STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. 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).	D5200		
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,	D5209		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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D5209	Continued From page 1	D5209		

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:

1. 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 fromstart 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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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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D5209	Continued From page 2 asked to provide its most recent personnel list from preanalytic, analytic, and postanalytic processes. 3. 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) a. Accessioning b. Extraction c. PCR d. Data Analysis ii. Wednesday to Friday (Day and Night Shift) a. Accessioning b. Extraction c. PCR d. Data Analysis 4. 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. 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	D5209		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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D5209	Continued From page 3 b. Extraction b.2. 2 out of 2 supervisors - no competency assessment b.1. 17 out of 38 extraction staff- no competency assessment 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) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 1 out of 42 accessioning staff - no competency assessment b. Extraction b.1. 1 out of 1 supervisor- no competency assessment b.2. 42 out of 57 extraction staff- no competency assessment c. PCR	D5209		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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D5209	Continued From page 4 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 competency assessment 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 competency assessment c. PCR c.1 2 out of 2 supervisor- no competency assessment c.2. 5 out of 15 PCR staff- no competency assessment	D5209		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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D5209	Continued From page 5 d. Data analysis d.1. 1 out of 1 Sign out manager d.2. 2 out of 3 data analysis staff- no competency assessment 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 competency assessment 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 showing	D5209		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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D5209	Continued From page 6 completed competency assessment for 236 out of 426 (approximately 55%) of the total laboratory staff, prior to processing, testing, and reporting patient results. 6. 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 samples but failed to ensure it followed the Quality Management Plan policies and procedures for competency assessment. Accession Number [redacted] 7. 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).	D5209		
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing	D5400		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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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). 3. 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). 4. 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).	D5400		
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)	D5407		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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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: 1. Backup procedure for Janus G3 instrument: Manual pipetting of reagents and master mix whenever pipetting errors are encountered with automated liquid handler a. 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. b. Review of the laboratory policies and	D5407		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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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. c. 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. [redacted] 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). 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 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.	D5407		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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D5407	Continued From page 10 2. Procedure for processing low volume for a storage (STO) plate a. 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. b. 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 there is not enough sample volume for a storage (STO) plate. c. 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. [redacted] 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).	D5407		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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D5407	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. [redacted]	D5407		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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D5407	Continued From page 12	D5407		

[redacted]

c. 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).

d. 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 procedure manual for issuing amended corrected reports for SARS-CoV-2.

CORRECTIVE ACTIONS

D5779 CFR(s): 493.1282(a) D5779

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

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 11/23/2020, for 38 out of 38 patient test records reviewed, it was determined that the laboratory failed to ensure it followed corrective action policies to ensure accurate and reliable patient test results.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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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. 2. 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." 3. 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. a. 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. i. A total of 22 patient test reports were	D5779		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5779	Continued From page 14 originally issued on 11/14/2020. Corrected 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. ii. 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. [redacted] c. Quality Exception Report (QER)-20-012 stated an error in releasing the incorrect file uploaded in LIMC. i. One (1) patient test report, accession number [redacted] as originally issued on 11/20/2020. A 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.	D5779		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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D5779	Continued From page 15 d. Quality Exception Report (QER)-20-013 and CAPA-20-004 stated an incorrect assigned data belonging to samples in a different batch were released to a different batch of plate. i. 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. ii. 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.  4. 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).	D5779		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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D5787	Continued From page 16 TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). 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 its test record provided the correct disposition of specimens, its corrected result, with incorrect result (noted as such) for SARS-CoV-2. Findings included: 1. 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. i. A total of 22 patient test reports were originally issued on 11/14/2020, and corrected	D5787 D5787		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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D5787	Continued From page 17 reports were subsequently issued on 11/25/2020. ii. The following are the accession numbers of the 14 out of 22 patient test results initially reported as "Positive" on 11/14/2020. [redacted] iii. The following are the accession numbers of the 8 out of 22 patient test results initially reported as "Negative" on 11/14/2020. [redacted] iv. On 11/25/2020, 11 days after the issuance of the original report, the report for the 22 patients were amended. v. 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. 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. b. Quality Exception Report (QER)-20-012 stated an error in releasing the incorrect file uploaded in LIMC.	D5787		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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D5787	Continued From page 18 i. One patient was originally issued on 11/20/2020, and corrected report was issued on 11/28/2020. ii. The patient test result was initially reported as "Positive" on 11/20/2020. Accession number: [redacted] iii. On 11/28/2020, 8 days after the issuance of the original report, the report was amended. iv. 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." v. The amended report indicated a false positive result was initially reported on 11/20/2020. c. Quality Exception Report (QER)-20-013 and CAPA-20-004 stated an incorrect assigned data belonging to samples in a different batch were released to a different batch of plate. 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. ii. The following are the accession numbers of the 5 out of 15 patient test results initially reported as "Positive" on 11/23/2020. [redacted]	D5787		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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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.

