STATEMENT OF DEFICIENC ES 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 SUPPL ER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) D PREFIX TAG	SUMMARY STATEMENT OF DEFICIENC ES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC DENTIFYING NFORMATION)	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	**D5200 -** CDPH Branch Laboratory had both Training/Orientation (CA-PER-SOP-001) and Competency (CA-PER-SOP-002 policies and procedures, which have been recently enhanced to more clearly delineate the different requirements for training assessment and competency assessment. Please note that on 02/07/2021 and 02/08/2021, no staff were due for 6-month or 12-month competency assessment because the laboratory had been open less than 6 months. The roster provided on 2/8/2021 was an official one, an issue being addressed through audit preparation training and exercises. A review of our records found that 412 / 412 (100%) of employees involved in the testing process have documented training; however, a limited number of delays in capturing training documentation were noted. These delays did not affect the Data Analysts, who are the only staff who report patient results, among whom 21/21 (100%) had no delay in training documentation.	3May2021
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/SUPPL ER REPRESENTATIVE'S SIGNATURE — TITLE: Laboratory Director — (X6) DATE: 03May2021

Any deficiency statement ending with an asterisk (*) denotes a deficiency which he institu ion may be excused from correcting providing it is determined that o her 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 he date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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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: 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	D5209	**Finding 1** Per the CLIA regulation, §493.1445 (12-13) the Laboratory Director has a responsibility to 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 is accomplished by establishing policies and procedures for monitoring individuals who conduct preanalytical, analytical and postanalytical phases of testing. CDPH Branch Laboratory had both Training/Orientation (CA-PER-SOP-001) and Competency (CA-PER-SOP-002 policies and procedures, approved by the Laboratory Director, in place prior to 24OCT2020. The original wording of the Quality Management Plan (CA-QM-SOP-001 v1 01NOV2020) states that evidence of completed job specific training is documented on a training and competency form or equivalent and that competency is conducted semi-annually in the first year of testing (at 6 months and 12 months and annually thereafter). The forms used to assess training were originally intended to document initial training that provided the evidence that personnel could perform their specific testing tasks reliably and to document the competency assessment due in both 6 and 12 months that would provide the evidence that the employee continued to know how to do their delegated tasks reliably and accurately. The laboratory acknowledges that the form documenting training and competency did not clearly differentiate the two processes. Prior to receipt of CDPH Inspection results on 23APR2021, the laboratory had already identified the need to revise and provide clarity to these two SOPS during the process mapping for the upcoming 6-month competency assessments that would begin in April (see Attachments D5209_1a, D5209_1b and D5209_1c). Please note that on 02/07/2021 and 02/08/2021, no staff were due for 6-month or 12-month competency assessment because the laboratory had been open less than 6 months. The Quality Management Plan was revised (v3. 11Apr2021) and in Section 6.2 Assessment of Competency, the misleading statement that both a separate competency in addition to the training documentation attesting that the individual is competent to perform the tasks was removed. (See Section 6.2 of the QMP: Attachment D5209_1c) Personnel competence is assessed at the following times for existing, new, or changed job processes and procedures: • 1st Year -- 6 months and 12months from start of training; and • Ongoing – at least annually throughout laboratory tenure after the first 12 months on a workstation; and • Remedial – when an assessment reveals the need for improvement.	3May2021

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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	Continued from page 2 **(1) Immediate Corrective Action:** The Personnel Orientation and Onboarding procedure (CA-PER-SOP-001 v2, 14Mar2021) has been updated to reflect and enhance current practice (see Attachment D5209_1a). A set schedule for a three-day orientation has been set. Training checklists (previously titled Training and Competency Assessment) have been updated to include all aspects of training (see D5209_1d). In addition, a roster with training status by shift is placed in each lab area so that any Supervisor can easily see training status (see example in Attachment D5209_1e). The Competency Assessment procedure (CA-PER-SOP-002v3 effective 3/8/2021 and v4 effective 4/11/2021, Attachment D5209_1b) was updated to define the process for competency assessment more clearly. Competency assessment forms were redesigned (in advance of 6-month competency window) to include all aspects of competency assessment as specified by 42 CFR 493.1451(b)(8). This required adding problem solving and testing of known (previously tested) samples to the forms, rather than capturing this assessment separately which would have been required if the original form had been retained. **(2) Patient Impact:** Dr. Adam Rosendorff, Laboratory Director, has determined that the changes made were organizational to improve understanding of these two processes (training versus competency) and that there is no impact on patient care or any patient harm as procedures for employee training and supervisor attestation of the ability of employee to perform procedures were in place at the time of initial employee training. **(3) Preventative Measure:** A summary PowerPoint was sent to all Managers and Supervisors explaining the changes and the new and updated forms on April 1, 2021 before the start of 6-month competency assessments of the technical staff on April 21, 2021. Members of the Quality Team met with each Supervisor performing 6-month competency assessments before they began assessments and several times during assessments to ensure they understood the changes to the process (see Attachment D5209_1f). **(4) Monitoring Mechanism:** Personnel and competency procedures will be updated as needed. The Quality team will continue to work with Managers and Supervisors to answer questions regarding what assessment needs to be done for laboratory staff. **Findings 2 and 3:** During the February 7 and February 8 investigation, an unofficial roster used for convenience in the laboratory was presented. Since this time, the CDPH Branch Laboratory has developed audit procedures that specify what laboratory documents may be shared and the manner in which they are to be given to regulatory agencies. **(1) Immediate Corrective Action:** A current roster of technical (Extraction, PCR, and Data Analysis) and non-technical (Accessioning) staff is used to provide training documentation. The lists are very similar but do have a few differences (see D-5209 Findings 4 and 5).	

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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	Continued from page 3 **(2) Patient Impact:** The unofficial roster is used by Managers and Supervisors as a reference for staff on shifts or in areas with which they do not work directly. Inaccuracies in this roster may result in inconvenience for laboratory staff, therefore, there is no impact on patient care. **(3) Preventative Measure:** An inspection work instruction has been drafted by the CDPH Branch Laboratory. This draft has been used as starting point for Quality team members, Supervisors, Managers, and the Laboratory Director to have a group training session on conducting an efficient audit. Two training sessions and mock inspection drills have been completed (see Attachments D5209_2a and D5209_2b). Successes and challenges of these mock drills are being used to complete the Inspection Work Instruction. Techniques from this training were used to efficiently meet requests from Laboratory Field Services during an on-site visit in March 2021. **(4) Monitoring Mechanism:** Additional mock inspection drills will be held on all shifts. Team performance during any audit or inspection is reviewed during post audit conference (as stipulated in the work instruction). Areas of effectiveness as well as areas for improvement will be documented and enter into the Continuous Improvement process (CAPA). **Findings 4 and 5.** The roster provided on 2/8/2021 was not an official one, therefore, the following numbers as presented in the LFS findings vary slightly (see Finding 3). A review of our records found that 412 / 412 (100%) of employees involved in the testing process have documented training.	

		Sun - Tue		Wed-Fri		Total
		Day	Night	Day	Night	
Accessioning		34/34	43/43	46/46	37/37	160
Extraction	Reformatter	36/36 (37 total)	46 / 46 (55 total)	38/38 (40 total)	48/48 (51 total)	183
	Chemagic	36/36 (37 total)	41/41 (55 total)	38/38 (40 total)	48/48 (51 total)	
PCR	RT-PCR Set-up	11/11	14/14	12/12	11/11	48
	AJ PCR	11/11	14/14	12/12	11/11	
Analysis		7/7	5/5	6/6	3/3	21
Total		89	117	104	102	412

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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	Continued from page 4 Due to the large number of staff onboarded in a short period of time to meet the emergency demands for COVID-19 testing capacity, there was a delay in entering training documentation in the new document control system. This made it difficult to track what was still needed. Efforts to collect and document training were delayed. Subsequently, notifications to Supervisors and Managers regarding forms that were not completed was delayed. In addition, delays in providing records upon audit request were due to limitations of the document control system being able to download a large number of documents at the time of onsite inspection. **Data Analysis** It is important to note that technologists in the Analysis group are the only staff who report patient results. 21/21 (100%) of the Data Analysts, as well as the Sign-Out Manager, had documented training prior to reporting patient results as documented on the Data Analysis (CA-PER-FM-015) initial training assessment form. Copies of this form, as well as a related but redundant form (see below) are provided in Attachments D5209_3a, D5209_3b and D5209_3z These records were provided to LFS via email on February 8 as requested. Confirmation of the sent email is provided in Attachment D5209_3zb. Due to uncertainty about workflow ahead of the laboratory opening, two forms were created (prior to any employee onboarding) to capture training needed to extract and analyze data after completion of RT-PCR: - Data Extraction (CA-PER-FM-014) - Data Analysis (CA-PER-FM-015) These tasks were separate to allow PCR technologists to review data prior to submitting for analysis; however, this workflow was never implemented in this laboratory. Both forms were completed for most analysts; however, four data analysts initially had only the Data Analysis form (CA-PER-FM-015) completed. The redundant Data Extraction form (CA-PER-FM-014) was initially maintained with the thought that the workflow could be implemented when sample volumes increased; however, this was not necessary. PCR All PCR technologists (48/48; 100%), as well as all PCR Supervisors (4/4), had documented training prior to processing patient samples (Attachments D5209_3c – D5209_3g). A review of records did reveal a minor anomaly in the training record. For several individuals training in PCR, the training form was completed and signed for the RT-PCR Set-up on the Janus G3 (CA-PER-FM-012); however, the form for the RT-PCR AJ thermocycler (CA-PER-FM-013) is not in the training record. A review of records indicates that technologists prepared the PCR batch on the RT-PCR Set-up and loaded the PCR plate to the AJ Thermocycler. Training on the RT-PCR Set-up, as well as data review, were completed by the trainer. These records indicate that the AJ thermocycler was loaded and started correctly. Since these are the tasks assessed for training, the individual being assessed performed the task correctly but the laboratory failed to properly document this aspect of the training.	

