations for each test system ations for each test system of the performed following the performed fol	or on sults ruary e ervals, h ocal, ratory. e r that stated stem	D5411			

If continuation sheet Page 48 of 123

		(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB				(X3) DATE SURVEY COMPLETED		
	05D2197416			B. WING 02/17/2021				
CDPH BRANCH LABORATORY			28454 L	RESS, CITY, STA IVINGSTON CIA, CA 913	AVE			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
D5411	control (QC) and quarandom review of particle period from 11/2: out of 60 patient test determined that the I followed the adopted subsequent revisions changes made in the procedures. Findings included: 1. Review of the lasspecification studies, (IFU) for Perkin Elme Acid Detection Kit, at procedures available inspection, the labora following: a. Decontamination Fi. Review of the labora following: a. Decontamination Fi. Review of the labora following: a. Decontamination Fi. Review of the labora following: b. Review of the labora following: coronavirus Nucleic Date 03/20/2020, Re 01/12/2021) stated up precautions #7 that, filter-tips should be do containing a 10% So After the operation, the instrument surface states freshly prepared 10% solution, and then clepure water. Finally, tworking surfaces for ii. Based on direct of the states of the states for	Ality assurance (QA) redition test records cover 2/2020 to 12/08/2020, for records reviewed, it was aboratory failed to ensu- FDA EUA IFU, the set the EUA IFU, and a laboratory's policies and boratory's performance EUA Instructions for L r New Coronavirus Nuc- nd current policies and during the on-site atory failed to provide the atory failed to provide the Protocol Protocol Protocol Protocol Sterile centrifuge tube isposed into a waste b dium Hypochlorite solu- ne work area surface ar hould be disinfected wi 6 Sodium Hypochlorite eaned with 75% Ethand urn on UV light to disin 30 minutes."	ing for 60 as ure it nd Jse Jse Jse cleic he Vew ective s and in tion. nd the th a ol or fect	D5411				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		· ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/17	7/2021	
	CDPH BRANCH LABORATORY 28454			RESS, CITY, ST LIVINGSTOI CIA, CA 91:	NAVE	·		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE	
D541 <sup>2</sup>	decontamination solu iii Due to safety cond Sodium Hypochlorite laboratory used etha iv. However, contrar concentration in the 70% ethanol, and no v. The laboratory fai manufacturer's instru- vi. The laboratory als performance specific ethanol is an effectiv 10% Sodium Hypoch centrifuge tubes and b. Heat Inactivation i. Review of the la Instructions for Use ( Coronavirus Nucleic. Date 03/20/2020, Re 01/12/2021) did not i procedures for swab ii. Review of the la procedures (Policy # Inactivation of Viral S the following: ii.a. Use of ov ii.b. Pre-cool	ution. erns with using 10% e solution with VTM, the nol. y to the specified ethan IFU, the laboratory, us t 75% ethanol. led to follow uctions specified in the so failed to provide eation studies showing e decontaminant instea lorite solution for discar filter-tips. n of Swab Samples boratory's FDA EUA (IFU) for Perkin Elmer I Acid Detection Kit (Effe evised 09/16/2020 and nclude the heat inactiv	nol ed IFU. 70% ad of rded New ctive ation at ed ius es Celsius	D5411				

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	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		· ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		0	2/17/2021	
CDPH BRANCH LABORATORY 2845			28454	RESS, CITY, ST. LIVINGSTOM ICIA, CA 913	NAVE			
(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 (EACH CORRECTIVE ACT CROSS-REFERENCED TO T DEFICIENC	ION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE	
D541	<ul> <li>iii. The laboratory fail specification studies swab samples.</li> <li>c. Storage Condition nasopharyngeal, oro anterior nasal swabs</li> <li>i. Review of the la Instructions for Use (Coronavirus Nucleic Date 03/20/2020, Ret 01/12/2021) stated the oropharyngeal, and a extracted nucleic acide -15 degrees Celsius.</li> <li>ii. Review of the la procedures (Title CA RNA/DNA Extraction Effective Date 11/03/ nucleic acids should degrees Celsius for I</li> <li>iii. The laboratory famanufacturer's instrutiv. The laboratory famanufacturer's instruction studies changing the storage extracted nucleic acid</li> <li>d. Thermal Cycler</li> <li>i. Review of the la Instructions for Use (Coronavirus Nucleic. Date 03/20/2020, Ret 03/2</li></ul>	led to provide performa for the heat inactivatio ons for pharyngeal, and (Extracted RNA) boratory's FDA EUA (IFU) for Perkin Elmer M Acid Detection Kit (Effe vised 09/16/2020 and nat, "Nasopharyngeal, anterior nasal swabs wit ds should be stored at - boratory's policies and -EXT-SOP-004 Title Via 0 Using the Chemagic 3 2020 stated that, "Extra be stored at -84 to -76 ong term storage." ailed to follow actions specified in the la ailed to provide perform showing the basis for a conditions requiremer ds.	New ective h the 25 to iral 360, acted IFU. ance ht for New ctive	D5411				

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	OF DEFICIEN	- ( )	PROVIDER/SUPP IDENTIFICATION			CONSTRUCTION	(X3) DATE S COMPLI	
			05D2	197416	B. WING		02	17/2021
	ROV DER OR S	BUPPLIER BORATORY		28454	RESS, CITY, STATE LIVINGSTON A ICIA, CA 91355	VE	i	
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D5411	Continue	d From page 51			D5411	DEFICIEN		
	1 37 de 2 50 de 3 42 de 4 94 de 5 94 de 55 de 65 de *Collect f degrees of Review o procedure SARS-Co Effective	Temperature egrees Celsius egrees Celsius egrees Celsius egrees Celsius egrees Celsius egrees Celsius egrees Celsius egrees Celsius egrees Celsius celsius step f the laboratory's es (Policy # CA- V-2-RT-PCR Us Date 11/04/2020 ycler parameters	2 minutes 5 minutes 35 minutes 10 minutes 10 seconds 15 seconds 45 seconds nal during the pcR-SOP-00 sing the Analy 0) stated the f	1 45 final 65 2, Title /tic,				
	Step	Temperature	Time	# of Cycles				
	1	25 degrees Celsius	2 minutes	Not indicated				
	2	50 degrees Celsius	15 minutes	Not indicated				
	3	95 degrees Celsius	2 minutes	Not indicated				
	4	95 degrees Celsius	3 seconds	Not indicated				
	5	60 degrees Celsius	30 seconds	Not indicated				

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			) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/	17/2021	
CDPH BRANCH LABORATORY 24			28454	RESS, CITY, ST LIVINGSTON ICIA, CA 913	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE ST BE PRECEDED BY FULL R ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE	
D5411	Title SARS-CoV-2-R Jena, Effective Date following thermal cyc Step Temperature 1 25 degrees Cels 2 50 degrees Cels 3 95 degrees Cels 4 95 degrees Cels 5 60 degrees Cels *Collect fluorescence degrees Celsius step iv. The instruction to during the final 60 de specified in laborator (ii) and d (iii) is not th the IFU, which indica signal during the fina v. The laboratory fa manufacturer's instru- vi. The laboratory fa performance specific the above-described parameters. e. Interpretation of i. Review of the FI Coronavirus Nucleica Date 03/20/2020, Re 01/12/2021) stated th kit with valid quality of	ne policies and proced T-PCR Using the Anal 11/04/2020, indicated clers dated 10/27/2020 e Time # of Cy ius 2 minutes 1 ius 15 minutes 1 ius 3 seconds 1 ius 3 seconds 1 ius 30 seconds 45 e signal during the final o "Collect fluorescences egrees Celsius step" y procedures identified the same as the instruct ated "Collect fluorescences alled to follow uction specified in the II ailed to provide the cation studies to suppor change in thermal cyc Test Results DA EUA IFU for PE Net Acid Detection Kit (Effe evised 09/16/2020 and ne expected results for	ytic the rcles foo signal d in d ion in nce tep." =U. =U. rt ler ew ctive the	D5411				
	i.b.SAF	RS-CoV-2 Detected						

	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SU ID PLAN OF CORRECTION IDENTIFICATIO			. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING	_	02/	17/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST. LIVINGSTOM ICIA, CA 913	NAVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE ST BE PRECEDED BY FULL RI JENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OI (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D541 <sup>-</sup>	Continued From pag	ge 53		D5411			
	i.c.Inv	valid					
	Director on 12/08/20 laboratory should be ii.a.SARS-Co ii.b.SARS-Co ii.c.Inconclus ii.d. Invalid iii. At the time of insp 12/09/2020, the labo performance specific updated interpretatio inconclusive result. 2. The following an the 60 randomly revi covering the period f 12/08/2020, wherein SARS-CoV-2 tests a failed to establish its	pection on 12/08/2020 a ratory failed to provide cation studies to suppo on of test results, to incl e the accession numbe ewed patient test recor	e : and rt the lude ers of rds ned it ostic				

If continuation sheet Page 54 of 123

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/17/2021		
CDPH BRANCH LABORATORY 284				RESS, CITY, STA IVINGSTON CIA, CA 913	AVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRC DEFICIENCY)	_D BE	(X5) COMPLETION DATE	
D541 <sup>-</sup>	<ol> <li>Based on the lat declaration signed by 12/16/2020, the labor approximately 430,000 from 11/02/2020 to 12</li> <li>The Laboratory I 12, 2021 at approxim laboratory's failure to instructions specified director also affirmed performance specific modification of the pro FDA EUA IFU. The la affirmed the laborato RT-PCR in vitro diag</li> </ol>	poratory's annual testin the laboratory director ratory reported 00 SARS-CoV-2 test reso 2/16/2020. Director affirmed (Febr hately 2:10 pm) the follow manufacturer's in the IFU. The laboral the absence of ation studies to support bocedure not indicated in aboratory director also ry failed to establish its nostic test P/P that inc a" through "1e", above. QUIPMENT,	or on sults uary atory rt the n the s luded	D5411				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/C		. ,	PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED	
AND FLAN	AND PLAN OF CORRECTION			A. BOILDING	<u> </u>	COMPLET	ED
	05D2197416			B. WING		02/1	7/2021
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D5415	Continued From pag	je 55		D5415			
	<ul> <li>materials, calibration supplies, as approprindicate the following (1) Identity and when or concentration.</li> <li>(2) Storage requirem (3) Preparation and e Other pertinent inform.</li> <li>This Standard is not Based on direct obset laboratory staff on Dereview of policies and control (QC) and qua random review of palt the period from 11/22 out of 60 patient test determined that the I labeled the reagents.</li> <li>Findings included:</li> <li>Review of the lal procedures (Policy # Labeling of Reagents: Date 12/09/2020) station labeling reagents:</li> <li>a. Name of the reagents</li> <li>a. Name of the reagents</li> <li>b. Expiration Date c. Initials of the period in the period is the period in the period is the period in the period is the period is the period is the period from 11/22 out of 60 patient test determined that the I labeled the reagents</li> <li>Findings included:</li> <li>Review of the lal procedures (Policy # Labeling of Reagents: Date 12/09/2020) station labeling reagents: a. Name of the reagents</li> <li>Expiration Date c. Initials of the period is the period is the period is the period is the period. Date of preparation period is the period. Date of preparation period is the period is the</li></ul>	a significant, titer, stren ents. expiration dates. mation required for pro- met as evidenced by: ervation, interviews with ecember 8 and 9, 2020 d procedures (P/P), qu lity assurance (QA) rec- tient test records cover 2/2020 to 12/08/2020, f records reviewed, it wa aboratory failed to ensi- as required. boratory's policies and CA-LABGEN-SOP-00. s and Solutions, Effecti- ted the following inform gent or solution rson preparing the labe ion, filtered, or aboratory (if applicable ns (e.g., temperature,	o gth pper use. n ), ality ords, ing for 60 as ure it 2 ve ation				

If continuation sheet Page 56 of 123

STATEMENT OF DEFICIENCIES (X AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/	17/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. LIVINGSTON CIA, CA 913	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIC CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE IE APPROPRIATE	(X5) COMPLETION DATE	
D5418	Continued From pag	ge 56		D5415				
	<ol> <li>2. During the laboration approximately 10:00 found with the follow properly:</li> <li>a. Elution Buffer x</li> <li>b. Magnetic Buffer</li> <li>c. Milli Q Water x 3 person, date preson, dat</li></ol>	ory tour on 12/08/2020 a.m., the laboratory w ving reagents not label 1- No initial of the perso x1 - No initial of the per - No expiration date, in epared, storage condition e the accession number ewed patient test recom	as ed on erson itial of the on. ers of rds					

