STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This Condition is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, it was determined that the Condition for FACILITY ADMINISTRATION was not met as mandated by CLIA in Subpart J of Title 42 of the Code of FederalRegulation. Findings included: 1. The laboratory failed to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was minimized (See D3003). 2. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials (See D3011). 3. The laboratory failed to retain records of test requisitions of all patients tested for	D3000	**(1 - D3003)** The laboratory has an Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and asceptic cleaning techniques all of work areas and equipment. The observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our procedure. Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for decontamination is 60. See section D3003 for more details. **(2 - D3011)** The finding was the observation, by inspectors, of two individuals working in the BSC at one time. Based on information from the BSC manufacturer we are permitted to have two individuals utilizing the hood at a time due to the type of work they are performing, sample tube decapping. Procedure CA-SAFE-POL-002, version 1 that was approved by the lab director with an effective date of 22Oct2020 was update (v6, approved by the director on 26Feb2021) to specify the number of individuals permitted in a BSC at one time, as established by the manufacturer. See section D3011 for more details. **(3 - D3027)** As stipulated in the contractual agreement with the State of California, all requisition data is collected on the electronic requisition form that is stored at Color Genomics (CLIA #05D2081492). Requisition data are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. The CDPH Branch Laboratory receives the confirmation of a test requisition for each sample by way of electronically requesting the data components during the accessioning process. This is completed by a system-to-system communication channel between the Color Genomics IT software system and the CDPH Branch Laboratory's LIMS software system. In the event that a test requisition is not available the response from the Color Genomics system indicates that the sample is not approved for processing and no collection date and time are provided. See section D3027 for more details.	8Mar2021

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature] MD	Laboratory Director	30March2021

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients . (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D3000	Continued From page 1 SARS-CoV-2, for at least two years (See D3027). 4. The laboratory failed to retain records of original test reports of all patients tested for SARS-CoV-2, for at least two years (See D3041).	D3000	Continued from page 1 **(4 - D3041)** CA-DC-SOP-003 v1 effective at the time of inspection states that patient results are retained for a minimum of 3 years. As stipulated in the contractual agreement with State of California, all reports are generated electronically through Color Genomics. Per their policies and procedures. (CLIA #05D2081492), reports are retained for 20 years and are accessible to CDPH Branch Laboratory for auditing purposes. In the event that a report must be amended, both the original and the amended reports are retained. Original and amended versions of the reports affected by the error on 04Dec2020 have been retained. See section D3041 for more details.	
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This Standard is not met as evidenced by: Based on interview with the laboratory staff on December 8, 2020, review of policies and procedures (P/P) for Quality Management Plan and FDA EUA IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, random review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was minimized. Findings included: 1. Decontamination Protocol a. During the laboratory tour at approximately 10:00 a.m., the laboratory staff stated the use of 70% Ethanol to decontaminate the working area at least twice a day for accessioning, heat inactivation, decapping of swab transport tubes (Festo Decapper), extraction (Chemagic 360), PCR set-up (Janus G3), and PCR (Analytik Jena).	D3003	**D3003** **Finding 1:** The laboratory has an Amplicon Contamination Prevention Plan, CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and aseptic cleaning techniques all of work areas and equipment. The observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our procedure (See Section 5.7.2). Additionally, a default Safety statement was included in the technical SOPS (listed in the findings) that contradicted the current approved practice and the Laboratory Quality Management Plan (approved by the director and in effect at time of inspection (CA-QM-SOP-001 va effective 01NOV2020) did not provide the robust environmental prevention and decontamination initiatives outlined in the Amplicon Contamination Prevention Plan. The FDA EUA instructions for use of the PKI nucelic Acid detection kit provided possible actions for preventing contamination; The decontamination prevention instructions do not impact the performance characteristics of the test and it is the Laboratory Director who determines the contamination prevention and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work surface area and the instruments is not approved by the Laboratory Director and therefore not included in the contamination prevention plan.	8Mar2021