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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	Continued from page 5 **Extraction** In the Extraction area, some staff currently perform only the Reformatter automated liquid handling procedure or the chemagic automated nucleic acid extraction procedure, therefore, the total number of training records for each is smaller than the total number of individuals in that area. A detailed list is provided in Attachments D5209_3h – D5209_3p. Of the 183 staff members in Extraction: • 173 have been trained to use the Reformatter liquid handler • 166 have been trained to use the chemagic automated nucleic acid extractor • Staff without current training for an instrument are not permitted to operate that instrument A review of records found that for the Reformatter: • 133 / 173 had completed training records at the time of training • 17 / 173 had an indication from the trainer that training was completed but a signature was not obtained • 23 / 173 were found to have inadequate documentation of training A review of records found that for the chemagic: • 149 / 166 had completed training records at the time of training • 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained • 10 / 166 were found to have inadequate documentation of training **(1) Immediate Corrective Action:** Any task for which a training form was not captured was re-assessed for the individual or that individual was removed from that testing process until re-assessment could be completed. **Analysis:** Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysts were assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. **PCR:** Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained. **Extraction:** For the 23 / 173 (13%) that were identified in mid-December to have a missing training document for the Reformatter automated liquid handler: • 11 of these individuals were re-assessed by a Supervisor in December 2020 and found to be adequately trained	

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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	Continued from page 6 • 2 were removed from testing and re-assessed in February 2021 and found to be adequately trained • 10 of these individuals were reassessed in January (2), February (7) and March (1) and found to be adequately trained. For the 10 / 166 (6%) were found in a mid-December to have a missing training document for the chemagic automated nucleic acid extractor: • 4 of these individuals were re-assessed by a Supervisor in December 2020 and found to be adequately trained • 6 of these individuals were reassessed in February (5) and March (1) and found to be adequately trained. All Extraction Supervisors were adequately trained (see Attachment D5209_3z). **Accessioning:** Accessioning consists mainly of barcode scanning. All unsatisfactory specimens are checked by a supervisor prior to rejecting the sample. Upon assessment, no performance issues were identified, therefore, there is no impact on patient care. Audit process: The ability to download records in bulk has no impact on patient care. Accessioning: The accessioning process for this laboratory requires: - Scanning of the barcode on the sample - Batching into groups of 94 samples for testing - Identifying unsatisfactory samples Although some accessioning staff performed heat inactivation prior to February 2021, most were trained in this procedure in February 2021 (see Attachments D5209_3q – D5209_3y). Review of records showed that 47 / 160 training records were delayed; however, all have been completed. These delayed signatures were spread across the four shifts. Training of accessioning staff for heat inactivation was documented appropriately by February 2021 for 158 / 160 of the accessioning staff. No staff were found to have deficiencies in training (see Attachments D5209_3q – D5209_3y). Audit process: Paper copies of personnel files have been created to aide in timeliness of audit responses. (1) Patient Impact: Data Analysts: The only staff who review and release data are the Data Analysts and the Sign-Out Manager. Training records for 21/21 data analysts and the Sign-Out Manager were completed, therefore, there was no impact on patient care. The impact of the failure to document training for Data Extraction (CA-PER-FM-015) is minimal because: - There is complete overlap in the tasks between Data Extraction and Data Analysis - Data Analysis cannot be completed without Data Extraction PCR: Training for all PCR staff was adequately captured except for one for four individuals. Since the data show the tasks were carried out correctly and the data were accepted by the trainer, there is evidence that this omission did not impact patient care. Extraction: The limited number of instances of missed training documentation identified are unlikely to impact patient care since the assay steps performed in extraction do NOT include data review or analysis.	
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing	D5400		

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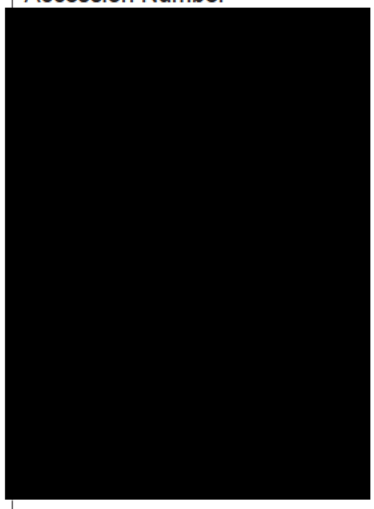
D5209	Continued From page 6 completed competency assessment for 236 out of 426 (approximately 55%) of the total laboratory staff, prior to processing, testing, and reporting patient results. 6. The following are the accession numbers of the 30 randomly reviewed patient test records covering the period 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  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	Accessioning: Accessioning consists mainly of barcode scanning. All unsatisfactory specimens are checked by a supervisor prior to rejecting the sample. Upon assessment, no performance issues were identified, therefore, there is no impact on patient care. Audit process: The ability to download records in bulk has no impact on patient care. **(3) Preventative Measure:** A more formal training program for new technologists has been put in place. Since the laboratory now has many performing employees there is more opportunity for new staff to observe procedures and work with trainers or supervisors. The redesigned training forms presented in Finding 1 help to facilitate this process. Paper copies of all personnel records have been created to facilitate audit requests more quickly and efficiently. **(4) Monitoring Mechanism:** A review of records from mid-December to present indicates: • There continues to be no documentation issues with the Data Analysts who are reviewing and releasing results. • In the PCR area, all 18 staff trained from mid-December 2020 to present have all training documentation properly completed • In Extraction, of the 42 individuals trained in mid-December or later, 42/42 were properly documented for the Reformatter automatic liquid handler and 41/42 (one delayed signature) were properly documented for the chemagic automated nucleic acid extraction procedure. • An insufficient number of new hires in Accessioning started since mid-December to assesses effectiveness; however, effectiveness will be assessed as new hires are made. • In addition to mock audit exercises, the monthly tracer audits conducted as part of the monthly audit schedule assess whether personnel documentation is available and complete. Finding 6: Of the 30 randomly selected samples: • 5/5 Accessioning personnel have complete training documentation • 5/5 Extraction personnel have complete training documentation. 1/5 had a delayed signature for Reformatter training at the time she ran 10 / 21 samples shown here; however, she was reassessed prior to running the remaining 11 / 21 samples. Upon reassessment she was determined to be adequately trained and all samples she ran were successful. • 3/3 PCR personnel have complete training documentation • 2/2 Data Analysts have complete training documentation (See Attachment D5209_4 for training documentation.) **(1) Immediate Corrective Action:** See findings 4 and 5.	
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing	D5400	**(2) Patient Impact:** See findings 4 and 5. **(3) Preventative Measure:** See findings 4 and 5. **(4) Monitoring Mechanism:** See findings 4 and 5.	

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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	Continued from page 6 • 2 were removed from testing and re-assessed in February 2021 and found to be adequately trained • 10 of these individuals were reassessed in January (2), February (7) and March (1) and found to be adequately trained. For the 10 / 166 (6%) were found in a mid-December to have a missing training document for the chemagic automated nucleic acid extractor: • 4 of these individuals were re-assessed by a Supervisor in December 2020 and found to be adequately trained • 6 of these individuals were reassessed in February (5) and March (1) and found to be adequately trained. All Extraction Supervisors were adequately trained (see Attachment D5209_3z). **Accessioning:** The accessioning process for this laboratory requires: • Scanning of the barcode on the sample • Batching into groups of 94 samples for testing • Identifying unsatisfactory samples Although some accessioning staff performed heat inactivation prior to February 2021, most were trained in this procedure in February 2021 (see Attachments D5209_3q – D5209_3y). Review of records showed that 47 / 160 training records were delayed; however, all have been completed. These delayed signatures were spread across the four shifts. Training of accessioning staff for heat inactivation was documented appropriately by February 2021 for 158 / 160 of the accessioning staff. No staff were found to have deficiencies in training (see Attachments D5209_3q – D5209_3y). **Audit process:** Paper copies of personnel files have been created to aide in timeliness of audit responses. **(1) Patient Impact:** Data Analysts: The only staff who review and release data are the Data Analysts and the Sign-Out Manager. Training records for 21/21 data analysts and the Sign-Out Manager were completed, therefore, there was no impact on patient care. The impact of the failure to document training for Data Extraction (CA-PER-FM-015) is minimal because: • There is complete overlap in the tasks between Data Extraction and Data Analysis • Data Analysis cannot be completed without Data Extraction **PCR:** Training for all PCR staff was adequately captured except for one for four individuals. Since the data show the tasks were carried out correctly and the data were accepted by the trainer, there is evidence that this omission did not impact patient care.	
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing	D5400	**Extraction:** The limited number of instances of missed training documentation identified are unlikely to impact patient care since the assay steps performed in extraction do NOT include data review or analysis.	

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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** - The CDPH Branch Laboratory recognizes the Janus G3 instrument protocol (CA-PCR-SOP-001) did not have detailed instructions on manual pipetting to accomplish the needed reagent transfer, it also did not expressly prohibit the technologist from doing so. Detailed instructions were added in a later version of protocol. Similarly, CDPH review of the Sample Transfer Using the Janus G3 protocol (CA-EXT-SOP-003) recognized that this SOP did not have specific guidance for situations with insufficient the sample volume. The determination that it could be a future need, the Laboratory Director requested an updated SOP. The Laboratory recognizes the Issuing Amended or Corrected Reports protocol (CA-SOP-RPT-003) version 1.0 was in draft mode and not signed by the part-time laboratory directors (24Oct2020 – 27Jan2021) but was approved by the currently Laboratory Director on 28Jan2021. **D5779, D5787, D5891** - CDPH Branch Laboratory had two overarching policies and procedures, approved the Laboratory Director, to directly address when and how to address problems that required corrective actions: The Quality Management Plan (QMP) and the Quality Exception Reporting (QER) and CAPA plan. When an error was detected, all stakeholders (Dr. Pan, California Dept of Public Health and Testing Task Force) in the testing process were notified. The laboratory acknowledges that a discretionary decision was made in the interest of public health to not give a patient conflicting information, but rather inform the patient an error was made and recommend re-testing, therefore, the language in the laboratory record for the repeated test/analysis and the result stated on the amended report are different. The CDPH Branch Laboratory is changing the notification procedures for amended reports so that Dr. Pan, the ordering clinician, is notified of the error and provided an individual record for each affected specimen.	3May2021
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)	D5407		