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STATEMENT OF DEFICIENCIES		(X1) PROVIDER/SUPPLIER/CLIA				(X3) DATE SURVEY COMPLETED	
		IDENTIFICATIONNUMB	IDENTIFICATION NUMBER:		3	COMPLET	ED
	05D2197416			B. WING		02/1	7/2021
-	ROV DER OR SUPPLIER			DRESS, CITY, ST			
CDPH BF	ANCH LABORATOR	Ŷ		LIVINGSTOI NCIA, CA 91:			
(X4) ID         SUMMARY STATEMENT OF DEFICIENCIES           PREFIX         (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY           TAG         OR LSC IDENTIFYING INFORMATION)				ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5415	Continued From pag	je 57		D5415			
D5417	<ol> <li>Based on the lat declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12</li> <li>The Laboratory ( February 12, 2021 a 2:10 pm) the laborator the reagents utilized</li> <li>TEST SYSTEMS, EQ INSTRUMENTS, RE CFR(s): 493.1252(d)</li> <li>Reagents, solutions, materials, calibration supplies must not be exceeded their expirator or are of substandard</li> <li>This Standard is not Based on direct obset laboratory staff on Do review of policies and control (QC) and qua random review of pai the period from 11/22 out of 60 patient test</li> </ol>	poratory's annual testin / the laboratory director ratory reported 20 SARS-CoV-2 test rest 2/16/2020. Director affirmed approximately pry's failure to label for testing. QUIPMENT, AGENT culture media, control materials, and other used when they have ation date, have deteriored d quality. met as evidenced by: ervation, interviews with ecember 8 and 9, 2020 d procedures (P/P), qu lity assurance (QA) rection 2/2020 to 12/08/2020, 1 records reviewed, it we aboratory failed to ens	r on sults rated, n ), ality ords, ring for 60 as	D5417			

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	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB			PLE CONSTRUCTION	(X3) DATE SU COMPLE	
74401 644							
		05D21974	0	B. WING		02/	17/2021
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CDPH B	RANCH LABORATOR	Y		LIVINGSTOI ICIA, CA 91:			
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
D5417	Continued From pag	ge 58		D5417			
	expiration dates.						
	Findings included:						
	<ol> <li>During the labor approximately 1 observed to hav Solution in dispo- expiration date.</li> <li>a.1. Lot # 26701</li> <li>12/03/2020 (2 disper a.2. Lot # A1001</li> <li>12/07/2020 (2 disper</li> <li>Review of the la procedures (Policy # Quality Management 11/01/2020) stated th should be used in test indicated expiration of</li> <li>The following and the 60 randomly revi- covering the period ff 12/08/2020, wherein SARS-CoV-2 tests a</li> </ol>	5, ExpirationDate: nsing bottles) (2002B, ExpirationDate nsing bottles) boratories policies and CA-QM-SOP-001, title Plan, Effective Date at reagents and chemic sting process within the date. e the accession number ewed patient test recor	ry was eaning its : : : : : : : : : : : : : : : : : : :				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
			7/2021					
_	OV DER OR SUPPLIER	Y	28454 L	RESS, CITY, STA IVINGSTON CIA, CA 913				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D5417	declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 5. The Laboratory 12, 2021 at approxim laboratory failed to m of its 70% Ethanol cle decontamination proc	poratory's annual testin y the laboratory directo ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed (Febr hately 2:10 pm) the ponitor the expiration da eaning solution utilized cedure.	r on sults uary ates in	D5417				
D5423	PERFORMANCE CFR(s): 493.1253(b)	ND VERIFICATION OF (2) modifies an FDA-clear		D5423				
		n, or introduces a test s						

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	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C		. ,		(X3) DATE SU	
AND PLAN (	OF CORRECTION	IDENTIFICATIONNUMB	ER:	A. BUILDING	3	COMPLE	TED
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NAME OF PI	ROV DER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Y		LIVINGSTO			
			VALEN	ICIA, CA 91:	355		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 60			ID PREFIX TAG	PROVIDER'S PLAN OF CORRI (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D5423	Continued From pag	je 60		D5423			
D5423	<ul> <li>(including methods d standardized method procedures), or uses performance specific the manufacturer mu test results, establish performance specific performance charact (2)(i) Accuracy.</li> <li>(2)(ii) Precision.</li> <li>(2)(ii) Analytical species (2)(iv) Analytical species substances.</li> <li>(2)(iv) Reportable ran system.</li> <li>(2)(v) Reportable ran system.</li> <li>(2)(vi) Reference inter (2)(vi) Reference inter (2)(vii) Any other performance description required for test performance to be laboratory staff on Dereview of the laborator EUA IFU Perkin Elmer Acid Detection Kit Reference inter (QA) records, random records covering the 12/08/2020, for 60 our reviewed, it was deter failed to establish and specifications prior to results.</li> <li>Findings included:</li> <li>Review of the laborator</li> </ul>	eveloped in-house and ls such as text book a test system in which ations are not provided st, before reporting par- for each test system t ations for the following eristics, as applicable: sitivity. cificity to include interfe- ge of test results for the ervals (normal values). formance characteristic ormance. met as evidenced by: ervation, interviews with ecember 8 and 9, 2020 ory's adopted FDA Appr er New Coronavirus Nit eacl Time Polymerase C policies and procedures (QC) and quality assum n review of patient test period from 11/22/202 ut of 60 patient test rec- ermined that the labora	a by tient he ering e test c n o, oved ucleic chain s rance 0 to ords tory	D5423			
		Acid Detection Kit, and					

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PREFIX (FACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (FACH CORRECTIVE ACTION SHOULD BE COM		OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/ IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED	
CDPH BRANCH LABORATORY         24454 LIVINGSTON AVE VALENCIA, CA 91355           (%4).0 MEEX TKG         SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PERCEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)         0 PREIX TKG         PROVIDER® PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)         0 DEFICIENCY)           D5423         Continued From page 61         D5423           current policies and procedures, the laboratory failed to provide documentation of established performance specifications for the performance characteristics listed in "a." through "f." as follows:         a. Clinical Performance Evaluation for specimens collected from asymptomatic individuals.         a. Clinical Performance Evaluation for specimens collected from asymptomatic individuals.         i. Review of the laboratory's FDA EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that. "Your product is a test for the qualitative detection of nucleic acid from SARS-COV-2 in human oropharyngeal and nasopharyngeal swab specimens collected by a HCP or self- collected under the supervision of a HCP form ANY INDIVIDUAL, including without symptoms or other reasons to suspect COVID-19 infection."         i. Review of the same EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) also stated that, "Perkin Elmer MUST further evaluate the collinical evaluation study within 30 calendar days of the date of this         iiiiii allowidia asin an FDA agreed upon post authorization collicial evaluation study within 30 calendar days of the date of this			05D21974	16	B. WING 02/17/20			7/2021
Prefix TAG         (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)         PREVX TAG         (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)         PREVX TAG           D5423         Continued From page 61         D5423           current policies and procedures, the laboratory failed to provide documentation of established performance specifications for the performance characteristics listed in "a." through "f." as follows:         a.           a.         Clinical Performance Evaluation for specimens collected from asymptomatic individuals.         i.           i.         Review of the laboratory's FDA EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal and nasopharyngeal swab specimens collected by a HCP or self- collected under the supervision of a HCP from ANY INDIVIDUAL, including without symptoms or other reasons to suspect COVID-19 infection."           ii.         Review of the same EUA and IFU for Perkin Elmer MWST further evaluate the clinical performance from ASYMPTOMATIC individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this	CDPH BRANCH LABORATORY 28454			28454 L	IVINGSTO	NAVE	1	
<ul> <li>current policies and procedures, the laboratory failed to provide documentation of established performance specifications for the performance characteristics listed in "a." through "f." as follows:</li> <li>a. Clinical Performance Evaluation for specimens collected from asymptomatic individuals.</li> <li>i. Review of the laboratory's FDA EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test 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 collected by a HCP or self- collected under the supervision of a HCP from ANY INDIVIDUAL, including without symptoms or other reasons to suspect COVID-19 infection."</li> <li>ii. Review of the same EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) also atted that, "Perkin Elmer MUST further evaluate the clinical performance from ASYMPTOMATIC individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this</li> </ul>	PREFIX	(EACH DEFICIENCY MUS	ST BE PRECEDED BY FULL R		PREFIX	(EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR	LD BE	(X5) COMPLETION DATE
<ul> <li>specifications for the performance characteristics listed in "a." through "f." as follows:</li> <li>a. Clinical Performance Evaluation for specimens collected from asymptomatic individuals.</li> <li>i. Review of the laboratory's FDA EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal and nasopharyngeal swab specimens collected by a HCP or self- collected under the supervision of a HCP from ANY INDIVIDUAL, including without symptoms or other reasons to suspect COVID-19 infection."</li> <li>ii. Review of the same EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) also stated that, "Perkin Elmer MUST further evaluate the clinical performance from ASYMPTOMATIC individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this</li> </ul>	D5423	current policies and procedures, the laboratory failed			D5423			
<ul> <li>specimens collected from asymptomatic individuals.</li> <li>i. Review of the laboratory's FDA EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test 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 collected by a HCP or self-collected under the supervision of a HCP from ANY INDIVIDUAL, including without symptoms or other reasons to suspect COVID-19 infection."</li> <li>ii. Review of the same EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) also stated that, "Perkin Elmer MUST further evaluate the clinical performance from ASYMPTOMATIC individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this</li> </ul>		to provide document specifications for the	tation of established pe e performance characte	erformance				
Perkin Elmer New Coronavirus Nucleic Acid         Detection Kit (01/12/2021) stated under the         product authorization that, "Your product is a test         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         collected by a HCP or self- collected under the         supervision of a HCP from ANY INDIVIDUAL,         including without symptoms or other reasons to         suspect COVID-19 infection."         ii. Review of the same EUA and IFU for Perkin         Elmer New Coronavirus Nucleic Acid Detection         Kit (01/12/2021) also stated that, "Perkin Elmer         MUST further evaluate the clinical performance         from ASYMPTOMATIC individuals in an FDA         agreed upon post authorization clinical evaluation         study within 30 calendar days of the date of this		specimens collected						
ii. Review of the same EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) also stated that, "Perkin Elmer MUST further evaluate the clinical performance from ASYMPTOMATIC individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this		Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test 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 collected by a HCP or self- collected under the supervision of a HCP from ANY INDIVIDUAL,						
submission to FDA." It was also stated under the kit limitations that, "nasal swab specimens self-collected under the supervision of or collected by a healthcare provider performance has not been determined." iii. The laboratory must provide its protocol and clinical performance evaluation from asymptomatic individuals, as stated by the		ii. Review of the sam Elmer New Coronavi Kit (01/12/2021) also MUST further evalua from ASYMPTOMAT agreed upon post aut study within 30 calen letter. Labeling upda submission to FDA." It was also stated "nasal swab specime supervision of or coll provider performance	the EUA and IFU for Perinus Nucleic Acid Detect o stated that, "Perkin El ate the clinical performa rIC individuals in an FE thorization clinical evalu- that days of the date o tes must be made after under the kit limitations ens self-collected under lected by a healthcare e has not been determ st provide its protocol a evaluation from	ction Imer ance DA Jation f this r s that, r the ined."				

