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		CPH889339 OF PROVIDER OR SURPLIED STREET AL		B. WING		04/22/2021	
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D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230			D5200			
	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed. This Condition is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: General Laboratory System was not met.						
D5209	Findings included: The laboratory failed to establish and follow written policies and procedures to assess competency for 236 out of 426 (approximately 55%) of the total laboratory staff prior to processing, testing and reporting patient samples for SARS-CoV-2 RT-PCR (See D5209). PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This Standard is not met as evidenced by: Based on interviews conducted with the laboratory staff on 02/07/2021 and 02/08/2921,		mples NT n d sess	D5209			

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.

YL3M11 State 2567

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE **DEFICIENCY**) D5209 D5209 Continued From page 1 review of electronic document control system, personnel files mailed by CDPH-Branch Lab at Laboratory Field Services (LFS) office on 02/11/2021, test records covering the period from 12/07/2020 to 01/13/2021, for 30 out of 30 patient test records reviewed, it was determined that the laboratory failed to follow written policies and procedures to assess competency for 236 out of 426 (approximately 55%) of the total laboratory staff prior to processing, testing and reporting patient samples for SARS-CoV-2 RT-PCR. Findings included: Review of the laboratory policies and procedures (SOP # CA-QM-SOP-001, Title Quality Management Plan, V2, Effective Date 03/01/2021) section 6.2 Personnel/Human Resource Management, subsection 6.2.1 Assessment of Competence stated that, Personnel competence is assessed at the following times for their existing, new, or changed job processes and procedures: Initially- after training and beforeworking independently 1st year- 6 months and 12 months from start of training Ongoing- at least annually throughout laboratory tenure after the first 12 months on a workstation Remedial- when an assessment reveals the need for improvement Non-technical employee competency assessments may be performed yearly at the discretion of the laboratory director." 2. At the time of complaint investigation on 02/07/2021 and 02/08/2021, the laboratory was

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE **DEFICIENCY**) D5209 Continued From page 2 D5209 asked to provide its most recent personnel list from preanalytic, analytic, and postanalytic processes. One of the general supervisors printed the laboratory's most recent personnel roster for the following 2 shifts: i. Saturday to Tuesday (Day and Night Shift) Accessioning a. Extraction b. **PCR** C. d. Data Analysis ii. Wednesday to Friday (Day and Night Shift) a. Accessioning Extraction b. **PCR** C. d. Data Analysis Review of the personnel records mailed to Laboratory Field Services office on 02/11/2021, it was determined that the laboratory failed to follow its written policies and procedures by allowing 236 out of 426 laboratory staff to work independently while the laboratory's documentation indicated that its training and competency protocols had not been completed as specified in its Quality Management Plan. Saturday to Tuesday (Day Shift) i. Accessioning a.1. 1 out of 1 supervisor (resigned) a.2. 37 out of 37 accessioning staff- completed

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING _ COMPLETED **CPH889339** B. WING _ 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY

CDPH BRANCH LABORATORY		28454 LIVINGSTON AVE VALENCIA, CA 91355					
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REG OR LSC IDENTIFYING INFORMATION)	ULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE		
	OR LSC IDENTIFYING INFORMATION)	ncy d)		CROSS-REFERENCED TO THE APPROPRIATE			
	a.2. 1 out of 42 accessioning staff - no competency assessmentb. Extraction						
	b.1. 1 out of 1 supervisor- no competency assessmentb.2. 42 out of 57 extraction staff- no competer assessment	ncy					
	c. PCR						

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING _ COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING_ 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER

CDPH BRANCH LABORATORY		28454 LIVINGSTON AVE VALENCIA, CA 91355					
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REG OR LSC IDENTIFYING INFORMATION)	SULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE		
D5209	Continued From page 4		D5209				
	c.1. 1 out 1 supervisor- no competency assessment						
	c.2. 7 out of 13 PCR staff - no competency assessment						
	d. Data Analysis						
	d.1 Sign out manager (not indicated)						
	d.2. 2 out of 2 data analysis staff- no compete assessment	ency					
	iii. Wednesday to Friday (Day Shift)						
	a. Accessioning						
	a.1. 1 out of 1 supervisor- no competency assessment						
	a.2. 47 out of 47 accessioning staff-no competency assessment						
	b. Extraction						
	b.1. 2 out of 2 supervisors- no competency assessment						
	b.2. 15 out of 42 extraction staff- no competer assessment	псу					
	c. PCR						
	c.1 2 out of 2 supervisor- no competency assessment						
	c.2. 5 out of 15 PCR staff- no competency assessment						

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA
IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