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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	**Finding 1** Through the course of laboratory operations situations and scenarios that had not happened in the past are identified. The solutions to these newly identified items are then reviewed with laboratory management and the laboratory director for appropriate mitigation. This is the same process that is followed at the CDPH Branch Laboratory. The CDPH Branch Laboratory recognizes the Janus G3 instrument protocol (CA-PCR-SOP-001) version 1.0 with an effective date between 27Oct2020 and 27Jan2021 did not have specific guidance for error situations that required manual pipetting of reagents. Through the identification of this scenario and the determination that it would be a future need, a subsequent update, version 2.0 of the SOP, was reviewed and implemented on 27Jan2021. The content is based on feedback from the clinical testing staff and our then newly hired full-time laboratory director. Reference section 11.4 for the specific instruction to the technologists. It is also important to note that manual pipetting is a standard laboratory practice that all technologists are proficient in. Although version 1.0 of the SOP did not provide detailed instructions on manual pipetting to accomplish the needed reagent transfer, it also did not expressly prohibit the technologist from doing so. Thus, manual pipetting would have been allowed following good laboratory practice. In response to finding 1e at no point did the laboratory director or anybody else present during the virtual meeting with LFS on 4/22/2021 (10.40am) make this affirmation. This statement is inaccurate. Please refer to attachment 1. **(1) Immediate Corrective Action:** The laboratory director approved an updated version of the CA-PCR-SOP-001 to include error scenarios that require manual pipetting on 27Jan2021. **(2) Patient Impact:** Upon review, the plate level quality controls passed as well as the internal control for the samples in question. As this was an acceptable deviation from the SOP tracking of the occurrences was not required; as there was no tracking, a look back between 27Oct2020 and 27Jan2021 is not possible. Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm for failure to document specific instructions for manual pipetting.	3May2021

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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	Continued from page 9 **(3) Preventative Measure:** Through the course of CDPH Branch Laboratory operations situations and scenarios occur that have not happened or have not been recognized are identified. We are a young laboratory and all possible errors or gaps in processes cannot be anticipated and/or documented. The solutions to these newly identified issues (omissions, discrepancies, errors in controlled documents) are reviewed with laboratory management and the laboratory director for appropriate mitigation and incorporation into SOPS, as appropriate. The current Laboratory Director participates in regular meetings with technical, general supervisors and wet laboratory managers to discuss improvement and regulatory initiatives. His review and approval of policy, plan, process, and procedures in advance of documented change is reiterated regularly. The laboratory staff and supervisors are encouraged to make requests for SOP updates withing 12 hours of identifying a needed change. In addition, the current Laboratory Director participates in regular meetings with the Quality team where any issue with document control (QER, Audit Process, or Gemba (walkthrough) observation) is discussed and documented with meeting minutes. The quality and laboratory groups update the SOPs and submit it for approval by the laboratory director. **(4) Monitoring Mechanism:** During any of the auditing processes, if any uncontrolled document is discovered or there has been a change in policy, process, plan or procedure, or use of a controlled document, that has not been signed off by the laboratory director and QA manager, this is noted as a nonconformance and would follow the CAPA corrective action process. As part of the Quality Management Plan the laboratory clinical staff and laboratory director perform biennial review of its SOPs to ensure they encompass the best practices being applied within the laboratory workflow. **Finding 2** This particular finding references 16 patient samples (12/03/20) with insufficient volume for a storage (STO) plate. After tracking down the specific incident that was not referenced in the LFS finding, it was determined that this QER-20-031 was not a low volume STO plate issue; rather, a cassette of specimens that was tipped during decapping, prior to extraction, and a small portion of some of the specimen volumes spilled. The Technical Supervisor on site was immediately notified. This was treated as a minor spill, remaining volumes in the sample tubes were determined to be adequate, and the specimens were submitted to Extraction for processing on the JanusG3 (CA-EXT-SOP-003). The reports for these 16 patient samples are attached as confirmation (see Attachment B_5). As LFS, an outside auditor, uncovered an omission in a procedure that they deemed deficient and critical, the CDPH Laboratory did review the Sample Transfer Using the Janus G3 protocol (CA-EXT-SOP-003) as we would any external audit response. It was recognized that this SOP did not have specific guidance for situations where the sample volume was insufficient for either the initial or the storage (STO) plate. While unsatisfactory specimen rejection is a preanalytical activity, through the identification of this scenario and the determination that it could be a future need, the Laboratory Director requested an updated SOP.	

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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	Continued from page 10 In response to finding 2e at no point did the laboratory director or anybody else present during the virtual meeting with LFS on 4/22/2021 (10:40am) make this affirmation. This statement is inaccurate. Please refer to attachment 1. **(1) Immediate Corrective Action:** For the particular incident referenced in Finding 2, there is no immediate corrective action. However, based on the LFS observation, the SOP has been updated, version 6.0, to reflect this scenario (see Attachment A). Reference section 7.1.1.2 for the specific instruction to the technologists. As minimum sample volume is 270ul and the storage plate is a backup to be used if needed, there is no action required for insufficient volume for the secondary backup storage plate. This is now referenced in the SOP. Supervisors in the Extraction section of the laboratory conducted in person training with their teams to discuss this update to the SOP as well as to invite discussion as to other situations that testing personnel have questioned. See Attachment D5407_2 for evidence of training that is in progress. **(2) Patient Impact:** Only one sample, D-6415087003 tested positive and review of batch QC for this sample as well as the batch heatmap did not indicate sample or batch contamination. Per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment or recommended patient action for the 16 samples referenced in this citation and there would not be patient harm. The results were reported. **(3) Preventative Measure:** Through the course of CDPH Branch Laboratory operations situations and scenarios occur that have not happened in the past are identified. We are a young laboratory and all possible errors or gaps in processes cannot be anticipated. The solutions to these newly identified items are reviewed with laboratory management and the laboratory director for appropriate mitigation and incorporation into SOPS, as appropriate. The current Laboratory Director participates in regular meetings with technical and general supervisors as well as wet-laboratory managers, to discuss improvement and regulatory initiatives. His review and approval of policy, plan, process, and procedures in advance of implementation is reiterated regularly. The laboratory staff and supervisors are encouraged to make requests for SOP updates withing 12 hours of identifying a needed change. In addition, the current Laboratory Director participates in regular meetings with the Quality team where any issue with document control (QER, Audit Process, or Gemba (walkthrough) observation) is discussed and documented with meeting minutes. The quality and laboratory groups update the SOPs and submit it for approval by the laboratory director. **(4) Monitoring Mechanism:** During any of the auditing processes, if any uncontrolled document is discovered or there has been a change in policy, process, plan or procedure, or use of a controlled document, that has not been pre-approved by the Laboratory Director and QA lead, then this is noted as a nonconformance and would follow the CAPA corrective action process. As part of the Quality Management Plan the laboratory clinical staff and laboratory director perform biennial review of its SOPs to ensure they encompass the best practices being applied within the laboratory workflow.	

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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	**Finding 3** CDPH Branch Laboratory recognizes the Issuing Amended or Corrected Reports protocol (CA-SOP-RPT-003) version 1.0 was in draft mode and not signed by the part-time laboratory directors (24Oct2020 -27Jan2021. Due to the rapid 2-month startup for this high-volume automated laboratory, this particular postanalytical process had not been software tested with Color, the 3rd party vendor releasing patient results. The 38 amended reports cited in this observation occurred during the 3rd and 4th week of laboratory operation. Additionally, not having dedicated fulltime laboratory directors on site during the laboratory startup was an identified risk as approval/decision making for complicated processes took longer than expected. Upon the hiring of our current, fulltime laboratory director (27Jan2021) the discussions were held, and the SOP was reviewed and approved on 08Feb2021. It is noted that there were no amended reports required for the month of January. In response to finding 1d at no point did the laboratory director or anybody else present during the virtual meeting with LFS on 4/22/2021 (10:40am) make this affirmation. This statement is inaccurate. Please refer to D5407 Attachment 1. **(1) Immediate Corrective Action:** The laboratory director approved the initial version the CA-SOP-RPT-003 on 08Feb2021. There were no edits or changes to the processes that the laboratory had followed in November and December. **(2) Patient Impact:** With respect to the health of the patient and community the current Laboratory Director, Dr. Adam Rosendorff, determined that the lack of an approved procedure did not impact the health of the patient as amended reports were generated and submitted as described in the draft procedure. Reference the patient impact response for D5779 for the look back review of all amended results generated in the early time period (Nov/Dec). See D5821 for discussion of patient impact related to timeliness of amended reports. **(3) Preventative Measure:** The current Laboratory Director participates in regular meetings with laboratory supervisors and wet lab managers to discuss improvement and regulatory initiatives. His review and approval of policy, plan, process, and procedures in advance of implementation is reiterated regularly. The laboratory staff and supervisors are encouraged to make requests for SOP updates within 12 hours (1 shift) of identifying a needed change. In addition, the current Laboratory Director participates in regular meetings with the Quality team where any issue with document control (QER, Audit Process, or Gemba (walkthrough) observation) is discussed and documented with meeting minutes. The quality and laboratory groups update the SOP and submit it for approval by the laboratory director. **(4) Monitoring Mechanism:** During any of the internal auditing and external inspection processes, if any uncontrolled document is discovered or there has been a change in policy, process, plan or procedure, or use of a controlled document, this is noted as a nonconformance and follows the CAPA corrective action process. As part of the Quality Management Plan the laboratory clinical staff and laboratory director perform biennial review of its SOPs to ensure they encompass the best practices being applied within the laboratory workflow.	