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D3003	Continued From page 2 b. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) stated only the temperature and humidity monitoring for environmental and safety monitoring. The laboratory failed to have written protocols to ensure the performance, frequency, and documentation of environmental decontamination. c. Review of the laboratory's policies and procedures for accessioning, heat inactivation, decapping, sample transfer, extraction, and PCR (Policy # CA-ACC-SOP-001, Title: Accessioning for SARS-CoV-2 Samples, Effective Date 12/05/2020; CA-EXT-SOP-001, Title: Heat Inactivation of Viral Swab Samples, Effective Date 11/18/2020; CA-EXT-SOP-002, Title: Decapping and Batch Preparation for Janus G3, Effective Date 12/03/2020; CA-EXT-SOP-003, Title: Sample Transfer Using the Janus G3, Effective Date 12/06/2020; CA-EXT-SOP-004, Title: Viral RNA DNA Extraction Using the Chemagic 360-D, Effective Date 11/03/2020) stated under Section 6.0 Occupational Health and Safety that, "while little is known about this novel virus, the comparable genetic characteristic with SARS-CoV and MERS-CoV suggest that 2019-nCoV may likely be susceptible to disinfectants including Sodium Hypochlorite for general surface disinfection, 75% ethanol, 0.5% Hydrogen Peroxide, Quarternary Ammonium, and Phenolic compounds, if used according to manufacturer's recommendations. VTM containing Guanidine may produce cyanide with bleach, therefore not recommended as cleaning agents in CDPH Branch Lab." (1) The laboratory's procedure failed to specify	D3003	Continued from page 2 Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for decontamination is 60. **(1) Immediate Corrective Action:** • Updated all technical protocols to reflect the current disinfectant in use, 70% Ethanol, the removal of UV references and the use of MTM instead of VTM (See Attachment 1 and their associated approval dates). • Updated the Quality Management Plan (CA-QM_SOP-001, Sections 6.3.4.7, 6.5.1, 6.8.1, approved by Lab Director and effective 01Mar2021) to reflect contamination prevention and monitoring that is in place, following current Amplicon Contamination Prevention Plan (SAFE-POL-019., v1.1, approved by Lab Director and effective 14Dec2020). **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. Appropriate quality control reactions are helpful in determining whether contamination has occurred. A patient lookback (from 28OCT2020 to 08DEC2020) and a patient lookforward (09DEC2020 to 28FEB2021) was conducted to review all positive and negative controls to look for the presence of viral targets that could indicate contamination. There was no evidence of contamination as values were well below 2% threshold. (See Attachment 1) The trend downward noted is due to a software change allowing for color compensation and better resolution and not attributable to EtOH or % of EtOH used. Per Dr. Rosendorff, the current Lab Director, there is no contamination of patient samples or test results. **(3) Preventative measure**: On 18Mar2021 Quality Specialists scanned the document control management (MediaLab) for additional references to VTM and 75% EtOH; none were found. Staff were provided access via MediaLab to the updated SOPs on the day the Lab Director approved the documents (refer to the SOPs in attachment 1). As this was a correction that reflected the current practice, no additional training was required.	

