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D5791	3. Based on the lab declaration signed by 12/16/2020, the labor	poratory's annual testing	ron	D5791			
	12, 2021 at approxim	Director affirmed (Februately 2:10 pm) the usure there was an ong r, assess and when					
D5800	POSTANALYTIC SYS CFR(s): 493.1290 Each laboratory that p must meet the applica	STEMS performs nonwaived teable postanalytic system .1291 unless HHS app	ms	D5800			8Mar2021

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5800 Continued From page 74 Findings 1-7: please see response to findings at D5801, a procedure specified in Appendix C of the State D5805, D5807, D5809, D5815, D5821, and D5891 below. Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the In regard to the 19 samples in question (D5801), we postanalytic systems and correct identified have verified that the samples were handled in problems as specified in §493.1299 for each accordance with the standard operating procedure specialty and subspecialty of testing performed. (SOP) in place on December 10, 2020 (CA-SOP-RPT-002). Based on the input from the CDPH laboratory directors', it was determined that results with This Condition is not met as evidenced by: IC dropout were better characterized as Invalid results. Based on the severity of the deficiencies cited This change in classification was implemented via the herein, it was determined that the condition onsite CDPH lab directors' discretion on December 11, Postanalytic Systems was not met as mandated 2020 with the SOP approved on December 13, 2020. by CLIA in Subpart K of Title 42 of the Code of During these two days, results were manual reported Federal Regulation. and staff were trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a LIMC update was implemented into production Findings included: to automated result code calculation thereby reducing any manual intervention by the data analyst staff. The laboratory failed to ensure the electronic system(s) it used, accurately and reliably Please refer to the Analysis Timeline. transmitted patient-specific data from the point of • 28Oct2020 – 11Nov2020 – results were reported data entry to final report destination. (See as per the IFU (cutoff < 42 as positive) D5801). • 11Nov2020 - 11Dec2020 - a lower Ct cutoff (< 37) was set for positive results based on Ct value observed during validation, reflecting a change in 2. The laboratory failed to ensure its test results interpretation from the IFU provided the correct interpretation for 11Dec2020 - 25Jan2021 - high Ct values (> 37 - < SARS-CoV-2 (See D5805). 42) were interpreted as inconclusive 25Jan2021 – present – high Ct values (> 37 - < 42) 3. The laboratory failed to ensure its accurate were interpreted as presumptive positive reference intervals determined by the laboratory were available for the authorized person, or The laboratory maintains duplicate original reports in individual responsible for using the test results addition to issuing amended reports with original (See D5807). results. 4. The laboratory failed to ensure it updated their clients regarding changes in the interpretation of results (See D5809). The laboratory failed to ensure it updated clients when the laboratory failed to release patient test results on time (See D5815).