O4/22/2021

NAME OF PROVIDER OR SUPPLIER

CDPH BRANCH LABORATORY

(X3) DATE SURVEY
COMPLETED

04/22/2021

CDPH BRANCH LABORATORY		28454 L VALENO			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REI 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
D5209	Continued From page 5		D5209		
	d. Data analysis				
	d.1. 1 out of 1 Sign out manager				
	d.2. 2 out of 3 data analysis staff- no compet assessment	ency			
	iv. Wednesday to Friday (Night Shift)				
	a. Accessioning				
	a.1. 1 out of 1 supervisor- no competency assessment				
	a.2. 31 out of 37 accessioning staff-no competency assessment				
	b. Extraction				
	b.1. 1 out of 1 supervisor- no competency assessment				
	b.2. 34 out of 46 extraction staff- no compete assessment	ency			
	c. PCR				
	c.1 0 out of 0 supervisor (open position)				
	c.2. 9 out of 14 PCR staff- no competency assessment				
	d. Data analysis				
d.1. Sign out manager (not indicated)					
	d.2. 3 out of 3 data analysis staff- no competency assessment				
5. There was no evidence submitted sho		ing			

` '		(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBI		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		СРН88933	39	B. WING		04/2	2/2021	
	ROVIDER OR SUPPLIER	4	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 COR (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE	
D5209	completed competen of 426 (approximately staff, prior to process patient results. 6. The following arthe 30 randomly reviec covering the period fr 01/13/2021, wherein reported 30 out of 30	cy assessment for 236 (55%) of the total laboring, testing, and report ethe accession number ewed patient test record from 12/07/2020 to the laboratory tested a SARS-CoV-2 patient ensure it followed the Plan policies and	ratory ing ers of ds	D5209				
D5400	03/25/2021, the labor 943,252 SARS-CoV- 03/25/2021, 6:43 p.m ANALYTIC SYSTEM CFR(s): 493.1250	• •	, f	D5400				

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED **CPH889339** B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE **DEFICIENCY**) D5400 D5400 Continued From page 7 must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed. This Condition is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: ANALYTIC SYSTEM was not met. Findings included: 1. The laboratory failed to ensure procedure manuals were updated, approved, signed, and dated by the current Laboratory Director (See D5407). 2. The laboratory failed to ensure it followed corrective action policies to ensure accurate and reliable patient test results (See D5779). The laboratory failed to ensure its test record provided the correct disposition of specimens, its corrected result, with incorrect result (noted as such) for SARS-CoV-2 (See D5787). 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). D5407 PROCEDURE MANUAL D5407 CFR(s): 493.1251(d)

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5407 D5407 Continued From page 8 Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This Standard is not met as evidenced by: Based on interviews with laboratory staff on February 7, and 8, 2021, 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 11/06/2020 to 01/13/2021, for 208 out of 208 patient test records reviewed, it was determined that the laboratory failed to ensure the laboratory director approved, signed and dated the backup procedure for Janus G3 instrument, such as manual pipetting of reagents and master mix whenever pipetting errors are encountered with the automated benchtop liquid handler workstation designed to automate-RT-PCR set-up, procedure for processing low volume for a storage (STO) plate, and the procedure for issuing amended or corrected reports. Findings included: Backup procedure for Janus G3 instrument: Manual pipetting of reagents and master mix whenever pipetting errors are encountered with automated liquid handler Based on review of the laboratory Quality Exception Reports (QER) documents on 02/07/2020 and 02/08/2020, the laboratory had issues with Janus G3 instrument giving pipetting errors on 12/10/2020 and 12/11/2020. The PCR technicians were instructed to begin manual pipetting of the reagents and master mix to the PCR plate. Review of the laboratory policies and

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5407 D5407 Continued From page 9 procedures (SOP # CA-PCR-SOP-001, Title SARS-CoV-2 RT-PCR Set-up Using Janus G3, Effective Date 11/04/2020) did not include the procedures for manual pipetting of reagents and master mix to the PCR plate whenever there are issues with the automated Janus G3 liquid handler. The following are the accession numbers of the 6 randomly reviewed patient test records covering the period from 12/09/2020 to 12/10/2020, wherein the laboratory performed manual pipetting of reagents and master mix to the PCR plate as a backup procedure for the automated Janus G3 liquid handler when it had issues with pipetting error. d. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST). The Laboratory Director affirmed (04/22/2021 at 10:40 a.m.) the laboratory failed to ensure the laboratory director approved, signed and dated the backup procedure for Janus G3 instrument, such as manual pipetting of reagents and master mix whenever pipetting errors are encountered with the automated benchtop liquid handler workstation designed to automate-RT-PCR set-up.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING IDENTIFICATION NUMBER: COMPLETED CPH889339 B. WING 04/22/2021 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 (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY **PREFIX PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5407 D5407 Continued From page 10 Procedure for processing low volume for a storage (STO) plate Based on review of the laboratory Quality Exception Reports (QER) documents on 02/07/2020 and 02/08/2020, the laboratory had an error scenario when there is not enough sample volume for a storage (STO) plate. Review of the laboratory policies and procedures (SOP # CA-EXT-SOP-003, Title Sample Transfer Using the Janus G3, Effective Date 12/06/2020) did not include the guidance to the technician for an error scenario when thereis not enough sample volume for a storage (STO) plate. The following are the accession numbers of the 16 reviewed patient test records on 12/08/2020, wherein the laboratory had an error scenario when there is not enough sample volume for a storage (STO) plate, and the procedure manual did not include the guidance on how to proceed with this low volume error. d. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST).