[redacted]

iv. The following are the accession numbers of the 2 out of 15 patient test results were reported as "Inconclusive" on 11/23/2020.

[redacted]

v. On 12/01/2020, 8 days after the issuance of the original report, the report for the 15 patients were amended.

vi. 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."

vii. The laboratory also added the following comments in the amended reports.

- AMENDED REPORT: The previously reported result (Detected) is not valid due to a laboratory process error. Recommendation: This patient should be retested.
- AMENDED REPORT: The previously reported result (Not Detected) is not valid due to

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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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 Lab LIMC 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. 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).	D5787		
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT 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 assurance (QA) records, random review of	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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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: 1. 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: a. 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). b. The laboratory failed to ensure it followed corrective action policies to ensure accurate and reliable patient test results (See D5779). c. 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).	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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D5791	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.  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).	D5791		
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 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 postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed. This Condition is not met as evidenced by:	D5800		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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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: 1. 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). 2. The laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results (See D5821). 3. 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)	D5800		
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:	D5805		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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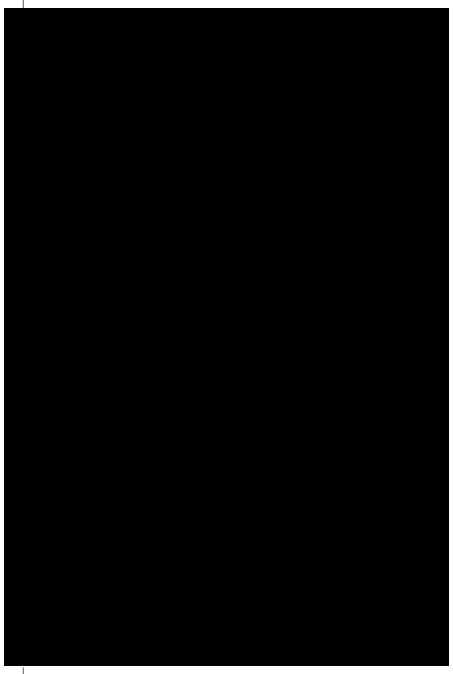
D5805	Continued From page 24 Based on interviews with laboratory staff on February 7, and 8, 2021, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/06/2020 to 01/13/2021, for 208 out of 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). 2. 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. 3. 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. 4. 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.	D5805		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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. i. 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. 	D5805		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5805	Continued From page 26	D5805		

[redacted]

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.

[redacted]

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.

[redacted]

iv. 6 out of 6 patient samples on 12/11/2020. QER 20-019. The samples were not scanned on the Janus Reformatter. The samples were discarded. These samples were not unsatisfactory. The laboratory failed toprovide

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5805	Continued From page 27 the correct condition and disposition of the specimens. [redacted] 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. [redacted] vi. 3 out of 3 patient samples on 12/22/2020. [redacted] 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." i. 3 out of 3 patient samples on 11/18/2020 (B0005492)			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5805	Continued From page 28	D5805		

[redacted]

ii. 2 out 2 patient samples on 12/04/2020

[redacted](identified missing on 12/07/2020)
(identified missing on 12/12/2020)

iii. 2 out 2 patient samples on 12/13/2020

[redacted]

iv. 49 out of 49 patient samples on 12/22/2020

[redacted]