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/0 IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
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D5423	<ul> <li>.under the "Condition</li> <li>v. The laboratory mulevaluation for nasal self-collected under the collected by a health</li> <li>b. Decontamination</li> <li>i. Review of the labor Use (IFU) for Perkin Acid Detection Kit (E09/16/2020 and 01/1 and precautions #7 the filter-tips should be disted to containing a 10% So the operation, the work surface should be disted to be sufface should be disted to be solved by the text of the laboratory staff of was utilizing 70% Ether laboratory staff of was utilizing 70% Ether laboratory staff of the laborato</li></ul>	s of Authorization." st provide the performa swab specimens the supervision of or care provider. n Protocol ratory's FDA EUA Instr Elmer New Coronaviru ffective Date 03/20/20/ 2/2021) stated under v hat, "Sterile centrifuge lisposed into a waste b dium Hypochlorite solu ork area surface and th sinfected with a freshly horite solution, and the pure water. Finally, tur ting surfaces for 30 mir pservation and interview n 12/08/2020, the labo nanol as their general ution. serns in using 10% Soc n with VTM, the laborat y to the specified n in the IFU, the ethanol, and not 75% led to follow actions specified in the so failed to specification	uctions for is Nucleic 20, Revised varnings tubes and in ution. After e instrument prepared in cleaned in on UV nutes." w with ratory	D5423			

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/0 IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 l	RESS, CITY, ST. LIVINGSTON CIA, CA 91:	NAVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	JLD BE	(X5) COMPLETION DATE
	tubes and filter-tips. c. Heat Inactivation i. Review of the la Instructions for Use ( Coronavirus Nucleic, Date 03/20/2020, Re	n for discarded centrifu n of Swab Samples boratory's FDA EUA (IFU) for Perkin Elmer I Acid Detection Kit (Effe evised 09/16/2020 and	New ctive				
	<ul> <li>01/12/2021) did not include the heat inactivation procedures for swab samples.</li> <li>ii. Review of the laboratory's policies and procedures (Policy # CA-EXT-SOP-001 Heat Inactivation of Viral Swab Samples indicated the following:</li> <li>ii.a.Use of oven to 70 degrees Celsius</li> <li>ii.b.Pre-cool centrifuge to 20 degrees Celsius</li> <li>ii.c. The use of centrifuge at 1200 RPM for 1 minute</li> </ul>						
	<ul> <li>the heat inactivation</li> <li>d. Storage Conditiona nasopharyngeal, oro anterior nasal swabs</li> <li>i. Review of the la Instructions for Use (Coronavirus Nucleic Date 03/20/2020, Ret 01/12/2021) stated the oropharyngeal, and a extracted nucleic acide -15 degrees Celsius.</li> <li>ii. Review of the la</li> </ul>	ons for pharyngeal, and (Extracted RNA) boratory's FDA EUA (IFU) for Perkin Elmer Acid Detection Kit (Eff evised 09/16/2020 and nat, "Nasopharyngeal, anterior nasal swabs wit ds should be stored at -	New ective th the -25 to				

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/ AND PLAN OF CORRECTION IDENTIFICATIONNUME					LE CONSTRUCTION	(X3) DATE SU COMPLE	
	05D2197416			B. WING		02/1	17/2021
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(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D5423	RNA/DNA Extraction Effective Date 11/03/ nucleic acids should degrees Celsius for la specification studies conditions requireme acids. e. Thermal Cycler I i. Review of the la Instructions for Use ( Coronavirus Nucleic/ Date 03/20/2020, Re 01/12/2021) stated th set-ups: Step Temperature 1 37 degrees Cels 2 50 degrees Cels 3 42 degrees Cels 5 94 degrees Cels 5 94 degrees Cels 55 degrees Cels 65 degrees Cels 65 degrees Cels *Collect fluorescence degrees Celsius step ii. Review of the la procedures (Policy # SARS-CoV-2-RT-PC	Using the Chemagic 3 (2020 stated that, "Extr be stored at -84 to -76 ong term storage." ed to provide performa to support the storage ent for extracted nucleio Parameters boratory's FDA EUA IFU) for Perkin Elmer I Acid Detection Kit (Effe- vised 09/16/2020 and he following thermal cy e Time # of Cy ius 2 minutes 1 ius 5 minutes 1 ius 35 minutes 1 ius 35 minutes 1 ius 10 seconds ius 15 seconds 45 ius 45 seconds e signal during the final oboratory's policies and CA-PCR-SOP-002, Ti R Using the Analytik 11/04/2020) stated the	racted ance c New ctive rcler rcles I 65	D5423			

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	EMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2197416						PLE CONSTRUCTION		(X3) DATE SUI COMPLET	
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D5423	Continued	From page	e 65			D5423				
	Step	Temperat	ture Time	1	‡ of Cycles					
	1	25 degre Celsiu	2 minute	s N	ot indicated					
	2	50 degre Celsiu	<ul> <li>15 minute</li> </ul>	s N	ot indicated					
	3	95 degre Celsiu	2 minute	s N	ot indicated					
	4 95 degrees Celsius 3 seconds Not indicated									
	5 60 degrees Celsius 30 seconds Not indicated									
	<ul> <li>iii. Review of the same policies and procedures Title SARS-CoV-2-RT-PCR Using the Analytik Jena, Effective Date 11/04/2020, indicated the following thermal cyclers dated 10/27/2020.</li> <li>Step Temperature Time # of Cycles 1 25 degrees Celsius 2 minutes 1</li> <li>2 50 degrees Celsius 15 minutes 1</li> <li>3 95 degrees Celsius 2 minutes 1</li> <li>4 95 degrees Celsius 3 seconds 1</li> <li>5 60 degrees Celsius 30 seconds 45</li> <li>*Collect fluorescence signal during the final 60 degrees Celsius step</li> <li>iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step "specified in laboratory procedures identified in d(ii) and d(iii) is not the same as the instruction in the IFU, which indicated "Collect fluorescence signal during the final 65 degrees Celsius step."</li> <li>v. The laboratory failed to provide performance</li> </ul>									
	specification	n studies t	o support the a hermo cyclerp	bove-						

STATEMEN	T OF DEFICIENCIES			. ,	PLE CONSTRUCTION	(X3) DATE SU	
AND PLAN	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER: 05D2197416				3	COMPLE	TED
		05D21974	16	B. WING		02/*	17/2021
NAME OF P	ROV DER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE		
CDPH B	RANCH LABORATOR	Y		LIVINGSTO			
			VALEN	CIA, CA 91	355		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D5423	D5423 Continued From page 66						
	f. Interpretation of Test Results						
	Nucleic Acid Detection Revised 09/16/2020 a expected results for the i.a. SARS-Co i.b. SARS-Co i.c. Invalid ii. Based on interview 12/08/2020 and 12/09 reporting the following ii.a. SARS-C ii.b. SARS-C ii.b. SARS-C ii.c. Inconclu ii.d. Invalid iii. The laboratory add expected results. At the 12/08/2020 and 12/09 provide performance so interpretation of test results.	oV-2 Not Detected oV-2 Detected isive ed "inconclusive" to the time of inspection or 0/2020, the laboratory fa specification studies for	/20/2020, the control as: rector on hould be e list of ailed to r updated ers of				
	covering the period f 12/08/2020, wherein procedure listed in th	rom 11/22/2020 to the laboratory modified he IFU of the SARS-Co orted results, but failed	d the V-2				
	specifications for the characteristics enum	performance lerated in "1 a. through p-by-step performance alculations, and					
	Accession Number						

If continuation sheet Page 67 of 123

	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA D PLAN OF CORRECTION IDENTIFICATIONNUMBER:				PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/17/2021	I
	CDPH BRANCH LABORATORY 28454 VALE						
(X4) ID PREFIX (E/ TAG	ACH 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 COMP	X5) PLETION ATE
3. dec 12/ app fror 4. 12, labo app	claration signed by /16/2020, the labor proximately 430,00 m 11/02/2020 to 12 The Laboratory I , 2021 at approxim poratory failed to pro plicable performan	poratory's annual testin the laboratory director ratory reported 00 SARS-CoV-2 test res	r on sults uary or the s.	D5423			
D3433 IMA			,	D5433		ontinuation sheet Page 68	

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:				. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17/202	21
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913		•	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	_D BE CO	(X5) MPLETION DATE
D5433	CFR(s): 493.1254(b) For equipment, instru developed in-house, modified by the labor function check protoco manufacturer, the lab maintenance protoco instrument, and test a necessary for accura and test result report perform and docume specified in paragrap This Standard is not Based on direct obse laboratory staff on Do review of policies and control (QC) and qua random review of pai the period from 11/22 out of 60 patient test determined that the I the established main centrifuges were per Findings included: 1. Review of the la procedures (Policy # Quality Management 11/01/2020) stated the every day of laborato instrument is not use workday, the log mus was not used."	(1) uments, or test systems commercially available atory, or maintenance cols are not provided by poratory must establish of that ensures equipme system performance the te and reliable test res ing. The laboratory mu nt the maintenance acti h (b)(1)(i) of this sectio met as evidenced by: ervation, interviews with ecember 8 and 9, 2020 d procedures (P/P), qua- lity assurance (QA) rec tient test records cover 2/2020 to 12/08/2020, f records reviewed, it wa aboratory failed to ensu- tenance protocol for formed and documente boratory's policies and CA-QM-SOP-001, Title Plan, Effective Date nat, "Logs are annotate	e and and y the a ent, at is ults st vities n. or ality ords, ing for 60 as ure d. e e e d a sure d.	D5433			

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB			PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING	<u> </u>	02/ <sup>.</sup>	17/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE IENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE IE APPROPRIATE	(X5) COMPLETION DATE
D5433	<ul> <li>did not annotate eve operation.</li> <li>a. Centrifuge SN # on 12/02/2020, 12/03 12/05/2020.</li> <li>3. The following are the 60 randomly revi covering the period f 12/08/2020, wherein</li> </ul>	ry day of laboratory JBR20K009, not annot 3/2020, 12/04/2020, an e the accession number ewed patient test recor from 11/22/2020 to the laboratory failed to ed maintenance protoc	d rs of ds	D5433			

If continuation sheet Page 70 of 123

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:				PLE CONSTRUCTION	(X3) DATE SUF COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5433	<ul> <li>4. Based on the lat declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12</li> <li>5. The Laboratory (February 12, 2021 at the laboratory failed fmaintenance was per ANALYTIC SYSTEM CFR(s): 493.1289(a)</li> <li>(a) The laboratory minimum written policies and pmechanism to monitor indicated, correct procanalytic systems assessment?</li> <li>This Standard is not Based on direct observation of 60 patient test determined that the I and follow written polong mechanism</li> </ul>	poratory's annual testin y the laboratory directo ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed tt approximately 2:10 p to ensure centrifuge formed and documente IS QUALITY ASSESSM (c) ust establish and follow procedures for an ongo or, assess, and when oblems identified in the cified in 493.1283. ust document all analyt	r on sults m) ed. /IENT / ing ic ic ic ic ic ic ic ic ic ic ic ic ic	D5433			

If continuation sheet Page 71 of 123

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
-	CDPH BRANCH LABORATORY 28454 VALE			RESS, CITY, ST. IVINGSTON CIA, CA 913	NAVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5791	<ul> <li>analytic systems spect through 493.1254.</li> <li>Findings included:</li> <li>1. Review of the laprocedures (Policy # Management Plan, E include an ongoing n document quality issi</li> <li>a. The laboratory famanuals for the Perk Nucleic Acid Detection Chain Reaction (RT- were established, av laboratory staff (See</li> <li>b. The laboratory famanuals for Perkin E Nucleic Acid Detection Chain Reaction (RT- were established, av laboratory staff (See</li> <li>b. The laboratory famanuals for Perkin E Nucleic Acid Detection Chain Reaction (RT- utilizing Chemagic 36 nucleic acids followe Analytik Jena Therm requirements specifie - (b)(14) (See D5403)</li> <li>c. The laboratory fa procedure manuals ff Coronavirus Nucleic. Polymerase Chain R diagnostic test utilizir isolation of the viral r RT-PCR assay on An were approved, signed Laboratory Director ( d. The laboratory fa</li> </ul>	cified in CFR 493.1251 boratory's policies and CA-QM-SOP-001, Qu ffective 11/01/2020) fai nechanism to perform of ues regarding the follow ailed to ensure the proc cin Elmer New Coronavion on Kit Real Time Polym PCR) in vitro diagnosti ailable, and followed b D5401). ailed to ensure the proc Elmer New Coronavirus on Kit Real Time Polym PCR) in vitro diagnosti 30 for the isolation of the d by the RT-PCR assa al Cycler met all the ed in 42 CFR 493.1251 b). ailed to ensure the upd for Perkin Elmer New Acid Detection Kit Real eaction (RT-PCR) in vin g Chemagic 360 for the nucleic acids followed the nalytik Jena Thermal C ed and dated by the cu	ality led to or wing: edure rirus herase c test y the edure c test e viral y on (b)(1) lated Time itro he by the cycler, irrent	D5791			

If continuation sheet Page 72 of 123

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING		02/	17/2021
	CDPH BRANCH LABORATORY 2845 VAL				ATE, ZIP CODE I AVE 855		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN O (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D579^	to the EUA IFU, and laboratory's policies D5411). e. The laboratory f reagents as required f. The laboratory f decontamination solu RT-PCR have not ex (See D5417). g. The laboratory f verified, and docume specification charact approved SARS-Cov h. The laboratory f established mainten centrifuges were per (SeeD5433). 2. The following are the 60 randomly revi covering the period f 12/08/2020, wherein establish and follow procedures for an or monitor, assess, and	changes made in the and procedures (See failed to ensure it labele (See D5415). failed to ensure it monit ution used for SARS-C acceeded the expiration failed to ensure it estable ented the performance eristics for its modified V-2 RT-PCR (See D542 failed to ensure the ance protocol for formed and documente e the accession number ewed patient test recor from 11/22/2020 to the laboratory failed to	tored oV-2 date ished, FDA 23). ed rs of rds	D5791			