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D3003	Continued From page 3 which disinfectant is being used at the CDPH Branch Lab. (2) At the time of the on-site survey on December 8, and 9, 2020, the laboratory was using Molecular Transport Media (MTM), not Viral Transport Media (VTM). The laboratory was also using 70% ethanol as a disinfectant, and not any of the disinfectants (75% ethanol, 0.5% Hydrogen Peroxide, Quaternary ammonium, and Phenolic compounds) specified in its procedure. (3) The laboratory failed to provide documentation and written protocol to ensure that 70% ethanol was sufficient to minimize environmental contamination. d. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021 for version 7.0) stated under Warnings and Precautions #10 that, "Sterile centrifuge tubes and filter-tips should be disposed into a waste bin containing a 10% Sodium Hypochlorite solution. After the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared 10% Sodium Hypochlorite solution, and then cleaned with 75% Ethanol or pure water. Finally, turn on UV light to disinfect working surfaces for 30 minutes." (1) The laboratory failed to utilize waste bin containing a 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. The laboratory failed to specify what was being used if it was not using 10% Sodium Hypochlorite.	D3003	**(4) Monitoring Mechanism:** Positive and Negative controls are monitored by the Sign Out Manager with trending review monthly and signature review by the Lab Director at the Quality Management Review. Batch runs are monitored for internal quality metrics for non-viral peaks and negative control positivity; Documented supervisor review is audited monthly by Quality Dept as part of the monthly end to end audit (Refer to 2021 Audit Schedule and the End to End 10 Specimen Audit Plan (CA-QM-FM-016) Appendix A: The Quality Management Plan has been revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 ver2.0 approved by Lab Director and effective 01Mar2021. See Attachment 1. Summary: The laboratory has a plan for Amplicon Contamination Prevention Plan (see CA-SAFE-POL-019). The use of 70% EtOH meets the standard set by CDC. Heat inactivation is an effective method to inactivate SARS-CoV-2. Disposal of MTM sample collection tubes that have been subjected to heat inactivation in bleach is not necessary. Therefore, the area in which the samples were handled was adequately decontaminated.	

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D3003	Continued From page 4 (2) The laboratory failed to provide written protocol for work area, and instrument surface disinfectants, and the use of UV light. 2. Decontamination Solution in the Testing Process a. During the laboratory tour on December 8, 2020 at approximately 10: 30 a.m., the laboratory was observed to have four 70% Ethanol Cleaning Solution in dispensing bottles beyond its expiration date. (1) Lot # 267015, Expiration Date: 12/03/2020 (2 dispensing bottles) (2) Lot # A10012002B, Expiration Date: 12/07/2020 (2 dispensing bottles) b. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) stated that reagents and chemicals should be used in testing process within their indicated expiration date. 3. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results, but failed to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized. Accession Number [redacted]	D3003	**Finding 2,3,4,5:** We acknowledge the failure to discard some of the ethanol reagent bottles that were in use past their expiration; 2 bottles 5 days past expiration and 2 bottles 1 day past expiration date. **(1) Immediate Corrective Action:** • The bottles were discarded and fresh ethanol was made available. Walkthrough conducted by the supervisory teams ensuring that all other reagents were labelled appropriately and in date to reflect the policies and procedures outlined the Quality Management Plan (CA-QM-SOP-001) • A new SOP, Labeling of Reagents and Solutions (CA-LABGEN-SOP-002) was approved by the Lab Director with an effective date of 09DEC2020 and reassigned in response to findings of improperly labeled reagents by the MediaLab Admin to all laboratory technologists on 24Feb2021 with a target completion date of 23Mar2021 (93% compliance). **(2) Patient Impact:** A lookback review of all QC performed on specimens received from 01DEC2020 to 12DEC 2020 was conducted and there was no evidence of contamination of patient samples as a result of the expired 70% ethanol. See QC report in Attachment 2. The power point shows the negative control analyzed data with the specified time frame and indicates percentage of possible negative contamination (but not contamination of patient's sample). The Laboratory Director affirms that there is no contamination impact to patient results reporting during this time period. **(3) Preventative measure:** • An audit, specific to compliance with equipment logs and reagent labeling and expiration (2021AUDIT- 005) carried out 26Feb2021 has been reported to Managers and Supervisors. Response is expected by15Mar2021 for any corrective actions and future preventative actions. • Supervisor daily checklists (implemented the first week of March 2021) utilized in shift to shift handoff communications include a daily check of reagents in their respective areas to insure compliance with labeling and expiration dates. An example of several completed checklists are included in Attachment 2. **(4) Monitoring mechanism:** In addition to the daily supervisor review of reagents, a monthly walkthrough audit conducted by quality organization has been added to the 2021 Audit Schedule.	