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AND PLAN OF CORRECTION IDENTIFICATION NUM		(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER CPH88933	ER:	A. BUILDING	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED 04/22/2021			
NAME OF BB	0.4050 00 0.4004.50		CTDEET ADDI	DESC CITY STA	TE ZID CODE	0-4/	22/2021		
	OVIDER OR SUPPLIER ANCH LABORATOR	ΥY	28454 L	DDRESS, CITY, STATE, ZIP CODE 4 LIVINGSTON AVE ENCIA, CA 91355					
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	ST BE PRECEDED BY FULL RE		ID PREFIX TAG	PROVIDER'S PLAN OF CORF (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE		
D5407	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 11 e. The Laboratory Director affirmed (04/22/2021 at 10:40 a.m.) the laboratory failed to ensure the laboratory director approved, signed and dated a procedure that will provide guidance to the technician who will encounter error due to low volume sample for storage plate. 3. Procedure for issuing amended or corrected reports a. At the time of complaint investigation during the early morning hours of 02/08/2021, the laboratory provided the drafted and unsigned policy and procedure titled, "Issuing Amended or Corrected Reports" (SOP # CA-SOP-RPT-003) which stated the procedural guidelines for issuing amended or corrected clinical patient test reports at CDPH Branch Laboratory, Valencia CA. b. The following are the accession numbers of the 38 out of 38 reviewed patient test records covering the period from 11/14/2020 to 11/23/2020, wherein the laboratory amended reports without an approved and signed policy and procedure for issuing amended or corrected reports for SARS-CoV-2.		D5407						

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	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE			LE CONSTRUCTION	(X3) DATE SUF		
AND PLAN C	F CORRECTION	IDENTIFICATION NOMBE	IK.	A. BOILDING		COMPLETI	בט	
		CPH88933	9	B. WING		04/2	2/2021	
NAME OF PF	OVIDER OR SUPPLIER		STREET ADDR	DDRESS, CITY, STATE, ZIP CODE				
CDPH BR	ANCH LABORATOR	Y		IVINGSTON				
			VALEN	CIA, CA 913	555			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUI CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5407	Continued From page 12			D5407				
D5779	03/25/2021, the labo 943,252 SARS-CoV-03/25/2021, 6:43 p.m d. The Laboratory at 10:40 a.m.) the lat laboratory director appearance of the procedure manual corrected reports for CORRECTIVE ACTI CFR(s): 493.1282(a) Corrective action policity be available and followaintain the laboratory patient specimens in accurate and reliable reports. This Standard is not Based interviews with 02/07/2021 and 02/0 and procedures (P/P) quality assurance (Quest records covering to 11/23/2020, for 38 records reviewed, it will laboratory failed to every construction of the second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed, it will be second covering to 11/23/2020, for 38 records reviewed.	Director affirmed (04/22 poratory failed to ensure oproved, signed, and datal for issuing amended SARS-CoV-2. ONS dicies and procedures moved as necessary to pry's operation for testing a manner that ensures a patient test results and met as evidenced by:	ust g less ind tient 2020 etive	D5779				

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5779 D5779 Continued From page 13 Findings included: 1. At the time of complaint investigation during the early morning hours of 02/08/2021, the laboratory provided the drafted and unsigned policy and procedure titled, "Issuing Amended or Corrected Reports" (SOP # CA-SOP-RPT-003) which stated the procedural guidelines for issuing amended or corrected clinical patient test reports at CDPH Branch Laboratory, Valencia CA. Review of the drafted laboratory policy and procedure for issuing amended or corrected reports, section 5 "Policy" stated, "In the event that a laboratory error is discovered, CDPH Branch Laboratory notifies Color genomics of the affected reports need to be corrected. The laboratory director, or individual with delegated responsibility must communicate the approval of the corrected reports to Color. Color Genomics will issue the corrected reports." Review of patient test records on 02/08/2021, the laboratory failed to ensure it followed the drafted policy and procedure for issuing amended and corrected reports through Color since Color Genomics did not have a system in place for correcting and retracting test reports. Executive Order N-52-20 provided temporary regulatory relief permitting a provider to disclose COVID-19 test results to a patient via the Internet or other electronic means, prior to reviewing patient test results. b. Quality Exception Report (QER)-20-010 and CAPA-20-005 stated errors in barcode entry in PCR Janus. A total of 22 patient test reports were