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	ENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IN OF CORRECTION IDENTIFICATIONNUMBER:			. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
	05D2197416			B. WING		02/1	02/17/2021	
	OV DER OR SUPPLIER			RESS, CITY, ST		-		
CDPH BR	ANCH LABORATOR	Ŷ		LIVINGSTOI ICIA, CA 913				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	_D BE	(X5) COMPLETION DATE	
D5791	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 4. The Laboratory I 12, 2021 at approxim	poratory's annual testin y the laboratory directo ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed (Febr ately 2:10 pm) the nsure there was an ong r, assess and when	r on sults uary	D5791				
D5800	POSTANALYTIC SY CFR(s): 493.1290	STEMS		D5800				
	must meet the applic	performs nonwaived te able postanalytic syste .1291 unless HHS app	ems					

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	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
	05D2197416			B. WING		02/1	02/17/2021	
CDPH BRANCH LABORATORY 2845			28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 91:				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5800	<ul> <li>a procedure specifies</li> <li>Operations Manual (requivalent quality tess monitor and evaluate postanalytic systems problems as specifie specialty and subspective subsection of the severith herein, it was determs Postanalytic Systems by CLIA in Subpart K Federal Regulation.</li> <li>Findings included: <ol> <li>The laboratory f system(s) it used, act transmitted patient-sidata entry to final rep D5801).</li> <li>The laboratory fareference intervals determed and the correct sARS-CoV-2 (See D3).</li> <li>The laboratory fareference intervals determed and the several for the individual responsible (See D5807).</li> <li>The laboratory fareference intervals determed and the several for the individual responsible (See D5807).</li> </ol> </li> </ul>	d in Appendix C of the CMS Pub. 7) that provi sting. The laboratory m e the overall quality of the and correct identified d in §493.1299 for each ecialty of testing perform met as evidenced by: y of the deficiencies cith ined that the condition is was not met as mand C of Title 42 of the Code ailed to ensure the elect curately and reliably pecific data from the po- port destination. (See ailed to ensure its test re- interpretation for 95805). ailed to ensure its accu- etermined by the labora e authorized person, or e for using the test resu- ailed to ensure it update g changes in the lts (See D5809). ailed to ensure it update pratory failed to release	des ust he h ned. ed lated e of tronic bint of bint of esults rate tory ults ed	D5800				

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	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIE AND PLAN OF CORRECTION IDENTIFICATION NUL				PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
7000 2000	AND PLAN OF CORRECTION IDENTIFICATION NUMBER			B. WING		02/17/2021	
						02/17	/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	v		RESS, CITY, ST. LIVINGSTOI	,		
ODI II DI				CIA, CA 91			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5800	Continued From pag	je 75		D5800			
	<ul> <li>6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821)</li> <li>7. The laboratory failed to establish and follow</li> </ul>						
	7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)						
D5801	01 TEST REPORT CFR(s): 493.1291(a)			D5801			
	electronic system(s) results and other pati accurately and reliable entry (whether interfa- final report destination includes the following (a)(1) Results reported (a)(2) Results and pare electronically reporter systems. (a)(3) Manually trans- transmitted results and information reported outside referral labor point-of-care testing This Standard is not Based on direct obsec laboratory staff on De- review of policies and control (QC) and qua- random review of pati- the period from 12/04 out of 32 patient test	ly sent from the point of aced or entered manua in, in a timely manner. g: ed from calculated data atient-specific data d to network or interfact cribed or electronically nd patient-specific directly or upon receip atories, satellite or	data Ily) to This a. ced t from 2020, ality ords, ing for 32 as				

If continuation sheet Page 76 of 123

	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/ IDENTIFICATIONNUMB				(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17/2021	
NAME OF P	ROV DER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Y		LIVINGSTOI			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL R ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETION	
D5801	Continued From pag	je 76		D5801			
	the electronic system	n(s) it used accurately	and				
		atient-specific data, fro final report destination					
	Findings included:						
		ubcontracts the prean ses of testing to an ou					
		B final patient test repo atory on 01/06/2021 we e" for SARS-CoV-2.					
	<ul> <li>a. The laboratory LIMC LIS report sent by the laboratory to the examiners via e-mail on 12/22/2020 showed a result of "Not Detected" for SARS-CoV-2.</li> <li>b. The final test result generated by COLOR showed a final result of "Negative"</li> </ul>						
		NC.	-				
		LIMC Final Test Report					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					
	Not	Detected Negative for SARS-CoV-2					

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	MENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIE LAN OF CORRECTION IDENTIFICATIONNU			. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		JRVEY TED	
		05D21974	16	B. WING		02/17		
CDPH BRANCH LABORATORY 284				RESS, CITY, ST. LIVINGSTON CIA, CA 91:				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE	
D5801	<ul> <li>3. Review of the e- the Director of Clinica and review of the 32 by the examiners on 1</li> <li>a. Thirteen (13) pa as "Not Detected" wh reported "Inconclusiv Reported as Not Det reported as Inconclus</li> <li>b. Nineteen (19) pa reported as "Inconclus"</li> </ul>	mail communication so al Informatics on 12/13 patient test records ob December 16, 2020 sh tient results were repo nen it should have bee re" on December 10,20 ected, but should be	ave	D5801				

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	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA D PLAN OF CORRECTION IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
	05D2197416					02/1	02/17/2021	
CDPH BRANCH LABORATORY 28454				RESS, CITY, ST LIVINGSTOI CIA, CA 91				
(X4) ID PREFIX ( TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
Ri as 4. el Ll by ac 5. de 12 ap fro 6. (F pr	s Invalid. The laboratory fa lectronically transmi IMC LIS, and the out y the laboratory, we ccuracy. Based on the lab eclaration signed by 2/16/2020, the labor pproximately 430,00 rom 11/02/2020 to 12 The Laboratory I February 12, 2021 a m) that the electroni	ailed to show the tted results between its tside entity subcontract re periodically verified poratory's annual testin the laboratory director ratory reported 00 SARS-CoV-2 test res 2/16/2020.	s ted for g r on sults	D5801				

If continuation sheet Page 79 of 123

	TEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA				PLE CONSTRUCTION	· · /	(X3) DATE SURVEY COMPLETED	
AND FLAN C	PLAN OF CORRECTION IDENTIFICATIONNUMBER: 05D2197416				<u> </u>	COMPLE		
		05D21974	16	B. WING		02/1	7/2021	
-		X		RESS, CITY, ST				
				LIVINGSTOI ICIA, CA 91:				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
D5801	D5801 Continued From page79 patient-specific data, from the point of data entry to final report destination.							
D5805	05805 TEST REPORT CFR(s): 493.1291(c)							
	<ul> <li>(c)(1) For positive particular patient's name and identify and patient identify (c)(2) The name and location where the teres (c)(3) The test report (c)(4) The test perfore (c)(5) Specimen sourt (c)(6) The test result of measurement or in (c)(7) Any information disposition of specime laboratory's criteria for This Standard is not Based on direct obserview of policies and control (QC) and quarandom review of patient test determined that the I test report provided to SARS-CoV-2.</li> <li>Findings included:</li> <li>1. Based on intervidirector on 12/08/2022 test results reported</li> </ul>	date. med. rce, when appropriate. and, if applicable, the nerpretation, or both. n regarding the conditioners that do not meet the or acceptability. met as evidenced by: ervation, interviews with ecember 8, 9, and 16, d procedures (P/P), quality assurance (QA) re- tient test records cover 4/2020 to 12/10/2020, records reviewed, it w aboratory failed to ensible correct interpretation the correct interpretation with the laboratory 20, there were several p	r a umber. ory units on and he h 2020, ality cords, ring for 32 as ure its on for					
		or SARS-Cov-2 should	have					

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	(XI) FROVIDER/SUFFLIER/CLIA		CONSTRUCTION	(X3) DATE S COMPL			
			05D2197416	B. WING		02	/17/2021
NAME OF PR	OV DER OR SUPPLIER		STREET ADD	DDRESS, CITY, STATE, ZIP CODE			
CDPH BR	ANCH LABORATOF	RY		LIVINGSTON A ICIA, CA 91355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MU	STATEMENT OF ST BE PRECED DENTIFYING INF	ED BY FULL REGULATORY	ID PREFIX TAG	PROVIDER'S PLAN C (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETIC DATE
D5805	<ul> <li>Continued From page 80</li> <li>been "Inconclusive"</li> <li>b. "Inconclusive" for SARS-CoV-2 should have been true "Invalid"</li> <li>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.</li> <li>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 to issue corrected reports.</li> </ul>		D5805				
	NOT DETECTED	Reported	Correct Interpretation				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
		Negative	Inconclusive				
	<b>⊢</b> ⊣	Negative	Inconclusive				

If continuation sheet Page 81 of 123

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	PLE CONSTRUCTION	· · ·	(X3) DATE SURVEY COMPLETED	
	05D2197416 PROV DER OR SUPPLIER STREE			B. WING		02/17/2021			
NAME OF PR	OV DER OR SUPPLIER		STR	EET ADD	RESS, CITY, ST	ATE, ZIP CODE	•		
CDPH BR	ANCH LABORATOR	Y		28454 I	LIVINGSTO	NAVE			
				VALEN	CIA, CA 91	355			
(X4) ID	SUMMARY S	TATEMENT O	F DEFICIENCIES		ID	PROVIDER'S PLAN OF CORREC	TION	(X5)	
PREFIX	(EACH DEFICIENCY MUS			TORY	PREFIX	(EACH CORRECTIVE ACTION SHOL		COMPLETION DATE	
TAG	OR LSC ID	ENTIFYING IN	IFORMATION)		TAG	CROSS-REFERENCED TO THE APPR DEFICIENCY)	OPRIATE		
DEOOE					DEOOE	,			
D5805	Continued From pag	ge 8 i			D5805				
	INCONCLUSIVE	Reported	Correct Interpretati	on					
		nconclusive	Invalid						
		nconclusive	Invalid						
		nconclusive	Invalid						
		nconclusive	Invalid Invalid						
		nconclusive	Invalid						
	Ir	nconclusive	Invalid						
		nconclusive	Invalid						
		nconclusive	Invalid						
	Ir	nconclusive	Invalid						
	Ir	nconclusive	Invalid						
	Inconclusive Invalid		Invalid						
	Ir	nconclusive	Invalid						
		nconclusive	Invalid						
		nconclusive	Invalid						
		nconclusive	Invalid						
		nconclusive	Invalid Invalid						
		nconclusive	Invalid						
		concrustice	interio						
	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.		atory director on orted CoV-2 test results						
D5807	4. The Laboratory (01/12/2021 at appro through email comm failed to ensure its te correct interpretation TEST REPORT CFR(s): 493.1291(d)	oximately 1 iunication tl est results p n for SARS-	1:58 a.m.) hat the laboratory provided the		D5807				
	Pertinent "reference as determined by the tests, must be availa who ordered the test individual responsibl	e laborator ible to the a ts and, if ap	y performing the authorized person oplicable, the	·					

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	ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA ID PLAN OF CORRECTION IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
	05D2197416			B. WING			02/17/2021	
CDPH BRANCH LABORATORY 2845			28454 L	RESS, CITY, ST. IVINGSTON 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 CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5807	This Standard is not Based on direct obse and procedures, qua assurance (QA) reco conducted with the la laboratory failed to er intervals determined available for the auth responsible for using Findingsincluded: 1. Based on review SARS-CoV-2, the lat test result and specifi value, "To learn more of the test, please se limitation section." 2. Review of the test limitation section did laboratory determine Negative, Inconclusive The report also indice Elmer New Coronavi Kit, 2019-nCOv-PCR (IFU)." Review of Perkin Elm Acid Detection Kit FD New Coronavirus Nu 03/20/2020, Revised	met as evidenced by: ervation, review of polic lity control (QC) and qu rds, and interviews aboratory staff, the nsure its accurate refer by the laboratory were porized person, or indivi- the test results.	uality rence idual for er the d (Ct) etails / and rand rand rand rkin tion Jse ucleic or PE ate	D5807				