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D5407	Continued From page 12 [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.	D5407	**D5779 Findings 1, 2, and 3** (with the 3 specific examples of amended reports) state that corrective action policies and procedures were not followed in a manner that ensures accurate and reliable patient test results. At startup, the laboratory had established 2 overarching policies and procedures, approved the Laboratory Director, to directly address when and how to address problems that required corrective actions: The Quality Management Plan (QMP) and the Quality Exception Reporting (QER) and CAPA plan. Each of the foundational Quality System Essentials (QSE) are supported by the Continuous Improvement and Occurrence Management QSE; its' purpose is to capture and analyze information originating from quality exceptions (QE). The specific process cited in this observation relates to analytical phase of detection and correction of errors discovered in previously reported patient results. Corrected reports are those issued when there is a demographic or transcription error; revised or amended reports are those issued when the final diagnosis changes, typically due to an error in the preanalytical, analytical or postanalytical process. • The observation in Finding 1 of the use of a drafted (not approved by Laboratory Director at time of the laboratory startup in November) has already been addressed in D5407. • The observation in Finding 2 is correct: The document does state that the laboratory director, or individual with delegated responsibility, communicates the approval of the amended report to COLOR which in turn, generates the amended report through standard reporting procedures. The observation in Finding 3 did corroborate the lab's documented nonconformance of a gap discovered during the laboratory's very first request for COLOR to submit an amended report (25Nov2020). This is documented as an omission in contractual vendor deliverables and laboratory process error that was overlooked during the 2-month start-up phase during the pandemic. Immediate corrective action was taken by the Laboratory and the gap was closed and the problem resolved within 5 days so that amended reports could be submitted and reported through the COLOR portal. o The key observation noted in section (i) of each of these Findings states the concern that there is no evidence to show that the amended reports were sent to each patient or to the authorized person who requested the test. o The CLIA regulation states: §493.1291 Standard: Test report. ➢ (k) When errors in the reported patient test results are detected, the laboratory must do the following: • (1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. • (2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. • (3) Maintain duplicates of the original report, as well as the corrected report.	3May2021
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) 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.	D5779		

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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	Continued from page 13 o Copies of both the Original and Amended Reports for each of these patient samples (38 total) are submitted with this response. See Attachments B_1, B_2 and B_3. o COLOR made results available on the portal for patient access as allowed by Executive Order N-52-20. **(1) Immediate Corrective Action:** • The Laboratory has notified Dr. Pan of each error. The original report, the amended report and a letter notifying her about the amended report has been submitted for each affected sample. • Original and Amended Reports with accompanying notification letters for the 38 records cited in this observation as well as the same documentation for subsequent incidences are attached (see Attachment C). The attachment also includes the acknowledgment of receipt from Dr. Pan. **(2) Patient Impact:** With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially detected results but later not detected results would likely result in patient psychological stress due to the diagnosis and need for quarantine or isolation. There would be minimal patient health impact as the decision on potential treatments or hospitalization would be made by the patient's medical provider on the basis of symptoms rather than a positive test result. With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially not detected results but later either detected or presumptive positive did pose a risk to the patient and the community due to the risk of viral transmission to close contacts and delay in seeking medical attention. This risk would be similar to a false negative result reported by any laboratory. **The College of American Pathology (CAP) field tested 11 indicators through their Q-TRACKS program and determined a statistical median rate of 2.8 test result corrections per 10,000 billable tests. Among results released in 2020 and in 2021, CDPH Branch Laboratory had ~0.83 and ~0.24 per 10,000 test result corrections which is lower than the median 2.8 reported by the CAP Q-TRACKS program, therefore, this error rate is determined to not be outside of industry standards (see D5821).** Quality Indicator Monitoring Guidance. College of American Pathology, 2011 (see Attachment D5821_2). **(3) Preventative Measure:** Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email, the original report, the amended report, the individual notification letter and the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder.	

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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. [redacted]ient test report, accession number [redacted] was 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	**Continued from page 14** **(4) Monitoring Mechanism:** An amended reports audit is conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both original and amended report. See FY2021 Audit Schedule, Attachment D5779_1. The Amended Report Audit Plan (see Attachment D5779_2) is updated to include the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a POST Analytical quality assessment metric, with a target of 100% or no incidences of failure to submit.	

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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. [redacted] 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		

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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	**D5787** **Findings 1 and 2** compare the language of original reports issued in error with the language used to amend the incorrect report. It states that our amended reports to not include the correct disposition of specimen (correct result) with the incorrect result. The finding correctly explains the testing errors that were discovered (and documented on QERs) after results had been reported. Theses 3 incidences in Nov/Dec that required amended reports are described in detail in D5779 Finding 3b (22 reports), 3c (1 report) and 3d (15 reports). Finding 2 specifically observes that the repeated result in the laboratory records (which is located in the documented QER's and LIMC) is not the same as the result on the amended report. Through the partnership and oversight by the California Department of Public Health and the Testing Task Force, all testing collected at California COVID-19 testing collection sites during the pandemic is performed under the Prescribing Order from Dr. Erica Pan, the Acting State Health Officer. The laboratory acknowledges that a discretionary decision was made in the interest of public health to not give a patient conflicting information, but rather inform the patient an error was made and recommend re-testing. Therefore, the language in the laboratory record for the repeated test/ analysis and the result stated on the amended report are different. The SOP that was in draft (See D5407 Finding 3 for a detailed summary) and later approved stated that all amended reports are reported as: "Unable to return results for this sample. The previously reported result (insert original result) is not valid due to a process error. The barcode, the test, and test date of the original report and the original result are in this document." The LFS finding that the first two incidences (1a:22 samples and 1b: 1 sample) did not contain the original result as part of the amended report is correct. The initial reporting of amended results did not conform to the requested language as stated in the SOP. The stakeholders (Dr. Pan, California Dept of Public Health and Testing Task Force) were aware of the original and amended results for these patients and the decision was made by the laboratory to not update the amended report again as it would not change the recommendation for the patient to be retested. All other amended reports generated since these two incidences contains the original result and date it was reported. In reviewing the process in light of the LFS observation in the 23April2021 findings, the CDPH Branch Laboratory is submitting an individual record for each affected specimen to Dr. Pan. This notification letter will contain the data from the laboratory record as well as the original data and date of testing. This notification and individual record are being submitted to Dr. Pan, the ordering clinician, to make the determination as to the appropriateness of patient notification based on previous result and the amount of time from the collection and original report. There is no change in the laboratory process of communicating a laboratory error to COLOR for creation of the amended report. Once posted, the patient has access to results. See D5779. **(1) Immediate Corrective Action:** • The Laboratory has notified Dr. Pan, through the Department of Public Health, that the original report and a letter of correction for all amended results will be submitted to her for all amended results.	3May2021

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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	**Continued from page 17** • **Original and Amended Reports with accompanying notification letters for the 38 records cited as well as the same documentation for subsequent incidences (Look forward from the first two months of operation) are attached (See Attachment C). The attachment also includes the acknowledgment of receipt from Dr. Pan.** **(2) Patient Impact:** With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially detected results but later not detected results would likely result in patient psychological stress due to the diagnosis and need for quarantine or isolation. There would be minimal patient health impact as the decision on potential treatments or hospitalization would be made by the patient's medical provider on the basis of symptoms rather than a positive test result. With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially not detected results but later either detected or presumptive positive did pose a risk to the patient and the community due to the risk of viral transmission to close contacts and delay in seeking medical attention. **(3) Preventative Measure:** Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email with the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder. **(4) Monitoring Mechanism:** An amended reports audit is conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both original and amended report. See D5791 for the FY2021 Audit Schedule and the Amended Report Audit Plan, which is updated to include the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a postanalytical quality assessment metric, with a target of 100% or no incidences of failure to submit.	

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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		

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D5787	Continued From page 19 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 thissample. Please disregard any previous reports as they were issued in error." vii. The laboratory also added thefollowing 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	D5787		

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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:** This particular finding 1 and 2 indicates that the laboratory failed to document all analytic systems assessment activities because it 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. As has been stated previously at startup, the laboratory had established 2 overarching policies and procedures, approved the Laboratory Director, to directly address when and how to address problems that required corrective actions: The Quality Management Plan (QMP) and the Quality Exception Reporting (QER) and CAPA plan. Each of the foundational Quality System Essentials (QSE) are supported by the Continuous Improvement and Occurrence Management QSE; its' purpose is to capture and analyze information originating from quality exceptions (QE) that occur in all phases of laboratory testing. The laboratory was, and continues, to follow these procedures as exceptions noted by LFS at time of inspection on 07Feb and 08Feb were documented, assigned QER reference numbers, and documented on the quality exception log. There is no regulatory requirement for a laboratory to assess any particular process with a quality indicator (42 CFR 493.1701); the selection is left to the discretion of the Laboratory Director. The initial Quality Management Plan, drafted and approved by the previous Lab Director, was a best attempt at how to assess, monitor and document quality activities during startup and indicated the possible indicators that would be selected for the three phases of laboratory testing: preanalytical, analytical and postanalytical. During the first two months of operation, analytical quality monitors of TAT, positivity rate, sample failure were monitored daily and submitted to key stakeholders, including Dr. Erica Pan. The audit process was implemented Q1 2021 as the laboratory was still heavily involved in onboarding new employees, qualifying new equipment, documenting process and workflow issues, and devising and implementing corrective action plans to meet the array of issues. All laboratories have events that deviate from prescribed workflow and processes; it is the reason for continuous improvement and occurrence management. The specific analytic process events, already documented by the laboratory, and cited in this observation, references 20 patient samples reflecting 2 separate quality exception reports (related to two separate documented quality exceptions): • 10 specimen IDs', described in QER-20-031, were associated with cassette of specimens that was tipped during decapping, prior to extraction; a small portion of some of the specimen volumes spilled. The Technical Supervisor on site was immediately notified. This was treated as a minor spill, remaining volumes in the sample tubes were determined to be adequate, and the specimens were submitted to Extraction for processing on the JanusG3 (CA-EXT-SOP-003). These 10 patient samples, which all tested negative, were correctly reported as negative (see D5407 Finding 2 and associated Attachment). CDPH Branch Laboratory respectfully submits that this QER is not applicable to the findings of a failure to have an (1a) an approved low volume STO or amended report procedure, or (2a) failure to follow corrective action plans as the QER stated the corrective action and all results were reported, and (3a) or failure to ensure the test record provided the correct disposition of specimens as there was no issue with the specimens and all results were reported.	3May2021
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		