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D3003	Continued From page 5 [redacted] 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized.	D3003	Continued from page 5 Supporting Documentation: a.Read notification of CA-LABGEN-SOP-002 approved by Lab Director and in effect 09Dec2020. b.Supervisor Daily Checklists (example of in use) - See CAP response document of completed checklists. c.2021 Audit Schedule d.2021Audit-005 Report (first page) e.CA-LABGEN-SOP-002 Labeling of Reagent and Solutions See Attachment 2 and Attachment 1. Summary Statement for Deficiency D3003, D5415, D5417, D5433 and D6093: In summary, expired reagents, such as the 70% EtOH, were only expired by a few days. Since the main concern of aging EtOH is evaporation and CDC states over 60% EtOH is effective, the risk posed is low, and negative controls on testing during this time did not indicated contamination.	
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection	D3011		29Mar2021

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D3011	Continued From page6 from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This Standard is not met as evidenced by: Based on interview with laboratory staff on December 8, 2020, review of policies and procedures (P/P) for General Facilities Safety Plan, random review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. Findings included: 1. During the laboratory tour on December 8, 2020 at approximately 11:00 a.m., the laboratory staff stated that COVID-19 sample transfer process is performed by one testing person per one Class II Type A2 Biosafety Cabinet (BSC) for safely working with materials contaminated with or potentially contaminated with infectious or biohazardous materials and for maintaining sterility of the materials inside. 2. During the laboratory tour on December 9, 2020, the laboratory was observed with two laboratory personnel working in one Biosafety Cabinet. 3. Review of the laboratory's policies and procedures (Policy # CA-SAFE-POL-002, Title: General Facilities Safety Plan, Effective Date 12/07/2020) failed to indicate the number of laboratory personnel who can utilize one BSC to ensure safety and minimize contamination. 4. The following are the accession numbers of the 60 randomly reviewed patient test records	D3011	**Findings 1-6**: The Biosafety hoods provide secondary containment controls and ventilation controls that only benefit the operation and improve the safety of the decapping operation. The laboratory contacted NuAire, the manufacturer of the BSL2 hoods used onsite and they confirmed there should be no operational problems having 2 personnel working in one cabinet at any given time. In the link provided in the attached documentation you will see that if the two cabinet operators are working with different types of work (dirty and clean) there would be an issue. However, in this situation, the two personnel would be performing the exact same process with the same reagents and materials. **(1) Immediate Corrective Action:** The CA-SAFE-POL-002 document was updated to reflect this. The current version is 6 which was approved by the Director on 26Feb2021. **(2) Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. The BSC manufacturer has confirmed that safety specifications to allow two individuals to decap in BSC for this assay. **(3) Preventative Measures**: CA-SAFE-POL-002 was assigned by MediaLab Admin to the performing employees to read and acknowledge the updated procedure by 31Mar2021. **(4) Monitoring Mechanism**: 21Audit009 initiated 23Mar2021, conducted by Quality, will audit the Extraction Area BSC's for compliance with number of personnel allowed at BSC at one time. Audit is random daily check for 30 days with on the spot education. (See 21Audit009) If compliance is noted, daily checks will cease and this safety observation will be added to the monthly wet lab departmental audit, conducted by Quality (See 2021 Audit Schedule). See Attachment 3	

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D3011	Continued From page 7 covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. Accession Number [redacted] 5. Based on the laboratory's annual testing	D3011		