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA			(X2) MULTIPLE CONSTRUCTION		` '	(X3) DATE SURVEY		
AND PLAN C	F CORRECTION	IDENTIFICATION NUMBE	ER:	A. BUILDING	S	COMPLET	ED	
		СРН88933	39	B. WING		04/2	2/2021	
NAME OF PE	ROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, STA	ATE, ZIP CODE			
CDPH BF	RANCH LABORATORY	Y		LIVINGSTON AVE				
			VALEN	CIA, CA 913	355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST	FATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
D5779	originally issued on 1 reports were subsequently and the issuently	1/14/2020. Corrected uently issued on 11/25/2 ance of the original repose submitted to show the sent to each patient on who requested the test that test results, which were the issuance of the o evidence to show that is sent to each patient on who requested the test of the original to each patient on who requested the test is sent to each patient on who requested the test is sent to each patient on who requested the test is sent to each patient on the patient of the each patient of the each patient of the each patient of the incorrect file each report, accession number in the patient of the each patient of the issue of the incorrect file each report was subsequent at an amended report was to the authorized personal test and amended report was to the authorized personal test reports.	cort. the or to st. rs of vere at or to st. umber uently ance e vas	D5779				

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		СРН88933	39	B. WING		04/	22/2021	
	ROVIDER OR SUPPLIER	Y	28454 L	DDRESS, CITY, STATE, ZIP CODE 4 LIVINGSTON AVE ENCIA, CA 91355				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF (EACH CORRECTIVE ACT CROSS-REFERENCED TO T DEFICIENC	ION SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
D5779	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		D5779					

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER			LE CONSTRUCTION	(X3) DATE SUF	
		СРН88933	19	B. WING		04/2:	2/2021
NAME OF PR	OVIDER OR SUPPLIER		STREET ADDI	RESS, CITY, STA	ATE, ZIP CODE		
	ANCH LABORATOR	v	28454 I	IVINGSTON	I AVE		
ODI II DI	ANOTICABOTATOR	•		CIA, CA 913			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES IT BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORREC' (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	(X5) COMPLETION DATE
	Continued From page 16			D5787			
D5787	TEST RECORDS			D5787			
D3707	CFR(s): 493.1283(a)			20.01			
	The laboratory must r	maintain an information	or				
		entification of the speci	men.				
		ime of specimen receip					
	the laboratory.						
		and disposition of speci	mens				
		laboratory's criteria for					
	specimen acceptabili						
	· / · /	nd dates of all specimer identity of the personne					
	performed the test(s)		EI WIIO				
		met as evidenced by:					
	Based interviews with	-					
		8/2021, review of polici	es				
	and procedures (P/P), quality control (QC) a	ind				
		A) records, review of pa					
		the period from 11/14/2	2020				
		out of 38 patient test					
	laboratory failed to er	was determined that the)				
		disposition of specimen	e ite				
	•	incorrect result (noted					
	such) for SARS-CoV-	`					
	Findings included:						
		ew with the laboratory s 2/08/2021, there were	taff				
		esults reported in error o	due				
	to the following:						
	a. Quality Exception	n Report (QER)-20-010)and				
		errors in barcode entry					
	PCR Janus.						
		ent test reports were 1/14/2020, and correcte	ed				

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY **PREFIX PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5787 D5787 Continued From page 17 reports were subsequently issued on 11/25/2020. The following are the accession numbers of the 14 out of 22 patient test results initially reported as "Positive" on 11/14/2020. The following are the accession numbers of the 8 out of 22 patient test results initially reported as "Negative" on 11/14/2020. iv. On 11/25/2020, 11 days after the issuance of the original report, the report for the 22 patients were amended. The laboratory indicated in the patient test reports, "Unable to return results for this sample. Please disregard any previous reports as they were issued in error. The following report are no longer valid and hereby rescinded." vi. The amended reports indicated 14 false positive results and 8 false negative results were initially reported on 11/14/2020. Quality Exception Report (QER)-20-012 stated an error in releasing the incorrect file uploaded in LIMC.

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		СРН88933	39	B. WING		04/2	2/2021
NAME OF PR	OVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, STA	ATE, ZIP CODE	•	
CDPH BR	ANCH LABORATOR	Y		IVINGSTON CIA, CA 913			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUST	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	CTION SHOULD BE THE APPROPRIATE	
D5787	Continued From page 18			D5787			
D3767	i. One patient was 11/20/2020, and corre 11/28/2020. ii. The patient test r "Positive" on 11/20/20 Accession number: iii. On 11/28/2020, 8 the original report, the iv. The laboratory in reports, "Unable to re Please disregard any were issued in error. longer valid and here v. The amended regresult was initially reported to a company control of the control of th	originally issued on ected report was issued result was initially report on the patient to exturn results for this same previous reports as the The following report are by rescinded." port indicated a false proported on 11/20/2020. In Report (QER)-20-013 an incorrect assigned on a different batch we at batch of plate.	ted as ee of est nple. ey e no ositive				
	i. A total of 15 patient test reports were originally issued on 11/23/2020, and corrected reports were subsequently issued on 12/01/2020.						
		e the accession numbe t test results initially rep 3/2020.					