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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	Continued from page 21 • However, As stated earlier, in D5407 Finding 2, the observation made by LFS of the low volume STO plate prompted a review (following the laboratory's continuous improvement and corrective action process for any external audit observation) of the documented QER and SOP related to that particular incident. It was determined that this particular scenario was not described and the Janus G3 Extraction SOP was updated, version 6.0, to provide instructions. Reference section 7.1.1.2 for the specific instruction to the technologists. This is a good example of how the laboratory's continuous process improvement and corrective action works. • 10 specimens, described in QER-20-010, did result in amended reports due to a barcode error. o Finding 1a: The discussion about failure to approve the Amended Report SOP has been described in detail in D5407 Finding 3. o Finding 1b: After discovery of the error, the error was documented as a QER and corrective action plan was put into place. o Finding 1c: Patients were notified that their original result had been issued incorrectly and were advised to be retested. The result of the test was not changed due to public health concerns that changing a result could result in confusion on the part of the patient. In addition, since time had passed it was also possible that the patient's infection status had changed and the result from the original specimen may no longer reflect the patient's true status. Therefore, the decision was made that the amended report should only state that the original report was issued in error and recommend that the patient be re-tested. **(1) Immediate Corrective Action:** The immediate corrective actions for each of the items addressed (1a) specific procedures not approved by Lab Director (2b) not following corrective action plan related to amended reports and (3b) not providing the correct disposition of specimens are fully addressed in D5407, D5779 and D5787 respectively. **(2) Patient Impact:** The patient impact for each of the items addressed (1a) specific procedures not approved by Lab Director (2b) not following corrective action plan related to amended reports and (3b) not providing the correct disposition of specimens are fully addressed in D5407, D5779 and D5787 respectively. **(3)Preventative Measure:** • Through the course of CDPH Branch Laboratory operations situations and scenarios occur that have not happened in the past are identified. We are a young laboratory and all possible errors or gaps in processes cannot be anticipated. The solutions to these newly identified items are reviewed with laboratory management and the laboratory director for appropriate mitigation and incorporation into SOPS, as appropriate. The current Laboratory Director participates in regular meetings with technical, general and operational supervisors to discuss improvement and regulatory initiatives.	

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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	**Continued from page 22** His review and approval of policy, plan, process, and procedures in advance of implementation is reiterated regularly. The laboratory staff and supervisors are encouraged to make requests for SOP updates withing 12 hours (1 shift) of identifying a needed change. In addition, the current Laboratory Director participates in regular meetings with the Quality team where any issue with document control (QER, Audit Process, or Gemba (walkthrough) observation) is discussed and documented with meeting minutes. The quality and laboratory groups update the SOPs and submit it for approval by the laboratory director prior to implementation. • For Amended Reports: Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email, the original report, the amended report, the individual notification letter and the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder. **(4) Monitoring Mechanism:** • During any of the auditing processes, if any uncontrolled document is discovered or there has been a change in policy, process, plan or procedure, or use of a controlled document, that has not been pre-approved by the Laboratory Director and QA lead, then this is noted as a nonconformance and would follow the CAPA corrective action process. As part of the Quality Management Plan the laboratory clinical staff and laboratory director perform biennial review of its SOPs to ensure they encompass the best practices being applied within the laboratory workflow. • During the monthly amended report audit, assessment is made of QERs associated with each event, the cause, the number of reports, the review of both original and amended report. The FY2021 Audit Schedule and the Amended Report Audit Plan (see Attachments D5779_1 and D5779_2) which is updated to include the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a POST Analytical quality assessment metric, with a target of 100% or no incidences of failure to submit. • Monitoring timely completion of QER and CAPA's has been added to the Quality Management Review with an expected documented signature approval of the written corrective plan targeted for completion within 15 days.	
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		

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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** - The CDPH Branch Laboratory the laboratory acknowledges that the outcome code for samples that become untestable due to laboratory error did not adequately consider the reporting language that would be used when this code was selected. This language will be revised. **D5821 and D5891** - The CDPH Branch Laboratory experienced a delay in sending notification of laboratory error during a 2-week period in late November and early December. Stakeholders, including Dr. Erica Pan, were notified of the amended results and the delay from time of identifying and solving the problem, retesting, resulting and posting to the Color portal. The CDPH Branch Laboratory strives for improvement which can be seen by our median response time in Q1 2021 of 17hours. The quality indicator for amended reports was initially set as a % of reported tests; no target metric was assigned in November or December. The College of American Pathology (CAP) field tested 11 indicators through their Q-TRACKS program and determined a statistical median rate of 2.8 test result corrections per 10,000 billable tests. Among results released in 2020 and in 2021, CDPH branch laboratory had ~0.83 and ~0.24 per 10,000 test result corrections which is lower than the median 2.8 reported by the CAP Q-TRACKS program.	3May2021
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	**D5805** **Findings 1-5** Samples submitted to the laboratory may be unsatisfactory for testing for a variety of reasons including preanalytical issues such as the sample container leaking or the container is missing swab. During the analytical process a sample may become unsatisfactory if the testing fails multiple times and a result cannot be obtained. A sample can also become untestable due to a laboratory error. The laboratory acknowledges that our code for samples that become untestable due to laboratory error ("UNSAT6") did not adequately consider the reporting language that would be used when this code was selected. These errors include lost, discarded or damaged specimens due to laboratory accidents, scanning errors, or mishandling of the specimen. Although the reporting language does not change the outcome of the test for the patient since retesting would be necessary, it does not accurately reflect the disposition of the sample. The laboratory acknowledges that the reporting language should be changed in the case of laboratory error. **(1) Immediate Corrective Action:** A request was made to Color Genomics by the Laboratory Director on April 30, 2021, to change the language of the report to say, "Test could not be completed due to laboratory error." It is expected that the change will be in effect no later than 01Jun2021.	3May2021

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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	**(2) Patient Impact:** Although the language used previously did not accurately describe that a laboratory error occurred, the patient was advised that no result was obtained, and that retesting was recommended. The language used on the report had no impact on patient care since the recommendation did not change. **(3) Preventative Measure:** The Accessioning Supervisor reviews all selected "UNSAT" codes prior to release to ensure the correct code has been selected. **(4) Monitoring Mechanism:** • As this occurrence has entered the CAPA process, an effectiveness check will be conducted for two consecutive days post implementation of the new report template language to verify implementation. • Samples unable to be tested due to laboratory error are reported on quality exception reports (QERs). Review of QERs by the Quality team during weekly scheduled meeting involves reviewing the incident with the laboratory section or Manager (technical supervisor). This process will include confirming that the correct "UNSAT" code has been applied in the event of a laboratory error. One patient report from each incident will be viewed to ensure correct UNSAT6 code was used, and correct report template used. • A daily email goes out to all key stakeholders (California Dept of Public Health, California Testing Taskforce, California Health and Human Services, including Dr. Erica Pan) that includes the number and type of UNSAT (Unsatisfactory specimens) received and tracked for trends and shifts. UNSAT Code 6 indicates Laboratory Error (see Attachment D8505_1). • Unsatisfactory Samples are also tracked as a key quality indicator and reported in monthly quality review.	

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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. [redacted]	D5805		

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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

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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] [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 [redacted]			

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D5805	Continued From page 28 [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]	D5805		

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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]

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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** This finding states that the laboratory did not promptly notify the authorized person ordering the test and, if applicable, the individual using the test results that an error in reporting had occurred. CFR 493.1291(k) states that the laboratory must perform the activities promptly but does not specifically define the number of days. Upon review of the QERs it was determined that the laboratory took action to provide corrected reports within the timeframes below. QER-20-010 – 3 days from incident to identification of issue; 4 days to perform the investigation and notification to Color Health which included rerunning the sample in question to confirm the results. QER-20-012 – 1 day from incident to identification of the issue; 4 days to perform the investigation and notification to Color Health which included rerunning the sample in question to confirm the results. QER-20-013 – 6 days from incident to identification of the issue; same day to perform the investigation and notification to Color Health The CDPH Branch Laboratory strives for improvement which can be seen by our median response time in Q1 2021 of 17hours (see Attachment D5821_1). There is no regulatory requirement for a laboratory to assess any particular process with a quality indicator (42 CFR 493.1701); the selection is left to the discretion of the Laboratory Director. The initial Quality Management Plan, drafted and approved by the previous Lab Director, was a best attempt at how to assess, monitor and document quality activities during startup and indicated the possible indicators that would be selected for the three phases of laboratory testing: preanalytical, analytical and postanalytical. Finding established benchmarks for a peer comparison for a large volume, automated one test (new) laboratory was not possible. The quality indicator for amended reports was initially set as a % of reported tests; no target metric was assigned in November or December. The College of American Pathology (CAP) field tested 11 indicators through their Q-TRACKS program and determined a statistical median rate of 2.8 test result corrections per 10,000 billable tests. Among results released in 2020 and in 2021, CDPH branch laboratory had ~0.83 and ~0.24 per 10,000 test result corrections which is lower than the median 2.8 reported by the CAP Q-TRACKS program. When CDPH Lab data exceed defined target of performance, the lab conducts a documented investigation to problem solve, determine root cause and implement corrective measures to improve the performance. Based on our performance to industry standard, the laboratory did not determine a quality issue with amended reports. Quality Indicator Monitoring Guidance. College of American Pathology, 2011 (see Attachment D5821_2).	3May2021
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		