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D3011	Continued From page 8 declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 until 12/16/2020. 6. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials.	D3011	**Findings 1-3, 5-7**	
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This Standard is not met as evidenced by: Based on interviews with staff and the laboratory director on December 8, 2020, the absence of test requisitions, and random review of test records covering the period from 11/22/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to retain records of test requisitions for SARS-CoV-2 patient testing. Findings included: 1. The laboratory performed SARS-CoV-2 RT-PCR laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples under the order of the State Health Officer. 2. Although the laboratory presented a blanket prescribing order for all California patients within the state from the State Health Officer, an authorized person; the laboratory does not	D3027	Per contractual agreement between CHHS and CDPH Branch Laboratory, all information is collected on the electronic requisition form that is stored at Color Genomics (CLIA #05D2081492) at established collection sites (see D5311). Data needed for testing is transferred to CDPH Branch Laboratory. Requisition data are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. (1) **Immediate Corrective Action:** Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and member of the Quality Assurance team received training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics on demand. (2) **Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. (3) **Preventative Measures**: Through the use of the laboratory leadership training checklist the lab will continue to ensure the quality assurance and laboratory director staff at the CDPH Branch Laboratory has access to the Color Genomics system and can effectively and efficiently access the data stored by Color Genomics, on demand. (4) **Monitoring Mechanism**: Monthly audits for FY 2021 to determine availability and compliance with all required elements are performed by the quality organization. The availability of the requisition and report was confirmed for 10 samples via a routine tracer audit performed 26Feb2021. See attachment 4 and attachment 5	29Mar2021

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D3027	Continued From page 9 generate a test requisition for each patient 3. During the initial stages of its application for a California clinical laboratory license, we requested the laboratory to submit an example test requisition that will be used. A test requisition is only one of the several requirements to be met, prior to receiving a laboratory license. On 10/20/2020, the laboratory submitted a documented titled, "Test Order Requisition_Covid 19 Sample Requisition- Example Only v.3." Even though the laboratory submitted an example requisition that will be used, the laboratory had not been generating a test requisition for each patient. 4. There was no mechanism in place to ensure a test requisition was generated for each patient. There was also no mechanism to ensure that test requisitions were retained by the laboratory. 5. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to provide test requisitions for each patient tested. Accession Number [redacted]	D3027	**Findings 1, 4-7** The CDPH Branch Laboratory receives the confirmation of a test requisition for each sample by way of electronically requesting the data components during the accessioning process. This is completed by a system-to-system communication channel between the Color Genomics IT software system and the CDPH Branch Laboratory's LIMS software system. In the event that a test requisition is not available the response from the Color Genomics system indicates that the sample is not approved for processing and no collection date and time are provided. The Color API for External Labs [External] document outlines the process for data transmission and the data fields exchanged. **(1) Immediate Corrective Action:** Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and member of the Quality Assurance team received training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics, on demand. **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measures:** Through the use of CA-PER-FM-031, Pre/Post Analytical QA Training Checklist,the lab will continue to ensure the quality assurance and laboratory director staff at the CDPH Branch Laboratory has access to the Color Genomics system and can effectively and efficiently access the data stored by Color Genomics, on demand. **(4) Monitoring Mechanism:** Monthly audits for FY 2021 to determine availability and compliance with all required elements are performed by the quality organization. The availability of the requisition and report was confirmed for 10 samples via a routine tracer audit performed 26Feb2021. An audit (2021Audit-008) of an additional 25 samples was initiated 11MAR2021 to verify that requisitions are available and include all necessary requisition elements. See attachment 4 and attachment 5	

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D3027	Continued From page 10 6. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 7. The laboratory director and testing personnel affirmed December 8, 2020 at approximately 11:00 a.m. that the laboratory failed to retain records of test requests.	D3027	**Findings 1-7**	
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This Standard is not met as evidenced by: Based on email communication with the laboratory director on 12/24/2020, the absence of original test reports, and review of test records covering the period from 12/02/2020 to 12/04/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to retain records of original test reports for SARS-CoV-2 patient testing. Findings included: 1. The laboratory performed SARS-CoV-2 RT-PCR laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples, and the final test reports were all generated through Color Laboratory. 2. The laboratory issued test results for	D3041	CA-DC-SOP-003 v1 effective at the time of inspection states that patient results are retained for a minimum of 3 years. As stipulated in the contractual agreement with State of California, all reports are generated electronically through Color Genomics. Per their policies and procedures. (CLIA #05D2081492), reports are retained for 20 years and are accessible to CDPH Branch Laboratory for auditing purposes. In the event that a report must be amended, both the original and the amended reports are retained. Original and amended versions of the reports affected by the error on 04Dec2020 have been retained. Confirmed through 3 external audits that ALL results that have been amended have an accessible original and amended report. **(1) Immediate Corrective Action:** Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and member of the Quality Assurance team received training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics, on demand. **(2) Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm as the amended reports and original reports are retained.	29Mar2021