	OF DEFICIENCIES	(X1) PROVIDER/SUPPLIER/C			LE CONSTRUCTION		(X3) DATE SURVEY	
AND PLAN O	F CORRECTION	IDENTIFICATION NUMBI	ER:	A. BUILDING	.	COMPLETED		
		CPH88933	39	B. WING		04/2	22/2021	
NAME OF PR	OVIDER OR SUPPLIER	•	STREET ADD	DDRESS, CITY, STATE, ZIP CODE				
CDPH BR	ANCH LABORATOR	Υ		LIVINGSTON				
			VALEN	CIA, CA 913	355			
(X4) ID PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENCIES T BE PRECEDED BY FULL RE ENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF ((EACH CORRECTIVE ACTIV CROSS-REFERENCED TO TH DEFICIENCY	E ACTION SHOULD BE COMPLET DATE		
D5787	Continued From page 19			D5787				
	iii. The following are the accession numbers of the 8 out of 15 patient test results initially reported as "Negative" on 11/23/2020.							
		e the accession numbe nt test results were repo 11/23/2020.						
		8 days after the issuance report for the 15 pation						
	reports, "Unable to re Please disregard any	vi. The laboratory indicated in the patient test reports, "Unable to return results for thissample. Please disregard any previous reports as they were issued in error."						
	vii. The laboratory a comments in the ame	also added thefollowing ended reports.						
	reported result (I to a laboratory p Recommendatio retested. • AMENDED REF	PORT: The previously Detected) is not valid d process error. on: This patient should b PORT: The previously Not Detected) is not val	oe					

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due to

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5787 D5787 Continued From page 20 a laboratory process error. Recommendation: This patient should be retested. AMENDED REPORT: The previously reported result (Inconclusive) is not valid due to a laboratory process error. This patient should be retested. viii. The amended reports indicated five (5) false positive, 8 false negative, and 2 inconclusive results were initially reported on 11/23/2020. 2. Based on review of CDPH Branch LabLIMC LIS reports and patient final test reports for SARS-CoV-2 from COLOR, the laboratory failed to provide the correct disposition of specimens, its corrected result, with incorrect result (noted as such) for SARS-CoV-2. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST). D5791 ANALYTIC SYSTEMS QUALITY ASSESSMENT D5791 CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This Standard is not met as evidenced by: Based on interviews with laboratory staff on 02/07/2021 and 02/08/2021, review of policies and procedures (P/P), quality control (QC) and quality

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assurance (QA) records, random review of

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: **CPH889339** B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5791 D5791 Continued From page 21 patient test records covering the period from 11/14/2020 to 01/13/2021, for 20 out of 20 patient test records reviewed, it was determined that 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 specified in CFR 493.1251 through 493.1283. Findings included: Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 03/01/2021) failed to include an ongoing mechanism to perform or document quality issues regarding the following: The laboratory failed to ensure the laboratory director approved, signed and dated the backup procedure for Janus G3 instrument, such as manual pipetting of reagents and master mix whenever pipetting errors are encountered with the automated benchtop liquid handler workstation designed to automate-RT-PCR set-up, procedure for processing low volume for a storage (STO) plate, and the procedure for issuing amended or corrected reports (See D5407). The laboratory failed to ensure it followed corrective action policies to ensure accurate and reliable patient test results (See D5779). The laboratory failed to ensure its test record provided the correct disposition of specimens, its corrected result, with incorrect result (noted as such) for SARS-CoV-2 (See D5787).

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/ IDENTIFICATION NUMBER CPH8893		ER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 04/22/2021		
NAME OF PROVIDER OR SUPPLIER			STREET ADDR	RESS, CITY, STA	TE. ZIP CODE		-
	ANCH LABORATOR	Υ		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 (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5791	2. The following and the 20 randomly revious reviews the period of 01/13/2021, wherein establish and follow procedures for an ormonitor, assess, and problems identified in 13. Based on the late 03/25/2021, the laboration of the procedure of the period of	Continued From page 22 2. The following are the accession numbers of the 20 randomly reviewed patient test records covering the period from 11/14/2020 to 01/13/2021, wherein 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			
D5800	POSTANALYTIC SY CFR(s): 493.1290 Each laboratory that must meet the applic requirements in §493 a procedure, specific Operations Manual (equivalent quality tesmonitor and evaluate postanalytic systems problems as specifie	, ,	ms proves State des ust ne	D5800			
	This Condition is not met as evidenced by:						

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5800 D5800 Continued From page 23 Based on the severity of the deficiencies cited herein, it was determined that the condition Postanalytic Systems was not met as mandated by CLIA in Subpart K of Title 42 of the Code of Federal Regulation. Findings included: The laboratory failed to ensure its test report provided the correct condition and disposition of specimens that were not tested for SARS-CoV-2 (See D5805). The laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results (See D5821). 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) D5805 TEST REPORT D5805 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.