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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D5805	Continued From page 29 [redacted]	D5805		

c. Invalidated (e.g. incorrect plates, lowvolume, improperly scanned barcodes) 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.

i. 50 out of 50 patient samples on 12/28/2020 (B0006916)

[redacted]

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5805	Continued From page 30 ii. 1 out of 1 patient sample on 01/02/2021 [redacted] d. Invalidated (e.g. incorrect plates, lowvolume, improperly scanned barcodes) specimens were reported as "Unsatisfactory sample. Test could 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 [redacted] [redacted] 5. Lost, discarded, and invalidated specimens due to laboratory accident, scanning errors, incorrect plates used, and low volume were reported as unsatisfactory samples. However, this does not provide the correct condition and disposition of the specimens. 6. 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).	D5805		
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following:	D5821		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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(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
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. i. A total of 22 patient test reports were originally issued on 11/14/2020. Corrected	D5821		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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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. ii. 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. [redacted] b. Quality Exception Report (QER)-20-012 stated an error in releasing the incorrect file uploaded in LIMC. i. One (1) patient test report, accession number [redacted] was originally issued on [redacted] 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. c. Quality Exception Report (QER)-20-013 and CAPA-20-004 stated an incorrect assigned data	D5821		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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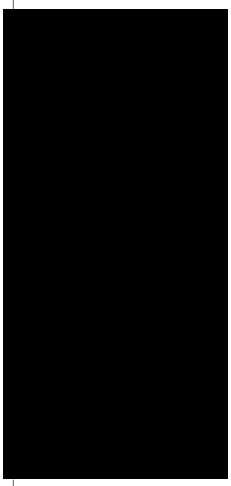
D5821	Continued From page 33 belonging to samples in a different batch were released to a different batch of plate. i. A total of 15 patient test reports were originally issued on 11/23/2020. Corrected reports were subsequently issued on 12/01/2020, 8 days after the issuance of the original report. There was no evidence submitted to show amended reports were sent to each patient or to the authorized person who requested the test. ii. 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).	D5821		
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT	D5891		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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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: 1. 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: a. 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).\ b. The laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results (See D5821). 2. The following are the accession numbers of	D5891		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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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).	D5891		
D6076	LABORATORY DIRECTOR 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:	D6076		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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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).	D6076		
D6094	LABORATORY DIRECTOR RESPONSIBILITIES 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: 1. 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). 2. The Laboratory Director failed to establish and follow written policies and procedures for an	D6094		

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	CPH889339	A. BUILDING _____ B. WING _____	04/22/2021

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D6094	Continued From page 37 ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891).	D6094		
D6102	LABORATORY DIRECTOR RESPONSIBILITIES 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. 2. One of the general supervisors printed the laboratory's most recent personnel roster for the following 2 shifts:	D6102		

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D6102	Continued From page 38 i. Saturday to Tuesday (Day and Night Shift) a. Accessioning b. Extraction c. PCR d. Data Analysis ii. Wednesday to Friday (Day and Night Shift) a. Accessioning b. Extraction c. PCR d. Data Analysis 3. 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	D6102		

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D6102	Continued From page 39 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) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 1 out of 42 accessioning staff - no competency assessment b. Extraction b.1. 1 out of 1 supervisor- no competency assessment b.2. 42 out of 57 extraction staff- no competency assessment c. PCR c.1. 1 out 1 supervisor- no competency assessment c.2. 7 out of 13 PCR staff - no competency	D6102		

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D6102	Continued From page 40 assessment d. 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) 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 competency assessment c. PCR c.1 2 out of 2 supervisor- no competency assessment c.2. 5 out of 15 PCR staff- no competency assessment d. Data analysis d.1. 1 out of 1 Sign out manager d.2. 2 out of 3 data analysis staff- no competency	D6102		

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D6102	Continued From page 41 assessment 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 competency assessment 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 4. 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	D6102		

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D6102	Continued From page 42 results, but failed to ensure all laboratory staff received appropriate training prior to processing and testing patient samples. Accession Number [redacted] 5. 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).	D6102		