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D3041	Continued From page 11 SARS-CoV-2 but should have been invalid due to laboratory process error on 12/04/2020. 3. CDPH Branch laboratory informed Color Laboratory about the test results reported in error which amended reports were issued on 12/07/2020. 4. CDPH Branch Laboratory has access with the test results for SARS-CoV-2 but failed to provide the original test results reported on 12/04/2020 and amended on 12/07/2020. 5. The following are the accession numbers of the 10 reviewed patient test records covering the period from 12/02/2020 to 12/04/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to provide original test reports for each patient tested. Accession Number [redacted] 6. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 7. The laboratory director affirmed (February 12, 2021 at approximately 2:00 pm) that the laboratory failed to retain records of original test	D3041	Continued from page 11: (3) **Preventative Measures:** Through the use of CA-PER-FM-031, Pre/Post Analytical QA Training Checklist, the lab will continue to ensure the quality assurance and laboratory director staff at the CDPH Branch Laboratory has access to the Color Genomics system and can effectively and efficiently access the data stored by Color Genomics, on demand. (4) **Monitoring Mechanism:** Audit of ALL Amended Reports to ensure compliance with SOP (availability of original report, original results included on the Amended Report, and confirmation of Amended Report notification to client and/or patient is incorporated into the 2021 Audit Schedule as a monthly audit, performed by the quality organization; included in the Quality Management Review. See attachment 5.	

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D3041	Continued From page 12 reports.	D3041	**D5300**	
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in §§493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in §493.1249 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, it was determined that the Condition for PREANALYTIC SYSTEMS was not met as mandated by CLIA in Subpart K of Title 42 of the Code of FederalRegulation. Findings included: 1. The laboratory failed to ensure it retained test requisitions for SARS-CoV-2 patient testing(See D5301). 2. The laboratory failed to ensure test requisitions included necessary information for accurate reporting of test results (See D5305). 3. The laboratory failed to ensure written policies and procedures for specimen submission and handling were followed (See D5311). 4. The laboratory failed to ensure it documented the date and time of receipt of all patient specimens for SARS-CoV-2 testing (See D5313).	D5300	CDPH Branch Laboratory receives all samples via Testing Task Force collection sites. These sites are registered with Color Genomics and operate under a standing order from Dr. Erica Pan, Acting State Health Officer, State Epidemiologist, Deputy Director, Center for Infectious Disease, CDPH. **(5301/5305/5313)** All data, including collection date and collection time, are collected on the electronic requisition form that is stored at Color Genomics (CLIA #05D2081492). All CLIA required requisition elements are included in the electronic requisition. Requisition data are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. Manual paper requisition forms are available for use in extreme emergent priority as requested by CHHS and documented as deviation from standard procedure. See section 5301, 5305, 5313 for more details. **(5311)** During the initial planning and execution of the CDPH Branch Laboratory project the laboratory team provided feedback to the state of California on the collection process and media. Specifically, the team outlined the process for administering the nasal swab sample, the contents of the collection kit, packaging, infectious agents' identification (UN3373) label, storage at room temperature, and shipping timeline. This information was then collated into the Testing Taskforce Playbook and the processes at the collection site and laboratory procedure CA-CLSRV-SOP-002. Color Genomics provides COVID-19 testing through its own laboratory. References to their corporate site collection materials is specific to their laboratory. Color Genomics is contracted by CDPH Branch Laboratory to provide kits that are comprised of a sample collection tube prefilled with MTM and barcoded with two identifiers, one collection card for the patient with a matching barcode, and an absorbent pad. All samples tested to date were collected in Color collection kits containing MTM. Procedure CA-CLSRV-SOP-002 specifies use of MTM. Procedure CA-ACC-ACC-001 incorrectly used VTM (viral transport media) as a generic term. This has been corrected to MTM; however, the rejection criteria in the procedure are sufficient since samples sent outside of the Color system are "Not Approved". See section 5311 for more details.	8Mar2021