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES IDENTIFICATIONNUMBER: A. BUILDING _ COMPLETED AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5800 Continued From page 75 D5800 The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821) 7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the The below details are for D5801, D5805, D5807, postanalytic systems (See D5891) D5809, D5821 1a D5801 D5801 TEST REPORT 8Mar2021 In regard to the 19 samples in question (D5801), we CFR(s): 493.1291(a) have verified that the samples were handled in accordance with the standard operating procedure The laboratory must have an adequate manual or (SOP) in place on December 10, 2020 (CA-SOPelectronic system(s) in place to ensure test RPT-002). Based on the input from the CDPH results and other patient-specific data are laboratory directors', it was determined that results accurately and reliably sent from the point of data with IC dropout were better characterized as Invalid results. This change in classification was implemented entry (whether interfaced or entered manually) to via the onsite CDPH lab directors' discretion on final report destination, in a timely manner. This December 11, 2020 with the SOP approved on includes the following: December 13, 2020. During these two days, results (a)(1) Results reported from calculated data. were manual reported and staff were trained by the (a)(2) Results and patient-specific data CDPH lab directors until the LIMC changes were electronically reported to network or interfaced implemented. On December 13, 2020, a LIMC update systems. was implemented into production to automated result (a)(3) Manually transcribed or electronically code calculation thereby reducing any manual intervention by the data analyst staff. transmitted results and patient-specific information reported directly or upon receipt from Please refer to the Analysis Timeline. outside referral laboratories, satellite or • 28Oct2020 - 11Nov2020 - results were reported point-of-care testing locations. as per the IFU (cutoff < 42 as positive) This Standard is not met as evidenced by: 11Nov2020 - 11Dec2020 - a lower Ct cutoff (< Based on direct observation, interviews with 37) was set for positive results based on Ct value observed during validation, reflecting a change laboratory staff on December 8, 9, and 16, 2020, in interpretation from the IFU review of policies and procedures (P/P), quality • 11Dec2020 - 25Jan2021 - high Ct values (> 37 control (QC) and quality assurance (QA) records, < 42) were interpreted as inconclusive random review of patient test records covering 25Jan2021 - present - high Ct values (> 37 - < the period from 12/04/2020 to 12/10/2020, for 32 42) were interpreted as presumptive positive out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY D5801 Continued from page 76 D5801 Continued From page 76 the electronic system(s) it used accurately and (1) Immediate Corrective Action: N/A, The reliably transmitted patient-specific data, from the specimens in question were resulted as per SOP. A point of data entry to final report destination. look forward from December 13, 2020 to December 31, 2020 verified that all samples were reported per Findings included: SOP versions 2 and 3.1. (2) Patient Impact: N/A, based on the lookback from The laboratory subcontracts the preanalytic October 28, 2020 to December 11, 2020, there were and postanalytic phases of testing to an outside 8,756 samples with results of IC Dropout that were entity, COLOR. reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. The following 13 final patient test reports Results were correctly reported as inconclusive emailed by the laboratory on 01/06/2021 were pursuant to the lab SOP. Additionally, per Lab Director Dr. Rosendorff, the future change in reported as "Negative" for SARS-CoV-2. definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), The laboratory LIMC LIS report sent by the and there would not be patient harm. laboratory to the examiners via e-mail on 12/22/2020 showed a result of "Not Detected" for (3) Preventative Action: No revision to SOP or SARS-CoV-2. process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily checklist is being completed at shift change by the b. The final test result generated by COLOR Data Analyst staff and verified by the Sign Out showed a final result of "Negative" Manager. LIMIC NOT DETECTED **Final Test Report** (4) Monitoring Mechanism: Monthly audits for data Report integrity are performed as stipulated in the 2021 audit Not Detected Negative for SARS-CoV-2 schedule by the Quality organization. The February Not Detected Negative for SARS-CoV-2 audit confirmed that the results matched the current SOP and process 100% of the time. Not Detected Negative for SARS-CoV-2 Not Detected Negative for SARS-CoV-2 Attachment 1: Sample Look Back and Look Forward Not Detected Negative for SARS-CoV-2 Attachment 2: 2021 Audit Schedule Not Detected Negative for SARS-CoV-2 Attachment 3: End to End Audit Plan Attachment 4: 2021 Audit-004 Report Not Detected Negative for SARS-CoV-2 Not Detected Negative for SARS-CoV-2

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING _ AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING_ 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5801 D5801 Continued From page 77 3. Review of the e-mail communication sent by the Director of Clinical Informatics on 12/13/2020, and review of the 32 patient test records obtained by the examiners on December 16, 2020 showed: a. Thirteen (13) patient results were reported as "Not Detected" when it should have been reported "Inconclusive" on December 10, 2020. Reported as Not Detected, but should be reported as Inconclusive b. Nineteen (19) patient results were reported as "Inconclusive" when it should have been reported as "Invalid" on December 10, 2020.

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Ē	LIMC LIS, and the ou	failed to show the nitted results between it utside entity subcontractere periodically verified	ted				
	declaration signed b	00 SARS-CoV-2 test re	or on				
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(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES IDENTIFICATIONNUMBER: A. BUILDING _ COMPLETED AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES ID (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREEIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) D5801 D5801 Continued From page 79 patient-specific data, from the point of data entry to final report destination. D5805 8Mar2021 D5805 TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure its test report provided the correct interpretation for SARS-CoV-2. Findings included: 1. Based on interview with the laboratory director on 12/08/2020, there were several patient test results reported in error as a result of incorrect data analysis and interpretation, such "Not Detected" for SARS-Cov-2 should have