If continuation sheet Page 83 of 123

PREFIX TAG       (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)       PREFIX TAG       (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       COMP DA         D5807       Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations       D5807       D5807         a.       Detected       a.       Detected       Detected		IT OF DEFICIENCIES OF CORRECTION		PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
CDPH BRANCH LABORATORY       28454 LIVINGSTON AVE VALENCIA, CA 91355         (X4) ID PREFIX TAG       SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)       ID PREFIX TAG       PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       COMP DA         D5807       Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations       D5807       D5807         a.       Detected       b.       Not Detected       ID						7/2021			
VALENCIA, CA 91355         (X4) ID PREFIX TAG       SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)       ID PREFIX TAG       PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       COMP DA         D5807       Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations       D5807       D5807         a.       Detected       Detected       D       Not Detected       D									
PREFIX TAG       (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)       PREFIX TAG       (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)       COMPI DA         D5807       Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations       D5807       D5807         a.       Detected       a.       Detected       a.	CDPH BR	RANCH LABORATOR	Ŷ						
Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations a. Detected b. Not Detected	PREFIX	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	DBE	(X5) COMPLETION DATE	
<ul> <li>Invalid</li> <li>Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory lested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results.</li> </ul>	D5807	Review of the update for analysis and repo (last final version on following interpretation a. Detected b. Not Detected c. Inconclusive d. Invalid 3. Random patients from 12/04/2020 to 12 tested and reported of patient test results whe ensure its accurate res determined by the last the authorized person for using the test results	ad policies and procedu rting of SARS-CoV-2 A 12/16/2020) indicated ons sampling covering the p 2/10/2020, the laborato but 32 out of 32SARS-0 hich the laboratory faile eference intervals boratory were available n, or individual respons lts.	Assay the period ory CoV-2 ed to e for sible VE alid)	D5807				

If continuation sheet Page 84 of 123

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/17	7/2021
	OV DER OR SUPPLIER ANCH LABORATOR	Y	28454 L	RESS, CITY, ST IVINGSTO CIA, CA 91			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5807 Continued From page 84				D5807			
	<ul> <li>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.</li> <li>5. The Laboratory Director affirmed on (Entrump. 42, 2024 at approximately 2:10)</li> </ul>						
	the laboratory were a authorized person, or for using the test resu	ry failed to ensure its ntervals determined by available for the r individual responsible					
D5809	TEST REPORT CFR(s): 493.1291(e)			D5809			
	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:						
	1. Based on em	nail communication with	n the				

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	F OF DEFICIENCIES		ER/SUPPLIER/CLIA CATIONNUMBER:		CONSTRUCTION	(X3) DATE S COMPL	
			05D2197416	B. WING		02	/17/2021
NAME OF PF	ROV DER OR SUPPLIER		STREET	ADDRESS, CITY, STATE	, ZIP CODE	20	
CDPH BF	RANCH LABORATOR	Y	284	54 LIVINGSTON A	VE		
			VA	LENCIA, CA 91355	5		
	CLIMMADY		Contraction of the second second		PROVIDER'S PLAN	OF CORRECTION	(X5)
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS		DEFICIENCIES ED BY FULL REGULATOR FORMATION)	ID PREFIX TAG	(EACH CORRECTIVE A CROSS-REFERENCED TO DEFICIEI	CTION SHOULD BE O THE APPROPRIATE	COMPLETIO
D5809	Continued From pa	ae 85		D5809			
laboratory director on 01/12/2021, and review of patients reported on 12/10/2020:				ents			
	a. Results were re "Negative" but shou "Inconclusive"						
	b. Results were re "but should have be						
	but should have be						
	2. The laboratory	failed to ens	ure it updated				
	their clients regardin						
	of results. The labor						
	subcontractor, failed						
	because the current						
	of issuing corrected						
	-						
	3. Random patient	sampling co	overing the period				
	from 12/04/2020 to 1						
	tested and reported						
	patient test results w						
	ensure it updated th		garding changed				
	in the interpretation	of results.					
	a. Below are test r						
	"Negative", but the o been "Inconclusive"		snould have				
		AC Report	Final Test Report				
		t Detected	Negative for SARS-CoV	*******			
		t Detected	Negative for SARS-CoV				
		Detected	Negative for SARS-CoV				
		t Detected	Negative for SARS-CoV				
		t Detected	Negative for SARS-CoV				
		t Detected	Negative for SARS-CoV				
			Negative for SARS-CoV				
			Negative for SARS-CoV				
		t Detected	Negative for SARS-CoV				
		t Detected	Negative for SARS-CoV				
			Negative for SARS-CoV				
		t Detected	Negative for SARS-CoV Negative for SARS-CoV				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
	05D2197416 NAME OF PROV DER OR SUPPLIER STREET		B. WING		02/17/2021		
NAME OF PROV DER OR SUPPLI CDPH BRANCH LABOR		28454 1	RESS, CITY, STAT LIVINGSTON CIA, CA 9135	AVE			
PREFIX (EACH DEFICIEN	IARY STATEMENT O CY MUST BE PRECEI LSC IDENTIFYING IN	DED BY FULL REGULATORY	id Prefix Tag	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE COMPLE	ETION	
"Inconclusive", been "Invalid"	est results that but the correct r	were reported as esult should have	D5809				
	Reported         Inconclusive         Inconclusive	Correct Interpretation Invalid					

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		· ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
	CDPH BRANCH LABORATORY 28			I RESS, CITY, ST LIVINGSTOI ICIA, CA 91;	NAVE	1	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5809	Continued From pag	je 87		D5809			
D5815	declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12 5. The Laboratory 1 (01/12/2021 at 11:58 communication that t ensure it updated its of the interpretation of r laboratory failed to is	00 SARS-CoV-2 test res 2/16/2020. Director affirmed a.m.) through email he laboratory failed to clients regarding chang	r on sults	D5815			
	<ul> <li>TEST REPORT CFR(s): 493.1291(h)</li> <li>When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.</li> <li>This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time.</li> <li>Findings included:</li> <li>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-</li> </ul>						

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBE			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
CDPH BRANCH LABORATORY 28454			28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91			
(X4) ID PREFIX TAG	ACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	A REAL PROPERTY AND A REAL	id Prefix Tag	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	DBE	(X5) COMPLETION DATE
48 h 2. the the the 3. from test pati dela 4. dec 12/' app from 5. (Fel that doc resu D5821 TES CFF Who are	e laboratory directo e laboratory start co e samples get to the Random patient s m 12/04/2020 to 12 ited and reported 5 tient test results wi lay in reporting pat <u>ccession # Collected</u> 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 12/04/2020 Based on the lab claration signed by /16/2020, the labor proximately 430,00 m 11/02/2020 to 12 The Laboratory I ebruary 12, 2021 a it the laboratory fai cumented delay in sults. ST REPORT (R(s): 493.1291(k)	communication with or on 01/08/2021, that punting for TAT when e laboratory. sampling covering the p 2/10/2020, the laborato 5 out of 32 SARS-CoV- th no documentation o tient test results. Received Reported 12/05/020 12/10/2020 12/05/020 12/10/2020 Doratory's annual testin of the laboratory director ratory reported 00 SARS-CoV-2 test res 2/16/2020. Director affirmed t approximately 2:10 p iled to ensure it reporting patient test	r on sults	D5815			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
CDPH BRANCH LABORATORY 28				RESS, CITY, ST IVINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5821	<ul> <li>(k)(1) Promptly notify ordering the test and using the test results</li> <li>(k)(2) Issue corrected authorized person or applicable, the individ (k)(3) Maintain duplic well as the corrected This Standard is not Based on direct obse and procedures, qua assurance (QA) reco conducted with the la laboratory through C promptly notified and the authorized person results, and maintaine report.</li> <li>Findings included:</li> <li>1. Based on email laboratory director on patients reported on through COLOR failed</li> <li>a. Notification and I Reports</li> <li>i. Based on email laboratory director or patients reported on through COLOR failed</li> </ul>	y the authorized persor , if applicable, the indiv of reporting errors. d reports promptly to the dering the test and, if dual using the test resu- cates of the original report. met as evidenced by: ervation, review of police lity control (QC) and quards, and interviews aboratory director, the OLOR failed to ensure issued corrected report nor individual using the ed duplicates of the original communication with the 01/12/2021, and review 12/10/2020, the laborated to perform the follow ssuance of Corrected communication with the 01/12/2021, and review and to perform the follow succession with the communication wit	ridual e ults. ort, as cies uality it ts to test ginal e w of tory ing: e	D5821			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION			(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
	05D2197416 NAME OF PROV DER OR SUPPLIER STREET			6	B. WING		02/1	7/2021	
NAME OF PR	OV DER OR SUPPLIER				RESS, CITY, STAT		~		
CDPH BR	ANCH LABORATO	₹Y			LIVINGSTON CIA, CA 913				
(X4) ID			F DEFICIENCIES		ID	PROVIDER'S PLAN OF CO		(X5) COMPLETION	
PREFIX TAG	(EACH DEFICIENCY MU OR LSC I	ist be preced Dentifying in		GULATORY	PREFIX	(EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)		DATE	
D5821	Continued From page 90				D5821				
	ii. Random patien from 12/04/2020 to tested and reported but should have be of 19 "Inconclusive" "Invalid" for SARS-0	12/10/2020 13 out of 1 en "Inconclu but should	, the laborato 3 "Not Detect isive" and 19 have been	ry ed" out					
	NOT DETECTED	Reported	Correct Inter	pretation					
		Negative	Inconcl	usive					
		Negative	Inconcl	usive					
		Negative	Inconcl	usive					
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl						
		Negative	Inconcl	usive					

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(AT) FROVIDER/SOFFLIER/CLIA		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
			05D2197416		B. WING		02/1	7/2021
NAME OF PR	NAME OF PROV DER OR SUPPLIER STREET AL			EET ADDRES	SS, CITY, STA	ATE, ZIP CODE		
CDPH BR	CDPH BRANCH LABORATORY 2845			28454 LIV	INGSTON	AVE		
			N 1	ALENCI	A, CA 913	355		
(X4) ID	SUMMARY S	TATEMENT OF	DEFICIENCIES	1	ID	PROVIDER'S PLAN OF CORRECT	ION	(X5)
PREFIX	(EACH DEFICIENCY MUS	T BE PRECED	ED BY FULL REGULAT	ORY	PREFIX	(EACH CORRECTIVE ACTION SHOUL	DBE	COMPLETION DATE
TAG	OR LSC ID	ENTIFYING IN	FORMATION)		TAG	CROSS-REFERENCED TO THE APPRO DEFICIENCY)	PRIATE	
DEADY					D 500 /			
D5821	Continued From page	je 91			D5821			
-	INCONCLUSIVE	Reported	Correct Interpretat	tion				
		conclusive	Invalid					
		conclusive	Invalid					
1		conclusive	Invalid					
l i		conclusive	Invalid					
	In	conclusive	Invalid					
	In	conclusive	Invalid					
	In	conclusive	Invalid					
	In	conclusive	Invalid					
	In	conclusive	Invalid					
	In	conclusive	Invalid					
		conclusive	Invalid					
		conclusive	Invalid					
		conclusive	Invalid					
		conclusive	Invalid Invalid					
	•••••••••••••••••••••••••••••••••••••••	conclusive	Invalid					
		conclusive	Invalid					
	********	conclusive	Invalid					
1		conclusive	Invalid					
1 1								
	b. Maintain duplica	tes of the c	original report					
	*** 200 x 200 x 20	21 942 H						
	i. Based on review							
	emailed by the labora							
	the laboratory throug							
	reports on 12/07/202							
	results on 12/04/202	o without p	roviding the					
	original report.							
	ii The following 10 out of 10SARS-CoV-2							
	<li>ii. The following 10 out of 10SARS-CoV-2 patient test results were amended:</li>							
	patient test results were amended:							

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUP IDENTIFICATION			LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
	05D2197416			B. WING		02/1	7/2021
NAME OF PF	NAME OF PROV DER OR SUPPLIER STREET AD			ESS, CITY, STA	TE, ZIP CODE		
CDPH BR				VINGSTON			
	Normal of Ende						(X5)
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			id Prefix Tag	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	COMPLETION DATE
D5821	Continued From p	age 92		D5821			
		Original Report	Amended				
	Accession #	12/04/2020	12/07/2020				
		Detected	*				
		Detected	*				
		Detected	*				
		Not Detected	*				
		Detected	*				
		Detected	*				
		Detected	*				
		Detected	*				
		Detected	*				
		Detected	*				
	*Unable to return re Please disregard an issued in error. Amended Report: T (detected/not detect error (Accession #s) Report Test Date: D Recommendation: T 2. Based on the declaration signed 12/16/2020, the lat approximately 430, from 11/02/2020 to	y previous reports he previously reported) is not valid due by Covid-19 Test. ecember 4, 2020 This patient should aboratory's annual by the laboratory d poratory reported 000 SARS-CoV-2 to	as they were ted result to a lab process be retested. testing irector on				
	3. The Laborator 12, 2021 at approx laboratory failed to and issued correct person or individua maintained duplica	ensure it promptly r ed reports to the au I using the test res	hat the notified uthorized ults and				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021
	CDPH BRANCH LABORATORY 28454			RESS, CITY, ST IVINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE
D5891	ASSESSMENT CFR(s): 493.1299(a) The laboratory must policies and procedu mechanism to monito indicated, correct pro- postanalytic systems This Standard is not 1. Based on direct laboratory staff on De- review of policies and control (QC) and qua random review of pati- the period from 12/04 out of 32 patient test determined that the I there was a mechani- calculated results, re systems, and patient CoV-2. Findings included: a. Prior to the sche Laboratory Field Sen- communication on N- we informed the labor into the report of incr inconclusive patient to news article on Nove excerpt of the e-mail "Please refer to the fe- https://www.newswea	STEMS QUALITY establish and follow wr res for an ongoing or, assess and, when oblems identified in the specified in §493.129 <sup>o</sup> met as evidenced by: observation, interviews ecember 8, 9, and 16, 2 d procedures (P/P), qua- lity assurance (QA) rec- tient test records cover 4/2020 to 12/10/2020, 1 records reviewed, it wa aboratory failed to ensis sm to periodically verif sults sent to interfaced specific data for SARS eduled on-site inspection vices (LFS) sent an e-r ovember 13, 2020, who ratory that we will be low eased number of test results, published i mber 10, 2020. Below communication: ollowing media report: ek.com/spike-bad-test- m-covid-19-testing-lab-c	1. s with 2020, ality ords, ing for 32 as ure y S- n, nail erein oking n a is the result	D5891			