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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	Continued from page 31 Through the partnership and oversight by the California Dept of Public Health and the Testing Task Force, the laboratory has put in place procedures to align with the contractual agreements for pre-analytical and postanalytical test order management, specimen collection and result reporting processes. The Laboratory has a Prescribing Order from the California Department of Public Health issued by Dr. Erica Pan, the Acting State Health Officer, to perform SARS-CoV-2 testing specifically on samples collected from participants at California COVID-19 testing collection sites. All results are released per the agreement between the State of California and the CDPH Branch Laboratory-related service agreements. There are two 'users' of the Covid testing conducted at this laboratory: Color Genomics and OptumServe; the ordering clinician is Dr. Pan. All placed electronic orders and samples obtained at California Dept of Public Health approved collection sites route through the COLOR database and portal. Results obtained at CDPH Branch Laboratory are transmitted electronically to COLOR for creation of the patient report and release of results to Optum Serve, the patient and CalREDIE through their online portal. Dr Pan receives aggregated test results on a daily basis via the CDPH Branch Laboratory daily update that includes the number of samples received, the number of samples received, the percentage positive, negative, unsatisfactory, invalid and presumptive positive over a 30 day sliding window. See D5805. As the contractual relationship with COLOR Genomics was being finalized shortly before the laboratory started testing, the focus for initial start-up was the routine report templates. The Laboratory Director had not formally approved CA-RPT-SOP-003 (Issuing Amended Reports procedure, see Attachment A) and the amended report templates. This is discussed in detail in D-5407 Finding 3. The 3 incidences noted in this observation occurred during a 2-week period in late November and early December. California Testing Task Force, California Dept of Public Health, including Dr. Erica Pan, and California Office of Health and Human Services were notified of the amended results and the delay from time of being aware of the problem, solving the problem, retesting and/or reanalyzing data, resulting and posting to the Color portal when COLOR (the 'user') was notified. The timeline for the 3 events is summarized in the table below. It is noted that that except for 20-010, COLOR's posting of the amended report to the portal occurs on the same day as notification. Results were made immediately available to the patient via the COLOR portal as approved by N-52-20 order. | QER#	Samples	Original Issued	Aware of Problem	# of Days Post Issue	RCA and Results in LIMC	COLOR Notified to Amend	Amended Report Issued to Portal	Days to Resolve Post Aware	LFS Stated Delay in Reporting | |---|---|---|---|---|---|---|---|---|---| | 20-010 | 22 | 14Nov | 17Nov | 3 | 21Nov | 21nov | 25Nov | 5 | 11 | | 20-012 | 1 | 20Nov | 25Nov | 1 | 27Nov | 28Nov | 28Nov | 3 | 8 | | 20-013 | 15 | 23Nov | 28Nov | 5 | 01Dec | 01Dec | 01Dec | 3 | 8 |	

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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 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. c. Quality Exception Report (QER)-20-013 and CAPA-20-004 stated an incorrect assigned data	D5821	Continued from page 32 In reviewing the process in light of the LFS observation, the CDPH Branch Laboratory is changing the notification procedures for amended reports so that Dr. Pan, the ordering clinician, can make the determination as to the appropriateness of patient notification based on previous result and the amount of time from the collection and original report. There is no change in the laboratory process of communicating a laboratory error to COLOR for creation of the amended report. Once posted, the patient has access to results. See D5779. **(1) Immediate Corrective Action:** Even though the California Dept of Public Health was already aware of these cited amended results, the Laboratory is supplying Dr. Pan, the ordering clinician, all original and amended reports with an accompanying letter notifying her the amended report has been submitted for each affected sample. The Original and Amended Reports with accompanying notification letters for the 38 records cited in this observation as well as the same documentation for subsequent incidences are attached (See Attachment C). **(2) Patient Impact:** With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially detected results but later not detected results would likely result in patient psychological stress due to the incorrect diagnosis and need for quarantine or isolation. There would be minimal patient health impact as the decision on potential treatments or hospitalization would be made by the patient's medical provider on the basis of symptoms rather than a positive test result. With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially not detected results but later either detected or presumptive positive did pose a risk to the patient and the community due to the risk of viral transmission to close contacts and delay in seeking medical attention. **(3) Preventative Measure:** Dr. Pan will be notified of all results issued in error. Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email, the original report, the amended report, the individual notification letter and the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder. CDPH Branch Laboratory and Color Health have touch point calls three times a week. A call between the Laboratory, Color Health and Optum Serve is held once a week. These formal communication channels, as well as real-time communication via email and phone ensures prompt response to a request to issue corrected reports or to be aware of upcoming corrected reports.	

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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. [redacted] 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	**Continued from page 33** **(4) Monitoring Mechanism:** An amended reports audit is conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both original and amended report. See FY2021 Audit Schedule and the Amended Report Audit Plan (see Attachments D5779_1 and D5779_2) is updated to include the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a postanalytical quality assessment metric, with a target of 100% or no incidences of failure to submit. **D5891** This particular finding 1 and 2 indicates that the laboratory failed to meet the CFR 493.1291 standard for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytical system/phase of laboratory, more specifically called the Test Report. The standard states that patient specific data (results) are accurately and reliably sent from the point of data entry to final report destination, in a timely manner. There are 12 points (a-l) with multiple subparts that define the requirements. As has been stated previously, in preparation for the start of testing last fall, the laboratory had established 2 overarching policies and procedures, approved by the Laboratory Director, to directly address when and how to address identified problems that required corrective actions: The Quality Management Plan (QMP) and the Quality Exception Reporting (QER) and CAPA plan. Each of the foundational Quality System Essentials (QSE) that support the laboratory's operations are supported by the Continuous Improvement and Occurrence Management QSE; its' purpose is to capture and analyze information originating from quality exceptions (QE) that occur in ALL phases of laboratory testing. The Quality Management Plan (v2 01Mar2021) in Section 5.5.3 specifically addresses the postanalytical mechanisms to monitor, assess, and when indicated, correct identified problems (see Appendix A). 5.5.3 Post-Analytical 5.5.3. 1 A key monitor for postanalytical testing is review of corrected/amended reports and availability of report and reporting matching LIMC results. Other process to consider: 5.5.3.2 Result Reporting and archiving data: report templates, final reports, amended reports, availability of reports. 5.5.3.3 Sample Management: storage of samples post testing, sample retention, sample indexing. The primary sample tube is not retained, but the extracted DNS is stored at least 1 month depending on testing volume and storage capacity.	3May2021
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT	D5891		

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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	The Quality Management Plan also provides parameters, otherwise known as key quality indicators, to monitor activities critical to patient outcome that will affect many patients. These indicators are evaluated by comparing the lab's performance against defined thresholds for performance and available published benchmarks. The type and number of monitored indicators are dependent on the laboratory's scope of care. This laboratory performs one test, SARS-CoV-2 RT-PCR and testing started in this laboratory the first of November, 2020. It takes a few months to establish performance thresholds and be able to track shifts and trends as quality issues are documented and process improvements are initiated. There is no regulatory requirement for a laboratory to assess any particular process with a quality indicator (42 CFR 493.1701); the selection is left to the discretion of the Laboratory Director. The initial Quality Management Plan, drafted and approved by the previous Lab Director, was a best attempt at how to assess, monitor and document quality activities during startup and indicated the possible indicators that would be selected for the three phases of laboratory testing: preanalytical, analytical and postanalytical. Finding established benchmarks for a peer comparison for a large volume, automated one test (new) laboratory was not possible. The quality indicator for amended reports was initially set as a % of reported tests; no target metric was assigned in November or December. The College of American Pathology (CAP) field tested 11 indicators through their Q-TRACKS program and determined a statistical median rate of 2.8 test result corrections per 10,000 billable tests. Among results released in 2020 and in 2021, CDPH branch laboratory had ~0.83 and ~0.24 per 10,000 test result corrections which is lower than the median 2.8 reported by the CAP Q-TRACKS program. When CDPH Lab data exceed defined target of performance, the lab conducts a documented investigation to problem solve, determine root cause and implement corrective measures to improve the performance. Based on our performance to industry standard, the laboratory did not determine a quality issue with amended reports. The laboratory acknowledges that it failed to detect the two specific observations made by LFS during its onsite visit on 07Feb and 08Feb. Following the receipt of the inspection report dated 23Apr2021, the lab implemented its Continuous Improvement and Occurrence Management Plan. Each of the observations were investigated, root cause analysis conducted, and corrective action plan(s) are designed and in process of being implemented. The immediate corrective action plans with preventative steps and monitoring mechanisms are presented here again. Finding 1a: Samples submitted to the laboratory may be unsatisfactory for testing for a variety of reasons including preanalytical issues such as the sample container leaking or the container is missing swab. During the analytical process a sample may become unsatisfactory if the testing fails multiple times and a result cannot be obtained. A sample can also become untestable due to a laboratory error. The laboratory acknowledges that our code for samples that become untestable due to laboratory error ("UNSAT6") did not adequately consider the reporting language that would be used when this code was selected. These errors include lost, discarded or damaged specimens due to laboratory accidents, scanning errors, or mishandling of the specimen.	