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	been "Inconclusive" b. "Inconclusive" for SARS-CoV-2 sho been true "Invalid" 2. Based on review of CDPH Branch L LIMC LIS reports emailed on 12/22/2020 SARS-CoV-2 final patient test reports er the laboratory director on 01/06/2021 fro COLOR, the laboratory failed to provide correct interpretation of results to the pat and how the laboratory conveyed this into its clients. a. In an e-mail communication with the laboratory director on 01/12/2021, the exasked if corrected reports were issued for affected patients. The laboratory director indicated that reports were not amended provide the correct interpretation of results considered that reports were not amended provide the correct interpretation of results considered that reports were not amended provide the correct interpretation of results considered that reports were not amended provide the correct interpretation of results considered that reports were not amended provide the correct interpretation of results considered that reports were not amended provide the correct interpretation of results considered that reports were not amended provided the correct interpretation of results considered that reports were not amended provided the correct interpretation of results considered that reports were not amended provided the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation of results considered that reports were not amended to indicate the correct interpretation o	ranch Lab 22/2020 ar orts email 021 from rrovide the the patien this inform with the , the exam sued for the director hended to of results	ed by ts, nation	D5805				
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	3. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12	the laborate tratory report to SARS-Co. 2/16/2020.	tory director ted oV-2 test res	r on				
D5807	4. The Laboratory I (01/12/2021 at appro through email communication failed to ensure its tecorrect interpretation TEST REPORT CFR(s): 493.1291(d) Pertinent "reference is as determined by the tests, must be available."	ximately 11: unication tha st results pr for SARS-C intervals" or a laboratory ble to the au	:58 a.m.) at the labora rovided the CoV-2. "normal" value of the performing athorized performing at the performance at the perform	alues, the erson	D5807	See response started in D5801		8Mar2021
	who ordered the tests individual responsible							

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING _ COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5807 Continued From page 82 D5807 This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results. Findings included: 1. Based on review of patient test reports for SARS-CoV-2, the laboratory indicated under the test result and specific genes cycle threshold (Ct) value, "To learn more about the technical details of the test, please see the test methodology and limitation section." 2. Review of the test reports methodology and limitation section did not indicate how the laboratory determined its results (Positive, Negative, Inconclusive, and Invalid). The report also indicated its reference, "Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, 2019-nCOv-PCR AUS Instructions for Use (IFU)." Review of Perkin Elmer New Coronavirus Nucleic Acid Detection Kit FDA Approved EUA IFU for PE New Coronavirus Nucleic Acid (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) indicated only the interpretation for the following: a. Detected b. Not Detected c. Invalid

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20000	laboratory director on 01/12/2021, and review of pareported on 12/10/2020: a. Results were reported as "Not detected" or							
	reported on 12/10/2020:							
	b. Results were	e reported as ' been true "Inv						
	2. The laboratory failed to ensure it updated their clients regarding change in the interpretation of results. The laboratory's outside entity subcontractor, failed to issue corrected reports because the current system it used is not capable of issuing corrected reports.			tation				
	of issuing corrected reports. 3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure it updated their clients regarding changed in the interpretation of results.							
	"Negative", but t		were reporte ult should ha	ed as ve				
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	NOT DETECTED	LIMC Report		at Report				
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	b. Below are te	et reculte that y	were renorts	ac ha				
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	been "Invalid"	at the contest is	coult official	11440				
	INCONCLUSIVE	Reported	Correct Inte	rpretation		1		
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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI			PLE CONSTRUCTION G	(X3) DATE SU COMPLET	
		05D21974	16	B. WING		02/1	7/2021
	ROVIDER OR SUPPLIER RANCH LABORATOR	Y		SS, CITY, ST VINGSTO IA, 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 CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5809	4. Based on the lab declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12 5. The Laboratory 1 (01/12/2021 at 11:58 communication that the declaration is the second of the laboratory 1 (01/12/2021) at 11:58 communication that the declaration is the second of the laboratory 1 (01/12/2021) at 11:58 communication that the declaration is the second of the laboratory 1 (01/12/2021) at 11:58 communication that the declaration is the second of the laboratory 1 (01/12/2021) at 11:58 communication that the declaration is the second of the laboratory 1 (01/12/2021) at 11:58 communication that the laboratory 1 (01/12/2021) at 11:58 communication the laboratory	poratory's annual testing the laboratory director ratory reported 00 SARS-CoV-2 test rese/16/2020. Director affirmed a.m.) through email the laboratory failed to clients regarding change esults because the	ron	D5809	See response started in D580	1	8Mar2021
	results within its estal laboratory must deter of the patient test(s) in the appropriate indivitesting. This Standard is not in Based on direct obse and procedures, qual assurance (QA) reconconducted with the lal laboratory failed to enwhen the laboratory firesults on time. Findings included: 1. Review of the lab procedures (Policy # Specimen Collection, Effective Date 12/07/2	met as evidenced by: rvation, review of polici ity control (QC) and qu rds, and interviews boratory staff, the asure it updated their cl ailed to release patient poratory's policies and CA-CLSRV-SOP-002, Storage, and Shipping	e gency notify ies ality ients test				