STATEMENT OF DEFICIENCIES (X AND PLAN OF CORRECTION		• •	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
				05D21974	16	B. WING		02/1	7/2021
NAME OF PI	NAME OF PROV DER OR SUPPLIER STREET AL				STREET ADD	ORESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	RANCH LABO	RATOR	Y			LIVINGSTON ICIA, CA 913			
(X4) ID	SU	IMMARY S	TATEMENT OF	DEFICIENCIE	S	ID	PROVIDER'S PLAN OF CORREC	ΓΙΟΝ	(X5)
PREFIX TAG	`		T BE PRECED ENTIFYING IN	ED BY FULL RI FORMATION)	EGULATORY	PREFIX TAG	(EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	COMPLETION DATE
D5891	Continued F	rom pag	je 94			D5891			
	LFS expects f * Evaluation during the af look-back. * How the lab correspondir * What is the * How the lab action. Is it th b. During th on 12/08/202 directors and requested fo investigation increased nu c. We review the Emergen laboratory's a New Corona "Examination Specimen Re the expected and negative	of report fected tin o identifie o solutio corrections mon the first do 20, we in d senior of and cor mber of in ved the lin or the lab and cor mber of in ved the lin or use n adopted virus Nu on and Int esults" s	ed patient t me period. ed the problon. ve action? itoring the o rking?" lay of the o terviewed l operations oratory's do rective acti inconclusiv nstructions Authorization test metho cleic Acid I erpretation ection show for the kit v	tests results Patient lem and the corrective n-site inspe laboratory personnel, a pocumented on regardin e patient res for Use (IFI on of the d, Perkin El Detection Ki of Patient wed a table	ection and g the sults. U) of Imer it. The listing				
	0	de thresho	Ы	Result Interpr	etation				
	IC (VIC/HEX)	· · · · · · · · · · · · · · · · · · ·	RF1ab ROX)	Acour merpr					
		Both targe		SARS-CoV-2 No	ot Datastad				
	<u>≤</u> 40	•••••••••••••••••••••••••••••••••••••••	ined or > 42						
	/	Both targe		SARS-CoV-2 De					
	/ One of the targets ≤ 42 SARS-CoV-2 Detected								
	>40 or Both targets needs to be re-tested from								
	Undetermined Undetermined or > 42 re-extraction or recollected								
	from patient for test.								

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIE ND PLAN OF CORRECTION IDENTIFICATION NU			(X2) MULTIPLE CONSTRUCTION A. BUILDING		( )	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/	17/2021	
	OV DER OR SUPPLIER	RY	28454	DRESS, CITY, STA LIVINGSTON ICIA, CA 913	AVE	·		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MU	STATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL RE DENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN (EACH CORRECTIVE A CROSS-REFERENCED TO DEFICIE	CTION SHOULD BE O THE APPROPRIATE	(X5) COMPLETION DATE	
D5891	calculating and inter we also asked the la 2020, to provide the System (LIS) and its interpretation of pati a. A policy and proc laboratory was not a 2020. b. Neither an unsign available on Decem e. Further interview on 12/08/2020, indic that patient test resu a result of incorrect interpretation. f. The following da conducted random s patient test records during the first week g. On December on-site at the labora patient test records. laboratory to send w records and its polic interpretation of pati h. The policy and p Dec. 16, 2020 show (i) An annotation document indicated, 10/29/2020" the doc	bare how the laboratory preting patient results, aboratory on December LIMC Laboratory Inforr spolicy and procedure f ent specimen results. edure signed by the available on December 8 hed policy and procedure aber 8, 2020. ws with the laboratory directed there was a possil lats were reported in error data analysis and ay on 12/09/2020, we sampling of an additionation with specimens collected December until 12/08/20 16, 2020, we went back tory to retrieve the addii We also asked the ia e-mail, the requested by and procedure for ent specimen results. procedure sent via e-mailed the following: on the top portion of	8, nation or 3, e was rector bility or as al 32 ed 020. tional	D5891				
State 2567					Z9Q211	If continuation she	et Page 96 of 123	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION			(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		. ,	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
			05D21974	16	B. WING		02/1	7/2021	
	OV DER OR S	SUPPLIER BORATOR	Y	28454 L	RESS, CITY, ST. IVINGSTON CIA, CA 913	NAVE			
(X4) ID PREFIX TAG	(EACH DE	FICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE	(X5) COMPLETION DATE	
D5891	Continued From page 96				D5891				
	an effecti	ve date of D	December 13, 2020.						
	<ul> <li>(iii) The Software Name was identified as LIMC, version 1.2</li> <li>i. The Detailed User Requirements Specifications section of the document showed the following policy for interpretation of patient specimen results.</li> </ul>			MC,					
				n					
	User	Ī							
	Requirement Number		Description						
			ule for the new SOP:						
	UR001		ed" Ct cutoff changed from 37 to 42 ROX >37 and <=42 will be called Detected".	as "Inconclusive"					
		• IC Failure sa	mples (HEX=0 or >40) will be releas	ed as "Invalid".					
		<ul> <li>No changes of</li> </ul>	on controls and "Detected" rules						
	<ul> <li>j. Comparative review of the IFU for the laboratory's adopted EUA method, and the laboratory's policy for interpreting patient specimen results, showed the laboratory added a result category of Inconclusive.</li> <li>k. There was no indication that this document identified as User Requirement Specifications CA-COMP-FM-001 Version 1.0, was approved, signed, and dated by the Laboratory Director.</li> </ul>			ded a					
				ns ved,					
	I. 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.								
			ling to have available, a ocedure for interpreting						

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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	
	05D2197416			B. WING		02/1	7/2021	
	CDPH BRANCH LABORATORY 2845			RESS, CITY, ST LIVINGSTOI 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 CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	JLD BE	(X5) COMPLETION DATE	
D5891	patient sample result to show it validated it category of "Inconclu patient test results or o. Review of the 32 retrieved on Decemb (i) Thirteen (13) p as "Not Detected" wh reported as Not Det reported as Inconclusiv (ii) Nineteen (19) p as "Inconclusive" wh reported as "Invalid"	s, the laboratory also f ts LIS to include a resu isive" prior to reporting in 11/02/2020. (See D5- 2 patient test records per 16, 2020 showed: atient results were reponden it should have been re" on December 10, 20 ected, but should be	It 423). orted n 020. orted ).	D5891				

If continuation sheet Page 98 of 123

STATEMENT	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/	CLIA		PLE CONSTRUCTION	(X3) DATE SL	JRVEY
AND PLAN O	FCORRECTION	IDENTIFICATIONNUMB	ER:	A. BUILDING	G	COMPLE	TED
		05D21974	116	B. WING		<b>02</b> /*	17/2021
NAME OF PF	ROV DER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Y		LIVINGSTO			
			VALEN	ICIA, CA 91	355		
(X4) ID PREFIX TAG	PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC IDENTIFYING INFORMATION)				PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AF DEFICIENCY)	IOULD BE	(X5) COMPLETION DATE
D5891	Continued From pag	je 98		D5891			
	<ul> <li>o. Based on the la declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 1</li> <li>p. The Laboratory (February 12, 2021 at the laboratory failed to periodically verify of sent to interfaced syst data for SARS-CoV-2</li> <li>2. Based on interv director on 12/08/202 12/16/2020 and ema 12/22/2020, 12/24/20 01/12/2021, review of quality control (QC) a records, it was determ failed to establish an procedures for an on</li> </ul>	boratory's annual testi / the laboratory director ratory reported 20 SARS-CoV-2 test re 2/16/2020. Director affirmed it approximately 2:10 pt to ensure was a mecha calculated results, resu- stems, and patient spe 2. iew with the laboratory 20, 12/09/2020 and il communication on 020, 01/06/2021 and f policies and procedu and quality assurance ( mined that the laboratory d follow written policies	or on esults om) that anism ults cific , res, (QA) ory s and				

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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	
		05D21974	16	B. WING		02/1	7/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91:				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5891	Continued From pag	je 99		D5891				
	problems identified ir specified in CFR 493	n the postanalytic syste 3.1291 (a)-(k).	ems					
	Findings included: a. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 11/01/2020)showed the laboratory failed to include an ongoing mechanism to perform or document quality issues regarding the following:							
	system(s) it used, a	failed to ensure th accurately and reliably from the point of data see D5801).	<pre>/ transmitted</pre>					
	c. The laboratory fa provided the correct SARS-CoV-2 (See D		esult					
	<ul> <li>d. The laboratory failed to ensure its accurate reference intervals determined by the laboratory based on LOD were available for the authorized person, or individual responsible for using the test results (See D5807).</li> <li>e. The laboratory failed to ensure its clients were updated regarding changes in the interpretation of results (See D5809).</li> </ul>							
	f. The laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time (See D5815).							
	notified and issued c authorized person or	ailed to ensure it promporrected reports to the individual using the teed duplicates of the orig	st					

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## Printed: 02/17/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROV DER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. W NG		02/1	7/2021	
Law has the second seco	NAME OF PROV DER OR SUPPLIER CDPH BRANCH LABORATORY			ESS, CITY, STA VINGSTON IA, CA 913				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENC ES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING NFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	ULD BE	(X5) COMPLETION DATE	
D5891	from 12/04/2020 to 1 32 out of 32 results r laboratory tested and results, but failed to	ge 100 ampling covering the period solution of the period solution of the postant	t for 2 Igoing	D5891				

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	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/0 IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SUF COMPLET	
		05D21974	16	B. WING		02/1	7/2021
-	ROV DER OR SUPPLIER	Ŷ	28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91:			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	ILD BE	(X5) COMPLETION DATE
D5891	Continued From page	je 101		D5891			
	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 m	00 SARS-CoV-2 test re 2/16/2020. Director affirmed (Febr nately 2:10 pm) that the nonitor, assess, and wh oblems identified in the	r on sults uary				
D6076				D6076			
	the qualification requition the subpart and prov	have a director who m irements of §493.1443 vides overall managem rdance with §493.1445	of ent				
	This Condition is not met as evidenced by: Based on the severity of the deficiencies cited herein, it was determined that the condition Laboratories Performing High Complexity Testing, Laboratory Director was not met:						
	Findings included:						
	quality of service pro system when the lab documentation of tra assessment, and con telephone, as necess personnel specific re reapportioned to tech supervisor, and clinic	nsultation electronically sary; delegated to qual sponsibilities which ca nnical supervisor, gene	ic e r or by ified n be rral				

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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	
		05D21974	16	B. WING		02/1	7/2021	
NAME OF PROV DER OR SUPPLIER CDPH BRANCH LABORATORY			28454	RESS, CITY, ST LIVINGSTON ICIA, CA 913	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D6076	<ul> <li>analysis and reportin taking place at a loca known physical locat State and CLIA appli</li> <li>2. The Laboratory Di environmental condit appropriate for the te</li> <li>3. The Laboratory testing personnel we chemical and biologie</li> <li>4. The Laboratory quality control progra maintained to assure provided, and to iden occur (See D6093).</li> <li>5. The Laboratory quality assurance ac maintained by the lab of services provided, quality as they occur</li> <li>6. The Laboratory Di adequate number of</li> </ul>	g of patient test results ation outside of the liste ion of the laboratory in cations (See D6082). rector failed to ensure ions of the laboratory a sting performed (See D Director failed to ensur re safe from physical, cal hazards (See D608 Director failed to ensur ms were established a the quality of services tify failures in quality as Director failed to ensure tivities were establishe poratory to assure the q and to identify failures (See D6094). rector failed to ensure laboratory personnel for th appropriate training	ed and its that are D6083). e that 4). re and 5 they ure d and uality 5 in it utilized or high	D6076				
	laboratory staff demo	Director failed to ensu onstrated competency p results (See D6102).						
D6082	CFR(s): 493.1445(e) The laboratory direct systems developed a	or must ensure that tes and used for each of th pratory provide quality	sting	D6082				