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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	Continued from page 35 Although the reporting language does not change the outcome of the test for the patient since retesting would be necessary, it does not accurately reflect the disposition of the sample. The laboratory acknowledges that the reporting language should be changed in the case of laboratory error. **(1) Immediate Corrective Action:** A request was made to Color Genomics by the Laboratory Director on April 30, 2021, to change the language of the report to say, "Test could not be completed due to laboratory error." It is expected that the change will be in effect no later than 07May2021. **(2) Patient Impact:** Although the language used previously did not accurately describe that a laboratory error occurred, the patient was advised that no result was obtained, and that retesting was recommended. The language used on the report had no impact on patient care since the recommendation did not change. **(3) Preventative Measure:** The Accessioning Supervisor reviews all selected "UNSAT" codes prior to release to ensure the correct code has been selected. **(4) Monitoring Mechanism:** • As this occurrence has entered the CAPA process, an effectiveness check will be conducted for two consecutive days post implementation of the new report template language to verify implementation. • Samples unable to be tested due to laboratory error are reported on quality exception reports (QERs). Review of QERs by the Quality team during weekly scheduled meeting involves reviewing the incident with the laboratory section or Manager (technical supervisor). This process will include confirming that the correct "UNSAT" code has been applied in the event of a laboratory error. One patient report from each incident will be viewed to ensure correct UNSAT6 code and correct report template is used. • A daily email goes out to all key stakeholders (California Dept of Public Health, California Testing Taskforce, California Health and Human Services, including Dr. Erica Pan) that includes the number and type of UNSAT (Unsatisfactory specimens) received and tracked for trends and shifts. UNSAT Code 6 indicates Laboratory Error. • Unsatisfactory Samples are also tracked as a key quality indicator and reported in monthly quality review.	
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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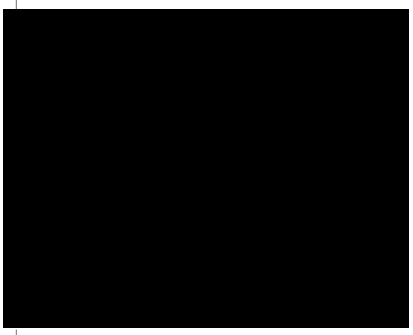
D5891	Continued From page 35 the 20 randomly reviewed patient test records covering the period from 11/14/2020 to 01/13/2021, wherein the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified 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	Continued from page 35 **Finding 1b:** In reviewing LFS observation and the laboratory's subsequent root cause analysis and findings, the CDPH Branch Laboratory is changing the notification procedures for amended reports so that Dr. Pan, the ordering clinician, can make the determination as to the appropriateness of patient notification based on previous result and the amount of time from the collection and original report. There is no change in the laboratory process of communicating a laboratory error to COLOR for creation of the amended report. Once posted, the patient has access to results. See D5779. **(1) Corrective Action:** Even though the California Dept of Public Health was already aware of these cited amended results, the Laboratory is supplying Dr. Pan, the ordering clinician, all original and amended reports with an accompanying letter notifying her the amended report has been submitted for each affected sample. The Original and Amended Reports with accompanying notification letters for the 38 records cited in this observation as well as the same documentation for subsequent incidences are attached (See Attachment C). **(2) Patient Impact:** With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially detected results but later not detected results would likely result in patient psychological stress due to the incorrect diagnosis and need for quarantine or isolation. There would be minimal patient health impact as the decision on potential treatments or hospitalization would be made by the patient's medical provider on the basis of symptoms rather than a positive test result. With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially not detected results but later either detected or presumptive positive did pose a risk to the patient and the community due to the risk of viral transmission to close contacts and delay in seeking medical attention. **(3) Preventative Measure:** Dr. Pan will be notified, within 12 hours of notification to COLOR of an amended report request, of all results issued in error. Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email, the original report, the amended report, the individual notification letter and the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder. **(4) Monitoring Mechanism:** An amended reports audit is conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both original and amended report. See FY2021 Audit Schedule and the Amended Report Audit Plan (see Attachments D5779_1 and D5779_2) is updated to include the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a postanalytical quality assessment metric, with a target of 100% or no incidences of failure to submit.	
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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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	D6076 The current full-time, on-site Laboratory Director (effective 27Jan2021) is actively involved in the day-to-day operations of the laboratory. The Quality Management Review process is now, as of Feb 2021, a monthly review, not a quarterly review. All laboratories have events that deviate from prescribed workflow and processes; it is the reason for continuous improvement and occurrence management. The Laboratory Director is actively overseeing enhancements to both Training/Orientation (CA-PER-SOP-001) and Competency (CA-PER-SOP-002 policies and procedures as evidenced by 412 / 412 (100%) of employees involved in the testing process have documented training and a successful roll-out of 6-month competency assessment.	03May2021
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 recordsreviewed, 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	**D6094** **1 and 2:** This finding states that the Laboratory Director failed to ensure quality assurance activities were established and maintained by the laboratory to assure the quality of services, and to identify failures as they occur in both the analytical and post analytical phases of testing.. A Quality Management Plan (QMP, See Attachment A) covering all the quality related processes of the 3 phases of laboratory testing (pre-analytical, analytical and post-analytical) as well as the associated activities that support those processes has been signed and in effect since 01Nov2020 (Shantelle Lucas, Lab Director), and most recently 4/11/2021 (Adam Rosendorff, Laboratory Director). It has undergone numerous improvements during that period, focusing on accurate result reporting, improved training and competency documentation, enhanced audit schedules, improved QER and CAPA reporting, timely reporting (turnaround time) and document management. The QMP is built on 9 core quality essentials- sets of coordinated activities that support the three phases of the laboratory workflow. Internal audits and external inspection/ audits ensure quality is maintained in all areas of the laboratory and problems identified and remedied before they have a chance to impact patient testing. In addition, daily, weekly, and monthly reviews focus on a comprehensive list of key performance indicators that are shared with all stakeholders. The QMP specifically addresses processes to monitor, capture and document non-conforming events as QERs, how to assess risk to determine if more in-depth actions in the forms of Root Cause Analysis (RCA) or CAPA. There is weekly documented review of all QERs and CAPAs to monitor progress, detect trends and initiate process improvements, as appropriate.	03May2021

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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	Continued from page 36 There is no regulatory requirement for a laboratory to assess any particular process with a quality indicator (42 CFR 493.1701); the selection is left to the discretion of the Laboratory Director. The initial Quality Management Plan, drafted and approved by the previous Lab Director, was a best attempt at how to assess, monitor and document quality activities during startup and indicated the possible indicators that would be selected for the three phases of laboratory testing: preanalytical, analytical and postanalytical. During the first two months of operation, analytical quality monitors of TAT, positivity rate, sample failure were monitored daily and submitted to key stakeholders, including Dr. Erica Pan. Regular monitoring of QC failure rates, audits of plate heatmaps, and review of customer complaints among other items are reviewed at monthly and quarterly quality management reviews. Currently, Patient look backs are conducted in the event that an instrument failure or other analytic problem is identified. Batches are reviewed for evidence of erroneous results (QC review by month, heatmap analysis, curve analysis). In addition we are reviewing positivity rates, and error rates daily to monitor for any unusual trends that would indicate a systemic analytic issue. PostAnalytical quality monitors included review of the number of amended reports as a percentage of total testing. Amended results are sent to COLOR for generation of the amended reports and upload to their result portal immediately upon learning of the need for such action, even before a QER is initiated. We have recently implemented a post-analytic QA process to ensure the accuracy of data released from VBL through patient reporting. (CA-RPT-SOP-004) The audit process was implemented in Q1 2021. Regular internal and external audits (CA-QM-FM-018) are conducted to monitor for compliance with all phases of laboratory workflow and support processes. A detailed Audit Schedule including monthly end to end patient audits, amended results audits, equipment maintenance documentation, Good Documentation Practices, adherence to SOPs, employee qualification and training documentation and good laboratory practice, reagent labeling compliance, Director timely review and approval of documents, and opportunities for re-training, where appropriate, are conducted. When non-conforming practices or non-compliance is observed, the exception enters the QER/CAPA process. The Quality Management Review process is now, as of Feb 2021, a monthly review, not a quarterly review. Management review includes Key Performance Indicators and targeted quality metrics and data to include summary information from the following	
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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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	(1) Assessment of Client feedback (2) Findings from internal audits (3) Findings from external audits (4) PT performance (5) Key Quality/Performance Indicator (KPI) a. Cancelled and Unsatisfactory Specimens b. Instrument Downtime c. Repeat Testing d. Compliance with Maintenance Documentation and GDP e. QC Failures f. TAT g. Positivity Rate h. Corrected Reports i. Safety Events j. Completed Competencies with the 3-month window 1. Equipment/Method Performance Comparisons 2. Staff Suggestions 3. Monitoring and resolution of complaints 4. Performance of Suppliers 5. Review of QERs and CAPAs 6. Suitability of procedures and sample requirement 7. *Verify EUA/IFU current version & impact/ applicability of modifications 8. *Updated or New method validations 9. Personnel Changes in Volume and Compliance Recommendations for Improvement 10. Follow-up actions from previous meetings **(1) Corrective Actions:** All laboratories have events that deviate from prescribed workflow and processes; it is the reason for continuous improvement and occurrence management. When these occur, the laboratory follows its QER and CAPA processes. Each of the findings observed in the 23Apr2021 Inspection Report findings from the LFS inspection on 07Feb and 08 Feb have been or are being addressed with corrective actions already in implementation phase. See D5779 for analytical and D5787 for post analytical process corrective actions. (2) Patient Impact: See D5779 and D5787.	
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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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	**(4) Monitoring Mechanism:** During any of the auditing processes, if any uncontrolled document is discovered or there has been a change in policy, process, plan or procedure, or use of a controlled document, that has not been pre-approved by the Laboratory Director and QA lead, then this is noted as a nonconformance and would follow the CAPA corrective action process. As part of the Quality Management Plan the laboratory clinical staff and laboratory director perform biennial review of its SOPs to ensure they encompass the best practices being applied within the laboratory workflow. During the monthly amended report audit, assessment is made of QERs associated with each event, the cause, the number of reports, the review of both original and amended report. The FY2021 Audit Schedule and the Amended Report Audit Plan (see Attachments D5779_1 and D5779_2) which is updated to include the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a POST Analytical quality assessment metric, with a target of 100% or no incidences of failure to submit.	

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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	Continued from page 36 Monitoring timely completion of QER and CAPA's has been added to the Quality Management Review with an expected documented signature approval of the written corrective plan targeted for completion within 15 days. CDPH Branch Laboratory, under the direction of Dr. Adam Rosendorff, will continue to follow its continuous improvement and occurrence management, auditing, and quality management review processes to identify, assess, monitor and when identified, correct problems identified in any of the laboratory workflow or ancillary processes.	
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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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	**D6102** **Finding 1 and 2** During the February 7 and February 8 investigation, an unofficial roster used for convenience in the laboratory was presented. Since this time, the CDPH Branch Laboratory has developed audit procedures that specify what laboratory documents may be shared and the manner in which they are to be given to regulatory agencies. **(1) Immediate Corrective Action:** A current roster of technical (Extraction, PCR, and Data Analysis) and non-technical (Accessioning) staff is used to provide training documentation. The lists are very similar but do have a few differences (see D-5209 Findings 4 and 5). **(2) Patient Impact:** The unofficial roster is used by Managers and Supervisors as a reference for staff on shifts or in areas with which they do not work directly. Inaccuracies in this roster may result in inconvenience for laboratory staff; however, there is no impact on patient care. **(3) Preventative Measure:** An inspection work instruction has been drafted by the CDPH Branch Laboratory. This draft has been used as starting point for Quality team members, Supervisors, Managers, and the Laboratory Director to have a group training session on conducting an efficient audit. Two training sessions and mock inspection drills have been completed (see D5209, Attachment D5209_Audit and Inspection Training). Successes and challenges of these mock drills are being used to complete the Inspection Work Instruction. Techniques from this training were used to efficiently meet requests from Laboratory Field Services during an on-site visit in March 2021. **(4) Monitoring Mechanism:** Additional mock inspection drills will be held on all shifts. Team performance during any audit or inspection is reviewed during post audit conference (as stipulated in the work instruction). Areas of effectiveness as well as areas for improvement will be documented and enter the Continuous Improvement process (CAPA). **Finding 3.** The roster provided on 2/8/2021 was not an official one, therefore, the following numbers as presented in the LFS findings vary slightly (see Finding 3). A review of our records found that 412 / 412 (100%) of employees involved in the testing process have documented training.	3May2021