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER		(X2) MULTIPLE A. BUILDING _	E CONSTRUCTION	(X3) DATE SURV COMPLETED	
		05D21974	16	B. WING		02/17/	2021
	OVIDER OR SUPPLIER ANCH LABORATOR	Y		SS, CITY, STAT		н	
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES ST BE PRECEDED BY FULL RE ENTIFYING INFORMATION)	S EGULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	.D BE	(X5) COMPLETION DATE
D5815	the laboratory direct the laboratory start of the samples get to the s	communication with or on 01/08/2021, that counting for TAT when he laboratory. It sampling covering the 12/10/2020, the laboratory 5 out of 32 SARS-CoV with no documentation of attent test results. It sampling covering the 12/10/2020, the laboratory cation test results. It sampling covering the 12/10/2020, the laboration of attent test results. It sampling covering the 12/10/2020, the laboration of 12/10/2020, the laboratory 12/10/2020, the laboratory director oratory reported 12/10/2020, the laboratory director oratory reported 12/16/2020. It procedures the laboratory director oratory reported 12/16/2020.	Result Inconclusive	D5815	Finding 1a, 2-3 See response in D5801		8Mar2021

NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY STREET ADDRESS. CITY, STATE. ZIP CODE 28454 LIVINGSTON AVE VALENCIA, CA 91355 (RACH DEPRIORSY MAYS TE PRECEDED STATE OF PROVIDERS FRANCE CORRECTION. RESCUENTIFYING INFORMATION) DS821 Continued From page 89 (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test and, if applicable, the individual using the test results of reporting perrors. (k)(2) Issue corrected report. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (CC) and quality assurance (CA) records, and intervews conducted with the laboratory director, the laboratory through COLDR failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results. Findings included: 1. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, the laboratory through COLDR failed to perform the following: a. Notification and Issuance of Corrected Reports i. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, "Not defected" but should have been "Inconclusive," and "Inconclusive" but should have been true "Invalid." The laboratory site of the unsure it notified and insued amended reports to the unifold and insued amended reports to the unifold and insued amended reports to the unifold and and several development to the unifold and an expert and the provided provided to the patients reported on 12/10/2020. "Not defected" but should have been "Inconclusive" but should have been true "Invalid." The laboratory directs to the unifold and inconclusive to the following: and "Inconclusive" but should have been true "Invalid." The laboratory directs to the unifold mended reports to the		OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C			PLE CONSTRUCTION G	(X3) DATE SURVEY COMPLETED	
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COPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91335 CAPITED GEACH DEPICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTEFINIS INFORMATION.) TAG CROSS-REFERENCED TO THE APPROPRIATE DS821 Continued From page 89 DS821 DS821 Continued From page 89 DS821 DS821 (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results (k)(3) Maintain duplicates of the original report. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (COC) and quality assurance (QA) records, and interviews conducted with the laboratory director, the laboratory through COLOR 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. Findings included: Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, "Not detected" but should have been "Inconclusive," and "Inconclusive" but should have been true "Invalid." The laboratory director on ensure it with the laboratory director on of 11/20/2021, and review of patients reported on 12/10/2020, "Not detected" but should have been true "Invalid." The laboratory director on ensure it inconclusive," and "Inconclusive" but should have been true "Invalid." The laboratory director on ensure it inconclusive," and "Inconclusive" and "Inconclusive" and "Inconclusive" and "Inconclusive" and "Inconclusive" and "Inconclusive" and "Inconclusiv	NAME OF PE	POVIDER OR SUPPLIER		STREET ADDR	ESS. CITY. ST	ATE, ZIP CODE		
VALENCIA, CA 91355			v					
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(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue cornected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. 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 director, the laboratory through COLOR 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. Findings included: 1. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, the laboratory through COLOR failed to perform the following: a. Notification and Issuance of Corrected Reports i. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, That detected but should have been "Inconclusive," and "inconclusive" but should have been Itnue "Invalid." "The laboratory direct on ensure it	PREFIX	(EACH DEFICIENCY MUS	T BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO	DBE COMP	PLETION
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individual using the test results.		(k)(1) Promptly notify ordering the test and, using the test results (k)(2) Issue corrected authorized person or applicable, the individual well as the corrected This Standard is not a Based on direct obse and procedures, qual assurance (QA) recorded the authorized person results, and maintainer report. Findings included: 1. Based on email alaboratory director on patients reported on through COLOR faile a. Notification and Is Reports i. Based on email alaboratory director on patients reported on through COLOR faile a. Notification and Is Reports i. Based on email alaboratory director on patients reported on through COLOR faile a. Notification and Is Reports i. Based on email alaboratory director on patients reported on the color of the color	the authorized person if applicable, the indiv of reporting errors. I reports promptly to the dering the test and, if dual using the test resurates of the original repreport. The as evidenced by: a evidenc	idual e lts. ort, as ies ies iality it ts to test inal e v of tory ing:				