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	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/0 IDENTIFICATIONNUMB			PLE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	OV DER OR SUPPLIER	Y	28454 L	RESS, CITY, ST IVINGSTOI CIA, CA 91		·	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D6082	Continued From pag	je 103		D6082			
D6082	performance, which i analytic, and postana This Standard is not 1. Preanalytic Syster Based on interviews director on December test requisitions, and records covering the 12/08/2020, for 10 ou reviewed, it was dete Director failed to ens provided in the prear of test requisitions fo testing was not retain Findings included: a. The Laboratory I retained records of te tested for SARS-CoV (See D3027). 2. Postanalytic Syste Based on email com	Includes the preanalytic alytic phases of testing met as evidenced by: n (Test Requisition) with staff and the labor of 8, 2020, the absence random review of test period from 11/22/202 ut of 10 patient test recommend that the Labora ure the quality of servin alytic system when re- r SARS-CoV-2 patient ned. Director failed to ensur est requisitions of all pat /-2, for at least two yea em (Test Report) munication with the la 20, the absence of orig	ratory of 0 to ords atory ce cords re it tients ars	D6082			
	reviewed, it was dete Director failed to ens provided in the posta	ut of 10 patient test rec ermined that the Labora ure the quality of servio malytic system when re s for SARS-CoV-2 pati	atory ce ecords				
	Findings included:						
	a. The Laboratory	Director failed to ensur	e it				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		( )	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/1	7/2021	
						<u>.</u>		
CDPH B	RANCH LABORATOR	Y		LIVINGSTOI				
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE ST BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D6082	Continued From pag	ge 104		D6082				
D6082	retained records of o patients tested for S/ two years (See D304 3. Postanalytic Syste Assessment, Consul Duties to Qualified P Analysis) Based on email com of Informatics on 12/ laboratory staff on 12 test records covering to 12/08/2020, for 60 records reviewed, the to demonstrate quali postanalytic system provide documentation assessment, and con telephone, as necess personnel specific re reapportioned to tech supervisor, and clinic data analysis and ref	riginal test reports of a ARS-CoV-2, for at leas 11). em (Training, Compete tation, and Delegation ersonnel in Remote Da munication with the Din 16/2020, interviews w 2/08/2020, review of pa g the period from 11/22 0 out of 60 patient test e Laboratory Director fi ty of service provided i when the laboratory fai on on training, competen sultation electronically sary; or delegated to qu sponsibilities which ca nnical supervisor, gene cal consultant during th mote reporting of patie lace at a location outsi	t ncy of ata rector ith the atient //2020 ailed n the iled to ency / or by alified n be eral ie time nt test	D6082				
	on 12/08/2020, a lapt nine data analysis la would enable access	iew with the laboratory top computer was issue boratory personnel wh to the laboratory's and facilitate patient tes	ed to ich					
	Data Analysis Staff a. SS b. RR c. AE d. SM	Perkin Elmer Compu VALLL015 VALLL014 VALLL020 VALLL013	iter VPN					

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STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/0	CLIA	(X2) MULTIF	PLE CONSTRUCTION	(X3) DATE SU	RVEY
AND PLAN (	OF CORRECTION	IDENTIFICATIONNUMB	ER:	A. BUILDING	G	COMPLET	ED
		05D21974	16	B. WING		02/1	7/2021
NAME OF P	ROV DER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE	-	
CDPH BI	RANCH LABORATOR	Y	28454	LIVINGSTO	NAVE		
			VALEN	CIA, CA 91	355		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE: T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	ILD BE	(X5) COMPLETION DATE
D6082	Continued From pag	je 105		D6082			
	e. FJ f. MW g. YZ h. WT i. MN b. Based on email Director of Clinical In remote workers need able to login to LIMC are Perkin Elmer IP at Laboratory Valencia I 165.88.16.###. Non-Valencia IP Add 1. By EV 2. 165.88.255.136 165. 165.88.176.91 163 165.88.176.91 163 165.88.192.131 165.88.176.64 165.88.254.202 c. Review of the lat procedures (Policy # Analysis and Reporti Assay, Version 1 Effe 13/2020, Version 2.0 16/2020, Version 3.0 12/16/2020, and Versi 12/16/2020, the Lab demonstrate quality of postanalytic system of failed to provide doct competency assess electronically or by te or delegate to qualifier responsibilities which to technical supervise and clinical consultar	VALLL017 VALLL021 VALLL022 VALLL033 VALL033 VALL023 communication with th formatics on 12/16/202 to connect to VPN to (LIS), so their IP addre address. The CDPH Br ab IP address range is resses Login By MN 88.254 5.88.254 5.88.254 boratory's policies and CA-RPT-SOP-002, Titl ng of SARS-CoV-2 ective Date 12/8- Effective Date 12/13- Effective Date 13/13- Effective Date 13/1	20, be sses ranch s				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			PLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/	17/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI ICIA, CA 91:	NAVE	i		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF ( (EACH CORRECTIVE ACTI CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
D6082	results were taking p of the laboratory faci d. Random review period from 11/22/202 laboratory tested and SARS-CoV-2 patient laboratory personnel remote reporting outs Branch laboratory in documentation of tra assessment, and cor telephone. e. Below are 30 re each for EV and MN remotely analyzed, a released remotely.	lace at a location outsi lity. of test records covering 20 to 12/08/2020, the d reported 60 out of 60 test results, showedtw to perform data analys side the location of CD Valencia without ining, competency nsultation electronically presentative examples	gthe vo sis and PH v or by were	D6082				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		051	02197416			02/17	7/2021	
NAME OF PR	OV DER OR SUPPLIER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE	-		
CDPH BR	ANCH LABORATOR	Y		IVINGSTO				
			VALENO	CIA, CA 913	355			
(X4) ID	SUMMARY S	TATEMENT OF DEFI		ID	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL		(X5) COMPLETION	
PREFIX TAG	A COLOR OF A	ENTIFYING INFORM		PREFIX	CROSS-REFERENCED TO THE APPRO		DATE	
			125.		DEFICIENCY)			
D6082	Continued From page	e 107		D6082				
	Data Analyzed by E							
	Accession Number	Date Reported	IP Address					
		11/22/2020	165.88.255.136					
		11/22/2020	165.88.255.136					
		11/22/2020	165.88.255.136					
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		11/23/2020	165.88.176.91					
		11/23/2020	165.88.176.91					
		11/23/2020	165.88.176.91					
		11/24/2020	165.88.192.131					
		11/24/2020	165.88.192.131					
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		11/24/2020	165.88.192.131					
		11/25/2020	165.88.176.64					
		11/25/2020	165.88.176.64					
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		11/27/2020	165.88.176.64					
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		11/27/2020	165.88.176.64					
		11/28/2020	165.88.254.202					
		11/28/2020	165.88.254.202					
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		11/30/2020	165.88.254.202					
		14/00/2020	200.00.207.202					

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	OF DEFICIENCIES CORRECTION				CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		050	02197416	B. WING		02	/17/2021	
NAME OF PRO	OV DER OR SUPPLIER	20	STREET ADD	RESS, CITY, STATE	, ZIP CODE			
CDPH BRA	ANCH LABORATO	RY	28454	LIVINGSTON A	VE			
			VALEN	CIA, CA 91355	5			
(X4) ID	SUMMARY	STATEMENT OF DEFI	CIENCIES	ID	PROVIDER'S PLAN O	F CORRECTION	(X5)	
PREFIX TAG	(EACH DEFICIENCY MU		FULL REGULATORY	PREFIX TAG	(EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	TION SHOULD BE THE APPROPRIATE	COMPLETIC	
D6082	Continued From pa	ge 108		D6082				
	See table below f	or data analyze	d by MN:					
	Data Analyzed by M	IN:						
	Accession Number	Date Reported	IP Address					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
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		12/07/2020	165.88.254.222					
		12/08/2020	165.88.254.200					
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		12/08/2020	165.88.254.200					
		12/00/2020	103.00.234.200					

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	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/CL IDENTIFICATIONNUMBE		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D219741	6	B. WING		<b>02/</b> 1	17/2021
-	ROV DER OR SUPPLIER	۲Y	28454	RESS, CITY, STA LIVINGSTON ICIA, CA 913	AVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MU	STATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL REC DENTIFYING INFORMATION)	GULATORY	ID PREFIX TAG	PROVIDER'S PLAN ( (EACH CORRECTIVE A CROSS-REFERENCED TO DEFICIEI	CTION SHOULD BE O THE APPROPRIATE	(X5) COMPLETION DATE
D6082	The total number of from 12/07/2020 to a g. The total number from 11/22/2020 to 1 h. Based on the lad declaration signed b 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1 i. The Laboratory Di p.m.) through email analysis personnel a CoV2 amplification t failed to provide doc assessment, and co telephone, as necess personnel specific reapportioned to tec supervisor, and clini analysis and remote	results reported by MN 12/08/2020 was 1,974. er of results reported byE 1/30/2020 was 13, 291. boratory's annual testing y the laboratory director oratory reported 00 SARS-CoV-2 test resu	on ults 20 at 12:15 two data e SARS- oratory ompetency or by alified be al e time data results	D6082			

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		、 <i>,</i>	PLE CONSTRUCTION	• •	(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING 02/*		7/2021		
-	OV DER OR SUPPLIER	Y	28454	DRESS, CITY, ST LIVINGSTON ICIA, CA 913	NAVE			
(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 CORREC (EACH CORRECTIVE ACTION SHOL CROSS-REFERENCED TO THE APPR DEFICIENCY)	ILD BE	(X5) COMPLETION DATE	
D6083	CFR(s): 493.1445(e) The laboratory direct physical plant and er laboratory are approp performed. This Standard is not on direct observation procedures, quality of assurance (QA) reco with the laboratory st 12/09/2020, review of period from 11/22/20 of 60 patient test reco determined that the L ensure that contamin equipment, instrument supplies for the labor Transcriptase-Polym (RT-PCR) was minim Findings included: 1. The laboratory fa contamination of pati instruments, reagent for the laboratory's C Transcriptase-Polym (RT-PCR) was minim LABORATORY DIRE CFR(s): 493.1445(e) The laboratory direct physical plant and er provide a safe enviro	ECTOR RESPONSIBIL (2) or must ensure that the invironmental conditions priate for the testing met as evidenced by: If it, review of policies and ontrol (QC) and quality rds, interviews conduct aff on 12/08/2020 and of test records covering 20 to 12/08/2020, for 6 ords reviewed, it was aboratory Director fails ation of patient speciments, reagents, materials ratory's COVID-19 Rev erase Chain Reaction nized. ailed to ensure that tent specimens, equipments, materials, and supple COVID-19 Reverse erase Chain Reaction nized (See D3003). ECTOR RESPONSIBIL	e s of the Based d ted the 50 out ed to hens, s, and erse nent, ies	D6083				
						antinuation of	t Page 111 of 123	

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STATEMENT	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C		. ,	PLE CONSTRUCTION	(X3) DATE SUF	RVEY
AND PLAN O	F CORRECTION	IDENTIFICATIONNUMB	ER:	A. BUILDING	3	COMPLET	ED
		05D21974	16	B. WING		02/1	7/2021
NAME OF PR	OV DER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Y		LIVINGSTO			
			VALEN	ICIA, CA 91	355		
(X4) ID PREFIX TAG	FIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D6084	Continued From pag	je 111		D6084			
	biological hazards. This Standard is not Based on interview w December 8, 2020, m procedures (P/P) for Plan, and review of to period from 11/22/20 of 60 patient test reco determined that the L ensure safety proced employees from phys and biohazardous ma Findings included: 1. The laboratory fa	met as evidenced by: vith laboratory staff on eview of policies and General Facilities Safe est records covering th 20 to 12/08/2020, for 6 ords reviewed, it was aboratory Director fail- lures were in place to p sical, chemical, biocher aterials.	ed to protect mical,				
D6093	CFR(s): 493.1445(e) The laboratory direct quality control progra maintained to assure services provided an as they occur. This Standard is not Based on direct obse conducted with the la 12/08/2020 and 12/0 records covering the 12/08/2020, for 60 ou reviewed, it was dete Director failed to ens were established and laboratory to assure	or must ensure that the ims are established an the quality of laborato d to identify failures in met as evidenced by: ervation, interviews aboratory staff on 9/2020, and review of period from 11/22/202 ut of 60 patient test rec ermined that the Labor ure quality control activ	e d ry quality test 0 to ords ratory <i>v</i> ities	D6093			