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This Standard is not met as evidenced by:

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5805 D5805 Continued From page 24 Based on interviews with laboratory staff on February 7, and 8, 2021, 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 11/06/2020 to 01/13/2021, for 208 out of 208 patient test records reviewed, it was determined that the laboratory failed to ensure its test report provided the correct condition and disposition of specimens that were not tested for SARS-CoV-2. Findings included: 1. Based on interviews with laboratory staff on 02/07/2021 and 02/08/2021, the laboratory had several incidents of lost, discarded, and invalidated patient samples for SARS-CoV-2 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR). Review of the laboratory's Quality Exception Reports (QER) and Corrective Action and Preventive (CAPA) documents, showed the laboratory had several incidents of lost, discarded, and invalidated specimens due to laboratory accident, scanning errors, incorrect plates used, and low volume. Review of CDPH Branch Lab SARS-CoV-2 final patient test reports emailed by the laboratory director on 03/18/2021, indicated the laboratory failed to provide the correct condition and disposition of specimens that were not tested for SARS-CoV-2. The test reports for the 208 patient test records we reviewed, were deemed unsatisfactory and appended with four different types of comments shown in "a" through "d" below.

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5805 D5805 Continued From page 25 a. Lost/Missing/Discarded (e.g. laboratory accident, scanning errors) specimens were reported as "Unsatisfactory sample. Test could not be completed. The specimen failed to produce a valid result after 2 attempts." There was no documentation submitted showing there were two attempts made to get a result, and what were the nature of these attempts. 62 out of 62 patient samples on 11/06/2020 (B0000455). QER 20-006 indicated four sample cassettes were inadvertently discarded. The laboratory reports indicating the samples were unsatisfactory, when in fact the samples were inadvertently discarded is misleading, and failed provide the correct condition and disposition of the specimens.

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/C AND PLAN OF CORRECTION IDENTIFICATION NUMBER		LIA	(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY		
		IDENTIFICATION NUMBER	ER:	A. BUILDING		COMPLE	TED
	СРН889339		39	B. WING		04/22/2021	
NAME OF PR	ROVIDER OR SUPPLIER		STREET ADD	RESS, CITY, STA	TE, ZIP CODE	_	
CDPH BR	RANCH LABORATOR	Υ	28454	LIVINGSTON	AVE		
			VALEN	CIA, CA 913	55		
(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 CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	IVE ACTION SHOULD BE DATE		
D5805	Continued From page	ge 26		D5805			
	ii. 8 out of 8 patient samples on 11/13/2020 (B0000992). QER 20-11. As new samples were being loaded, old samples were being discarded. Eight samples were mistakenly discarded. These samples were not unsatisfactory. The laboratory failed to provide the correct condition and disposition of the specimens. iii. 2 of 2 patient samples on 11/26/2020. QER 20-016. These samples were inadvertently tossed out. These samples were not unsatisfactory. The laboratory failed to provide the correct condition and disposition of the specimens.		nples not de QER de				
	QER 20-019. The sa the Janus Reformation discarded. These sa	It samples on 12/11/202 Imples were not scanne er. The samples were mples were not aboratory failed toprovio	ed on				

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 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 (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5805 Continued From page 27 the correct condition and disposition of the specimens. v. 4 out 4 patient samples on 12/13/2020. QER 20-023. These four samples were also noted in QER 20-019. The samples were not scanned on the Janus Reformatter. The samples were discarded. These samples were not unsatisfactory. The laboratory failed to provide the correct condition and disposition of the specimens. vi. 3 out of 3 patient samples on 12/22/2020. b. Lost/Missing/Discarded (e.g. laboratory accident, scanning errors) specimens were reported as "Unsatisfactory sample. Test could not be completed. The test could not be completed because the sample was unsatisfactory." 3 out of 3 patient samples on 11/18/2020

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(B0005492)

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY		
AND PLAN OF CORRECTION			IDENTIFICATION NUMBER:		<u> </u>	COMPLETED		
CPH889339		9	B. WING		04/22/2021			
NAME OF PROVIDER OR SUPPLIER STREET AD			STREET ADDR					
CDPH BR	ANCH LABORATOR	(IVINGSTON CIA, CA 913				
(X4) ID PREFIX TAG	REFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	CTION SHOULD BE COMPLETION DATE		
D5805	5 Continued From page 28			D5805				
D3803	ii. 2 out 2 patient sa (ident iii. 2 out 2 patient sa	amples on 12/04/2020 ified missing on 12/07/2 ified missing on 12/12/2 imples on 12/13/2020 ent samples on 12/22/2	2020)	D3603				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
	СРН889339		39	B. WING		04/	04/22/2021	
CDPH BRANCH LABORATORY 28454 L			DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355					
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	(EACH CORRECTIVE ACTIVE CROSS-REFERENCED TO THE	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		
D5805	(X4) ID SUMMARY STATEMENT OF DEFICIENCIES PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY		D5805					