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	ROVIDER OR SUPPLIER RANCH LABORATOR	ATORY 28454 VALE			DRESS, CITY, STALLIVINGSTON	AVE		
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D5821	Continued From page	ge 90			D5821			
ř	ii. Random patient from 12/04/2020 to 1 tested and reported but should have bee of 19 "Inconclusive" "Invalid" for SARS-C	2/10/2020, 13 out of 13 n "Inconclu but should	the laborate 3 "Not Detections sive" and 19 have been	ory eted" out		*		
	NOT DETECTED	Reported	Correct Inte	erpretation				
		Negative	Inconc	lusive				
		Negative	Inconc	lusive				
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	OF DEFICIENCIES OF CORRECTION		R/SUPPLIER/CL CATIONNUMBER 05D219741	R:	(X2) MULTIPLE A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPL	
NAME OF PE	ROVIDER OR SUPPLIER			STREET ADD	RESS, CITY, STATE	, ZIP CODE		
	RANCH LABORATO	ORY			IVINGSTON A			
					CIA, CA 91355			
(X4) ID	SLIMMAR	Y STATEMENT OF	DEFICIENCIES		ID	PROVIDER'S PLAN O	E CORRECTION	(X5)
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D5821	Continued From	page 91			D5821			
	INCONCLUSIVE	Reported	Correct Inter	pretation				
		Inconclusive	Inval					
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		, mediciosite	***************************************	-				
	i. Based on rev emailed by the lab the laboratory thro reports on 12/07/2 results on 12/04/2 original report.	ough COLOR is 2020 for reporte 020 without pro 10 out of 10SA	test records r on 12/24/20 ssued amended SARS-Co oviding the	020, ded				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
05D219			219741	16	B. WING		02/17/2021	
CDPH BRANCH LABORATORY 28454				28454 LI	RESS, CITY, STATE, ZIP CODE LIVINGSTON AVE CIA, CA 91355			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)				ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	ON SHOULD BE COMPLETION DATE	
D5821	Continued From page 92				D5821	D5821 Finding 1b, 2-3: 1. In the event that a report must be amended, both the original and the amended reports are retained.		
	Accession #	Original Report 12/04/2020 Detected Detected Detected Detected		pended 07/2020 * *		2. Original and amended versions of the reaffected by the error on 04Dec2020 have b retained. See Attachment 5.	ive Action: N/A, Duplicates of maintained. The amended inal report's result and date as a	
		Not Detected Detected Detected	. , , , , , , , , , , , , , , , , , , ,	*		(1) Immediate Corrective Action: N/A, I the original reports are maintained. The ar reports contain the original report's result reference.(2) Patient Impact: N/A, based on a look		
		Detected Detected Detected Detected		*		October 28, 2020 to December 11, 2020 the process has been in place to maintain the original and amended report. The amended report maintains the original results, original reported date, as well as the updated results.		
	*Unable to return results for this sample. Please disregard any previous reports as they were issued in error.			y were		 (3) Preventative Action: No revision to S process is placed into use until the Lab Dir Rosendorff, has provided written approval (4) Monitoring Mechanism: As part of the audits schedule we are auditing for the preoriginal and amended reports. This is stipted. 	rector, Dr. e monthly sence of all	
Amended Report: The previously reported result (detected/not detected) is not valid due to a lab process error (Accession #s), Covid-19 Test.				sult ab process		2021 audit schedule that is performed by the Quality organization.		
	Report Test Date: December 4, 2020 Recommendation: This patient should be retested.							
 Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report. 				g on				