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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		

		Sun - Tue		Wed-Fri		Total
		Day	Night	Day	Night	
Accessioning		34/34	43/43	46/46	37/37	160
Extraction	Reformatter	36/36 (37 total)	46 / 46 (55 total)	38/38 (40 total)	48/48 (51 total)	183
	Chemagic	36/36 (37 total)	41/41 (55 total)	38/38 (40 total)	48/48 (51 total)	
PCR	RT-PCR Set-up	11/11	14/14	12/12	11/11	48
	AJ PCR	11/11	14/14	12/12	11/11	
Analysis		7/7	5/5	6/6	3/3	21
Total		89	117	104	102	412

Continued from page 38

Due to the large number of staff onboarded in a short period of time to meet the emergency demands for COVID-19 testing capacity, there was a delay in entering training documentation in the new document control system. This made it difficult to track what was still needed. Efforts to collect and document training were delayed. Subsequently, notifications to Supervisors and Managers regarding forms that were not completed was delayed. In addition, delays in providing records upon audit request were due to limitations of the document control system being able to download a large number of documents at the time of onsite inspection.

Data Analysis
It is important to note that technologists in the Analysis group are the only staff who report patient results. 21/21 (100%) of the Data Analysts, as well as the Sign-Out Manager, had documented training prior to reporting patient results as documented on the Data Analysis (CA-PER-FM-015) initial training assessment form. Copies of this form, as well as a related but redundant form (see below) are provided in Attachment D5209_3a, D5209_3b and D52093z. These records were provided to LFS via email on February 8 as requested. Confirmation of the sent email is provided in Attachment D5209_3zb.

Due to uncertainty about workflow ahead of the laboratory opening, two forms were created (prior to any employee onboarding) to capture training needed to extract and analyze data after completion of RT-PCR:

- Data Extraction (CA-PER-FM-014)
- Data Analysis (CA-PER-FM-015)

These tasks were separate to allow PCR technologists to review data prior to submitting for analysis; however, this workflow was never implemented in this laboratory. Both forms were completed for most analysts; however, four data analysts initially had only the Data Analysis form (CA-PER-FM-015) completed. The redundant Data Extraction form (CA-PER-FM-014) was initially maintained with the thought that the workflow could be implemented when sample volumes increased; however, this was not necessary.

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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	Continued from page 39 **PCR** All PCR technologists (48/48; 100%), as well as all PCR Supervisors (4/4), had documented training prior to processing patient samples (Attachments D5209_3c – D5209_3g). A review of records did reveal a minor anomaly in the training record. For several individuals training in PCR, the training form was completed and signed for the RT-PCR Set-up on the Janus G3 (CA-PER-FM-012); however, the form for the RT-PCR AJ thermocycler (CA-PER-FM-013) is not in the training record. A review of records indicates that technologists prepared the PCR batch on the RT-PCR Set-up and loaded the PCR plate to the AJ Thermocycler. Training on the RT-PCR Set-up, as well as data review, were completed by the trainer. These records indicate that the AJ thermocycler was loaded and started correctly. Since these are the tasks assessed for training, the individual being assessed performed the task correctly but the laboratory failed to properly document this aspect of the training. **Extraction** In the Extraction area, some staff currently perform only the Reformatter automated liquid handling procedure or the chemagic automated nucleic acid extraction procedure, therefore, the total number of training records for each is smaller than the total number of individuals in that area. A detailed list is provided in Attachments D5209_3h – D5209_3p. Of the 183 staff members in Extraction: • 173 have been trained to use the Reformatter liquid handler • 166 have been trained to use the chemagic automated nucleic acid extractor • Staff without current training for an instrument are not permitted to operate that instrument A review of records found that for the Reformatter: • 133 / 173 had completed training records at the time of training • 17 / 173 had an indication from the trainer that training was completed but a signature was not obtained • 23 / 173 were found to have inadequate documentation of training A review of records found that for the chemagic: • 149 / 166 had completed training records at the time of training • 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained • 10 / 166 were found to have inadequate documentation of training **(1) Immediate Corrective Action:** Any task for which a training form was not captured was re-assessed for the individual or that individual was removed from that testing process until re-assessment could be completed. **Analysis:** Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysts were assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form.	

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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	Continued from page 40 **PCR:** Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained. **Extraction:** For the 23 / 173 (13%) that were identified in mid-December to have a missing training document for the Reformatter automated liquid handler: • 11 of these individuals were re-assessed by a Supervisor in December 2020 and found to be adequately trained • 2 were removed from testing and re-assessed in February 2021 and found to be adequately trained • 10 of these individuals were reassessed in January (2), February (7) and March (1) and found to be adequately trained. For the 10 / 166 (6%) were found in a mid-December to have a missing training document for the chemagic automated nucleic acid extractor: • 4 of these individuals were re-assessed by a Supervisor in December 2020 and found to be adequately trained • 6 of these individuals were reassessed in February (5) and March (1) and found to be adequately trained. All Extraction Supervisors were adequately trained(see Attachment D5209_3z). . **Accessioning:** The accessioning process for this laboratory requires: • Scanning of the barcode on the sample • Batching into groups of 94 samples for testing • Identifying unsatisfactory samples Although some accessioning staff performed heat inactivation prior to February 2021, most were trained in this procedure in February 2021 (see Attachments D5209_3q – D5209_3y). Review of records showed that 47 / 160 training records were delayed; however, all have been completed. These delayed signatures were spread across the four shifts. Training of accessioning staff for heat inactivation was documented appropriately by February 2021 for 158 / 160 of the accessioning staff. No staff were found to have deficiencies in training (see Attachments D5209_3q – D5209_3y). **Audit process:** Paper copies of personnel files have been created to aide in timeliness of audit responses. **Training Process:** The Personnel Orientation and Onboarding procedure (CA-PER-SOP-001 v2, 14Mar2021) has been updated to reflect and enhance current practice see Attachment D5209_1a. A set schedule for a three-day orientation has been set. Training checklists (previously titled Training and Competency Assessment) have been updated to include all aspects of training (see D5209_1d). In addition, a roster with training status by shift is placed in each lab area so that any Supervisor can easily see training status (see example in Attachment D5209_1e).	

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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	Continued from page 41 **(2) Patient Impact:** **Data Analysts:** The only staff who review and release data are the Data Analysts and the Sign-Out Manager. Training records for 21/21 data analysts and the Sign-Out Manager were completed, therefore, there was no impact on patient care. The impact of the failure to document training for Data Extraction (CA-PER-FM-015) is minimal because: • There is complete overlap in the tasks between Data Extraction and Data Analysis • Data Analysis cannot be completed without Data Extraction **PCR:** Training for all PCR staff was adequately captured except for one for four individuals. Since the data show the tasks were carried out correctly and the data were accepted by the trainer, there is evidence that this omission did not impact patient care. **Extraction:** The limited number of instances of missed training documentation identified are unlikely to impact patient care since the assay steps performed in extraction do NOT include data review or analysis. **Accessioning:** Accessioning consists mainly of barcode scanning. All unsatisfactory specimens are checked by a supervisor prior to rejecting the sample. Upon assessment, no performance issues were identified, therefore, there is no impact on patient care. Audit process: The ability to download records in bulk has no impact on patient care. **(3) Preventative Measure:** A more formal training program for new technologists has been put in place - see. Since the laboratory now has many performing employees there is more opportunity for new staff to observe procedures and work with trainers or supervisors. The redesigned training forms presented in D5209 Finding 1 help to facilitate this process. A summary PowerPoint was sent to all Managers and Supervisors explaining the changes and the new and updated forms on April 1, 2021 before the start of 6-month competency assessments of the technical staff on April 21, 2021. Members of the Quality Team met with each Supervisor performing 6-month competency assessments before they began assessments and several times during assessments to ensure they understood the changes to the process. Paper copies of all personnel records have been created to facilitate audit requests more quickly and efficiently. **(4) Monitoring Mechanism:** A review of records from mid-December to present indicates: • There continues to be no documentation issues with the Data Analysts who are reviewing and releasing results. • In the PCR area, all 18 staff trained from mid-December 2020 to present have all training documentation properly completed • In Extraction, of the 42 individuals trained in mid-December or later, 42/42 were properly documented for the Reformatter automatic liquid handler and 41/42 (one delayed signature) were properly documented for the chemagic automated nucleic acid extraction procedure.	

STATEMENT OF DEFICIENC ES 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 SUPPL ER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

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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	Continued from page 42 • An insufficient number of new hires in Accessioning started since mid-December to assesses effectiveness; however, effectiveness will be assessed as new hires are made. • In addition to mock audit exercises, the monthly tracer audits conducted as part of the monthly audit schedule assess whether personnel documentation is available and complete. **Finding 4** Of the 30 randomly selected samples: • 5/5 Accessioning personnel have complete training documentation • 5/5 Extraction personnel have complete training documentation. 1/5 had a delayed signature for Reformatter training at the time she ran 10 / 21 samples shown here; however, she was reassessed prior to running the remaining 11 / 21 samples. Upon reassessment she was determined to be adequately trained and all samples she ran were successful. • 3/3 PCR personnel have complete training documentation • 2/2 Data Analysts have complete training documentation (See D5209 finding 6 for training documentation.) **(1) Immediate Corrective Action:** See finding 3 **(2) Patient Impact:** See finding 3 **(3) Preventative Measure:** See finding 3 **(4) Monitoring Mechanism:** See finding 3	