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	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	NOV DER OR SUPPLIER	Y	28454	RESS, CITY, ST LIVINGSTOI CIA, CA 91			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	(X5) COMPLETION DATE	
D6093	<ul> <li>manuals were establic followed by laborator</li> <li>2. The laboratory farmanuals met the requered CFR 493. 1251 (b)(1)</li> <li>3. The laboratory farmanuals were updated by the current D5407).</li> <li>4. The laboratory farmadopted FDA EUA IF to the EUA, and charmadopted FDA EUA IF to the EUA, and charmadopted as required (c)</li> <li>5. The laboratory farmadopted as required (c)</li> <li>6. The laboratory farmation solution and the contamination solution of the contamina</li></ul>	ailed to ensure procedu ished, available to, and y personnel (See D540 uirements specified in )-(b)(14) (See D5403). ailed to ensure procedu ed, approved, signed a Laboratory Director (S ailed to ensure it follow FU, the subsequent rev ages made in the laboration res (See D5411). ailed to ensure reagents See D5415). ailed to ensure the ution used forSARS-Co ed past the labeled	d 01). edure 42 ure nd ee ed the risions atory's s were	D6093			
	and verified performative reporting patient test	ance specifications pric results using its modifi -CoV-2 RT-PCR (See	or to				
D6094	established maintena centrifuges were per (SeeD5433).	CTOR RESPONSIBIL		D6094			

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	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/0 IDENTIFICATIONNUMB		· ,	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	ROV DER OR SUPPLIER	Y	28454	RESS, CITY, ST LIVINGSTON ICIA, CA 913	AVE	-	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIE T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D6094		-		D6094			
	quality assessment p maintained to assure	for must ensure that the programs are establishe the quality of laborato d to identify failures in	ed and ry				
	Based on direct obse conducted with the la 12/08/2020 and 12/0 records covering the 12/08/2020, for 60 or reviewed, it was dete Director failed to ens activities were establ laboratory to assure		0 to ords atory by the				
	Findings included:						
	establish written polio ongoing mechanism	rector failed to ensure cies and procedures fo to monitor, assess, an ect problems identified i (See D5391).	r an d				
	follow written policies ongoing mechanism	irector failed to establis s and procedures for a to monitor, assess, an ect problems identified te D5791).	n d				
	follow written policies ongoing mechanism	rector failed to establish s and procedures for an to monitor, assess, an ect problems identified i s (See D5891)	n d				
D6101	LABORATORY DIRE	ECTOR RESPONSIBIL	ITIES	D6101			

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	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/0 IDENTIFICATIONNUMB		· /	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING		02/ <sup>.</sup>	17/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI ICIA, CA 91	NAVE		
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CC (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	I SHOULD BE	(X5) COMPLETION DATE
D6101	CFR(s): 493.1445(e) The laboratory direct number of laboratory appropriate educatio training to provide ap properly supervise a and report test result personnel responsib subpart. This Standard is not Based on direct obse conducted with the la 12/08/2020, 12/09/20 review of test record 11/22/2020 to 12/08/ test records reviewed Laboratory Director f adequate number of complexity testing, w training and experier accurate and reliable reporting. Findings included: 1. Analytic Testing a. Based on intervi designated as Perkir Global Laboratory O supervision to the an and observation of la 12/16/2020, lack of t written delegation of that there was inade analytic phase of tess b. Review of CMS	(11) for must employ a suffice personnel with the n and either experience opropriate consultation, nd accurately perform to is in accordance with the ilities described in this met as evidenced by: ervation, interviews aboratory staff on 020, and 12/16/2020, a s covering the period fr 2020, for 60 out of 60 period d, it was determined the failed to ensure there we supervisors for high with appropriate education the in order to provide test performance and Supervision few with the laboratory in Elmer Genomics GM perations who was pro- alytic testing laboratory aboratory personnel on raining documents, lac duties, it was determined quate supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of the supervision of t	e or tests ne and rom atient at the vas an ion, staff viding vstaff, k of ied e	D6101			

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	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE S COMPL	
		05D21974	16	B. WING		02	/17/2021
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI ICIA, CA 91:	NAVE		
(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 ( (EACH CORRECTIVE ACTI CROSS-REFERENCED TO TI DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE
D6101	<ul> <li>indicate the name of supervisor, who was analytic testing labor</li> <li>2. Data Analysis Statistical Laboratory statist Molecular and Supervisor who was Clinical Laboratory Statist analysis on 12/08/200 documents, lack of wwas determined that supervision of laboratistical data analysis.</li> <li>b. Review of CMS Statistical the name of interviewed providing analysis personnel.</li> <li>c. Based on interviding analysis personnel.</li> <li>data and special interviewed on 12/08/2020. The two on CMS 209 were all 3. Random patient from 11/22/2020 to 12 laboratory tested and SARS-CoV-2 patient</li> </ul>	the interviewed general providing supervision is atory staff on 12/16/20 upervision observation and intervi- taff designated as Prind and Special Diagnostics providing supervision to ccientist performing dat 20, lack of training ritten delegation of dution there was inadequate tory personnel perform 209, signed and dated lon 10/15/2020, did not the general supervisor g supervision to the dat ew with the Laboratory 20, the Principal Scientia al Diagnostics Supervision g supervision to the dat /2020 was no longer ause the person was o ring the inspection on general supervisors list so not available onsite. sampling covering the p 2/08/2020, showed the d reported 60 out of60 test results, when ther on of laboratory person	to the 20. iew cipal so a a es, it ning by the	D6101			

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	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:				PLE CONSTRUCTION	(X3) DATE SU COMPLE		
		05D21974	16	B. WING		02/1	02/17/2021	
	ROV DER OR SUPPLIER RANCH LABORATOR	Y	28454	RESS, CITY, ST LIVINGSTOI ICIA, CA 91	NAVE			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	ULD BE	(X5) COMPLETION DATE	
D610 <sup>,</sup>	<ul> <li>4. Based on the lat declaration signed by 12/16/2020, the labo approximately 430,00 from 11/02/2020 to 12</li> <li>5. The Laboratory (12/16/2020 at 1:00 pt)</li> </ul>	poratory's annual testin y the laboratory directo ratory reported 00 SARS-CoV-2 test res 2/16/2020.	r on sults led to	D6101				

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	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLE	
		05D21974	16	B. WING		02/	17/2021
	ROV DER OR SUPPLIER	Y	28454	DRESS, CITY, ST. LIVINGSTON ICIA, CA 913	NAVE		
(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 CO (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO THI DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
D6101		e 117 esting with appropriate pervision accordingly.		D6101			
D6102	LABORATORY DIRE CFR(s): 493.1445(e)	ECTOR RESPONSIBIL (12)	ITIES	D6102			
	testing patients' spect the appropriate educe receive the appropriate complexity of the ser demonstrated that the operations reliably to results. This Standard is not Based on direct obsec conducted with the la 12/08/2020, 12/09/20 review of test records 11/22/2020 to 12/08/2 test records reviewed Laboratory Director f staff received approp reporting patient test Findings included: 1. Data Analysis Pe Branch Lab a. Based on direct with the Clinical Labor performing data anal determined that the O laboratory's current of procedures. b. Review of policies analysis, it was deter	aboratory staff on 020 and 12/16/2020, ar s covering the period fr 2020, for 60 out of 60 pa d, it was determined tha ailed to ensure all labo oriate training prior to results. erformed at CDPH observation and intervior pratory Scientist (CLS) ysis on 12/08/2020, it w CLS was not updated or lata analysis policies a es and procedures for or mined at the time of	ave and e ing curate nd om atient at the ratory iew was n the nd data				
		2020, the laboratory ha sting data analysis polic					

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	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB		. ,	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	ROV DER OR SUPPLIER	Y	28454 L	RESS, CITY, ST. LIVINGSTON CIA, CA 913			
(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 CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPF DEFICIENCY)	ULD BE	(X5) COMPLETION DATE
D6102	and procedures. c. The following are the 60 randomly revi covering the period f 12/08/2020, wherein reported 60 out of 60 results, but failed to e	e the accession number ewed patient test recor	ds ind test aff	D6102			

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			X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		PLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		05D21974	16	B. WING		02/ <sup>,</sup>	17/2021	
	ROV DER OR SUPPLIER	Y	28454	RESS, CITY, ST LIVINGSTON ICIA, CA 913	NAVE			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RI ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF COF (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE / DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D6102	<ol> <li>Data Analysis Pe CDPH Branch Lab (F</li> <li>a. Based on review determined that the t performed data analy the CDPH Branch La documentation on ho reporting, direction ar or by telephone when delegated personnel remote data analysis</li> <li>b. Review of policie CA-PER-SOP-002, T Assessment) failed to remote reporting.</li> <li>c. Random review of period from 11/22/202 laboratory tested and SARS-CoV-2 patient laboratory personnel outside the location of Valencia without doc reporting.</li> <li>d. Below are 30 rep each for EV and MN,</li> </ol>	erformed Outside Remote Reporting) y of test records, it was wo laboratory staff who ysis from the location of b did not have training ow to handle remote ind consultation electron the Laboratory Directo were not with them du es and procedures (Poli Title Competency to include training for of test records covering 20 to 12/08/2020, the d reported 60 out of 60 test results, showed to to perform data analys of CDPH Branch labora umented training for re-	o putside l nically or and ring icy # gthe wo sis atory in emote	D6102				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		1982 - C. 201	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2197416		B. WING	B. WING		02/17/2021	
NAME OF PR	OV DER OR SUPPLIER		STREET A	ADDRESS, CITY, ST	ATE, ZIP CODE	-		
CDPH BR	ANCH LABORATOR	Y	2845	4 LIVINGSTON	AVE			
			VAL	ENCIA, CA 913	55			
(X4) ID	SUMMARY S	TATEMENT OF DEF	ICIENCIES	ID	PROVIDER'S PLAN OF CORRECT	ION	(X5)	
PREFIX	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	DDL	COMPLETION DATE		
170			in in in it	140	DEFICIENCY)			
D6102	Continued From page 120		D6102					
	Data Analyzed by E	V:						
	Accession Number	Date Reported	IP Address	-				
		11/22/2020	165.88.255.136	-				
		11/22/2020	165.88.255.136					
		11/22/2020	165.88.255.136					
		11/22/2020	165.88.255.136					
		11/23/2020	165.88.176.91					
		11/23/2020	165.88.176.91					
		11/23/2020	165.88.176.91					
		11/23/2020	165.88.176.91					
		11/24/2020	165.88.192.131					
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		11/25/2020	165.88.176.64					
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		11/27/2020	165.88.176.64	-				
		11/27/2020	165.88.176.64					
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		11/27/2020	165.88.176.64	-				
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		11/29/2020	165.88.254.202	-				
		11/29/2020	165.88.254.202	-				
		11/29/2020	165.88.254.202					
		11/30/2020	165.88.254.202	- [				
		11/30/2020	165.88.254.202					
S				22			9	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		10 C 10 C	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2197416		B. WING	B. WING		02/17/2021	
NAME OF PRO	OV DER OR SUPPLIER		STREET AD	ORESS, CITY, STAT	E, ZIP CODE			
CDPH BR	ANCH LABORATOR	Y	28454	LIVINGSTON	AVE			
			VALE	NCIA, CA 9135	5			
(X4) ID	SUMMARY S	TATEMENT OF DEFIC	CIENCIES	ID	PROVIDER'S PLAN OF CORRECT	ION	(X5)	
PREFIX	(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			PREFIX TAG	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	COMPLETION DATE		
D6102	Continued From page 121			D6102				
	Data Analyzed by MN:							
	Accession Number	Date Reported	IP Address					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222 165.88.254.222					
		12/07/2020 12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/07/2020	165.88.254.222					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
		12/08/2020	165.88.254.200					
e. The total number of results reported by MN								
	from 12/07/2020 to 12/08/2020 was 1,974.							
	f. The total number of results reported byE√ from 11/22/2020 to 11/30/2020 was 13,291.							

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION C. BU LDING		(X3) DATE SURVEY COMPLETED	
05D21		05D21974	16	D. WING		02/17/2021		
NAME OF PROV DER OR SUPPLIER ST CDPH BRANCH LABORATORY			28454	I ADDRESS, CITY, STATE, ZIP CODE 454 LIVINGSTON AVE LENCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE		
D6102	<ol> <li>Based on the lat declaration signed by 12/16/2020, the labor approximately 430,000 from 11/02/2020 to 12</li> <li>The Laboratory II (12/16/2020 at 1:00 p ensure the laboratory</li> </ol>	poratory's annual testir / the laboratory directo ratory reported 00 SARS-CoV-2 test re: 2/16/2020.	r on sults led to	D6102				

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