, ,		(X1) PROVIDER/SUPPLIER/C		(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY	
AND PLAN OF CORRECTION		IDENTIFICATION NUMBER:		A. BUILDING		COMPLETED	
		CPH88933	39	B. WING		04/22/2021	
NAME OF PR	OVIDER OR SUPPLIER		STREET ADD	RESS, CITY, STA	ATE, ZIP CODE	<u> </u>	
CDPH BR	ANCH LABORATOR	Υ		LIVINGSTON			
			VALEN	ICIA, CA 913	355		
(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 CORR (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AF DEFICIENCY)	ACTION SHOULD BE COMPLETION DATE TO THE APPROPRIATE		
D5805	Continued From pag	ge 30		D5805			
	ii. 1 out of 1 patien	t sample on 01/02/2021					
	d. Invalidated (e.g.	incorrect plates, lowvo	lume,				
		barcodes) specimens w					
		factory sample. Test co	uld				
	not be completed." The test could not be completed because the sample was						
	unsatisfactory.						
	i. 16 out of 16 patient samples on 01/13/2021						
	i. 16 out of 16 pati	ent samples on 01/13/2	021				
	5. Lost, discarded, and invalidated specimens						
	due to laboratory accident, scanning errors, incorrect plates used, and low volume were						
		i, and low volume were actory samples. Howeve					
		the correct condition a					
	disposition of the spe	ecimens.					
	6. Based on the lab	poratory director's email	on				
		ratory has processed 1					
	943,252 SARS-CoV-	-2 patient samples as of					
	03/25/2021, 6:43 p.n	n. (PST).					
D5821				D5821			
	CFR(s): 493.1291(k))					
	When errors in the re	eported patient test resu	ılts				
	are detected, the lab						
	following:	•					

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5821 D5821 Continued From page 31 (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. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This Standard is not met as evidenced by: Based interviews with laboratory staff on 02/07/2021 and 02/08/2021, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, review of patient test records covering the period from 11/14/2020 to 11/20/2020, for 38 out of 38 patient test records reviewed, it was determined that the laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results. Findings included: 1. Executive Order N-52-20 provided temporary regulatory relief permitting a provider to disclose COVID-19 test results to a patient via the Internet or other electronic means, prior to reviewing patient test results. 2. Based on interview with the laboratory staff on 02/07/2021 and 02/08/2021, there were several patient test results reported in error due to the following: a. Quality Exception Report (QER)-20-010 and CAPA-20-005 stated errors in barcode entry in PCR Janus. A total of 22 patient test reports were originally issued on 11/14/2020. Corrected

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5821 D5821 Continued From page 32 reports were subsequently issued on 11/25/2020, 11 days after the issuance of the original report. There was no evidence submitted to show the amended reports were sent to each patient or to the authorized person who requested the test. The following are the accession numbers of the 22 out of 22 patient test results, which were amended 11 days after the issuance of the original report, with no evidence to show that amended reports were sent to each patient or to the authorized person who requested the test. b. Quality Exception Report (QER)-20-012 stated an error in releasing the incorrect file uploaded in LIMC. One (1) patient test report, accession number was originally issued on corrected report was subsequently issued on 11/28/2020, 8 days after the issuance of the original report. There was no evidence submitted to show that an amended report was sent to the patient, or to the authorized person who requested the test. Quality Exception Report (QER)-20-013 and

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CAPA-20-004 stated an incorrect assigned data

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5821 D5821 Continued From page 33 belonging to samples in a different batch were released to a different batch of plate. A total of 15 patient test reports were originally issued on 11/23/2020. Corrected reports were subsequently issued on 12/01/2020, 8 days after the issuance of the original report. There was no evidence submitted to show amended reports were sent to each patient or to the authorized person who requested the test. The following are the accession numbers of the 15 out of 15 patient test results which were amended 8 days after the issuance of the original report, with no evidence to show that amended reports were sent to each patient or to the authorized person who requested the test. 3. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST). POSTANALYTIC SYSTEMS QUALITY D5891 D5891 **ASSESSMENT**

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5891 D5891 Continued From page 34 CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291. This Standard is not met as evidenced by: Based on interviews with laboratory staff on 02/07/2021 and 02/08/2021, 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 11/14/2020 to 01/13/2021, for 20 out of 20 patient test records reviewed, it was determined that 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 specified in CFR 493.1291. Findings included: Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 03/01/2021) failed to include an ongoing mechanism to perform or document quality issues regarding the following: The laboratory failed to ensure its test report provided the correct condition and disposition of specimens that were not tested for SARS-CoV-2 (See D5805).\ The laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results (See D5821). The following are the accession numbers of

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5891 D5891 Continued From page 35 the 20 randomly reviewed patient test records covering the period from 11/14/2020 to 01/13/2021, wherein 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. 3. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST). D6076 LABORATORY DIRECTOR D6076 CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart. 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:

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6076 D6076 Continued From page 36 1. The Laboratory Director failed to ensure quality assurance activities were established and maintained by the laboratory to assure the quality of services provided, and to identify failures in quality as they occur (See D6094). 2. The Laboratory Director failed to ensure the laboratory staff demonstrated competency prior to reporting patient test results (See D6102). LABORATORY DIRECTOR RESPONSIBILITIES D6094 D6094 CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This Standard is not met as evidenced by: Based on interviews conducted with the laboratory staff on 02/07/2021 and 02/08/2021, and review of test records covering the period from 12/07/2020 to 01/13/2021, for 30 out of 30 patient test records patient test records reviewed, it was determined that the Laboratory Director failed to ensure quality assurance activities were established and maintained by the laboratory to assure the quality of services provided, and to identify failures in quality as they occur. Findings included: The Laboratory Director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791). The Laboratory Director failed to establish and follow written policies and procedures for an

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6094 D6094 Continued From page 37 ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891). D6102 LABORATORY DIRECTOR RESPONSIBILITIES D6102 CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This Standard is not met as evidenced by: Based on interviews conducted with the laboratory staff on 02/07/2021 and 02/08/2921, review of personnel files mailed by CDPH-Branch Lab at Laboratory Field Services (LFS) office on 02/11/2021, test records covering the period from 12/07/2020 to 01/13/2021, for 30 out of 30 patient test records reviewed, it was determined that the Laboratory Director failed to ensure 236 out of 426 (approximately 55%) of the total laboratory staff received appropriate training prior to processing, and testing patient samples for SARS-CoV-2 RT-PCR. Findings included: 1. At the time of complaint investigation on 02/07/2021 and 02/08/2021, the laboratory was asked to provide its most recent personnel list from preanalytic, analytic, and postanalytic processes. One of the general supervisors printed the laboratory's most recent personnel roster for the following 2 shifts:

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6102 Continued From page 38 D6102 Saturday to Tuesday (Day and Night Shift) a. Accessioning b. Extraction **PCR** C. d. Data Analysis Wednesday to Friday (Day and Night Shift) ii. Accessioning a. Extraction b. **PCR** C. Data Analysis d. Review of the personnel records mailed to Laboratory Field Services office on 02/11/2021, it was determined that the laboratory failed to follow its written policies and procedures by allowing 236 out of 426 (approximately 55%) of the total laboratory staff to work independently while the laboratory's documentation indicated that its training and competency protocols had not been completed as specified in its Quality Management Plan. i. Saturday to Tuesday (Day Shift) a. Accessioning a.1. 1 out of 1 supervisor (resigned) a.2. 37 out of 37 accessioning staff- completed b. Extraction b.1. 2 out of 2 supervisors - no competency assessment b.2. 17 out of 38 extraction staff- no competency assessment

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX **PREFIX** TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6102 Continued From page 39 D6102 c. PCR c.1. 1 out of 1 supervisor- no competency assessment c.2. 4 out of 13 PCR staff - no competency assessment d. Data Analysis d.1. 1 out of 1 Sign out manager (not indicated) d.2. 4 out of 4 data analysis staff- no competency assessment ii. Saturday to Tuesday (Night Shift) Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 1 out of 42 accessioning staff - no competency assessment Extraction b.1. 1 out of 1 supervisor- no competency assessment b.2. 42 out of 57 extraction staff- no competency assessment PCR c.1. 1 out 1 supervisor- no competency

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assessment

c.2. 7 out of 13 PCR staff - no competency

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6102 Continued From page 40 D6102 assessment Data Analysis d.1 Sign out manager (not indicated) d.2. 2 out of 2 data analysis staff- no competency assessment iii. Wednesday to Friday (Day Shift) Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 47 out of 47 accessioning staff-no competency assessment b. Extraction b.1. 2 out of 2 supervisors- no competency assessment b.2. 15 out of 42 extraction staff- no competency assessment PCR c.1 2 out of 2 supervisor- no competency assessment c.2. 5 out of 15 PCR staff- no competency assessment Data analysis d.1. 1 out of 1 Sign out manager

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d.2. 2 out of 3 data analysis staff- no competency

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6102 Continued From page 41 D6102 assessment iv. Wednesday to Friday (Night Shift) Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 31 out of 37 accessioning staff-no competency assessment Extraction b.1. 1 out of 1 supervisor- no competency assessment b.2. 34 out of 46 extraction staff- no competency assessment PCR c.1 0 out of 0 supervisor (open position) c.2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d.1. Sign out manager (not indicated) d.2. 3 out of 3 data analysis staff- no competency assessment The following are the accession numbers of the 30 randomly reviewed patient test records covering the period from 12/07/2020 to 01/13/2021, wherein the laboratory tested and reported 30 out of 30 SARS-CoV-2 patient test

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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	
	СРН889339		39	B. WING		04/22/2021		
CDPH BRANCH LABORATORY 28454 L			DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355					
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL 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		
D6102	results, but failed to e received appropriate and testing patient sa Accession Number 5. Based on the lab 03/25/2021, the labor	ensure all laboratory statraining prior to proces amples. oratory director's email ratory has processed 1, 2 patient samples as of	on,	D6102				