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D5300	Continued From page 13 5. The laboratory failed to ensure it established written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic system (See D5391).	D5300	Continued from page 13 **(5391)** The lab acknowledges that its written policies and procedure to monitor, assess, and when indicated, to correct problems identified were not clearly defined in an overall plan and were scattered throughout multiple SOPs. In acknowledgement of this observation, the laboratory completed a major revision of its Quality Management Plan (CA-QM-SOP-001, v2), approved by the Lab Director and effective as of 01MAR2021. Refer to the Appendix A, Section 5.5.1 for specific preanalytical measure that are assessed at CDPH Branch Laboratory. Refer to Sections 6.1 for Leadership Oversight and Section 6.4 for Continuous Improvement and Occurrence Management and Section 6.5 for Process Management of all 3 of the phases of lab testing (preanalytical, analytical and post analytical). In addition, a new SOP, PreAnalytical QA Process (CA-ACC-SOP-003 v1, approved by Lab Director on 24FEB2021 was created to define the procedural guidelines for internal sample tracking for quality assurance purposes). See D5391 for specific details.	
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This Standard is not met as evidenced by: Based on interviews with testing personnel and the laboratory director on December 8, 2020, the absence of written policies and procedures (P/P) for retaining test requisitions, the absence of test requisitions for each patient tested, and random review of test records covering the period from 11/02/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to retain records of test requests for SARS-CoV-2 patient testing. Findings included: 1. The laboratory performed SARS-CoV-2 RT-PCR laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples under the order of the State Health Officer. 2. Although the laboratory presented a blanket prescribing order for all California patients within the state from the State Health Officer, an authorized person; the laboratory does not generate a test requisition for each patient. 3. During the initial stages of its application for a California clinical laboratory license, we asked the	D5301	**D5301** **Findings 1-3, 5-7** Per contractual agreement with CHHS and CDPH Branch Laboratory, all information is collected on the electronic requisition form at established collection sites operating under the standing order from Dr. Pan. Requisition form information is stored at Color Genomics (CLIA #05D2081492; see D5311). Data needed for testing is transferred to CDPH Branch Laboratory. Requisition data are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. The lab did create a paper requisition to be used in extreme emergency and/or downtime procedures; it was never intended for routine use as stipulated in the contractual arrangement between CDPH and CHHS. **(1) Immediate Corrective Action:** CA-CLSRV-SOP-002 was updated on 11Mar2021 to reflect the acceptance of Dr. Pan's standing order. Also updated QMP (CA-QMP-SOP-001 v2, approved by Lab Director on 01MAR2021) , Section 5.5.1.1 outlining the process of test order management and the use of a standing order from Dr. Pan, as stipulated by CHHS. Refer to Appendix A. **(2) Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measures**: Through the use of the CA-PER-FM-031, Pre/Post Analytical QA Training Checklist, the lab will continue to ensure that current and future quality assurance staff and laboratory director(s) at CDPH Branch Lab have the knowledge and training to monitor, and produce when requested, a patient requisition from the Color Genomics database.	29Mar2021

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D5301	Continued From page 14 laboratory to submit an example test requisition that will be used. A test requisition is only one of the several requirements to be met, prior to receiving a laboratory license. On 10/20/2020, the laboratory submitted a documented titled, "Test Order Requisition Covid 19 Sample Requisition- Example Only v.3." Even though the laboratory submitted an example requisition that will be used, the laboratory had not been generating a test requisition for each patient. 4. The laboratory failed to provide a written policy on the use of standing orders. There was no mechanism in place to ensure a test requisition was generated for each patient. 5. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to provide test requisitions for each patient tested. Accession Number [redacted] 6. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.	D5301	**(4) Monitoring Mechanism:** Monthly audits for FY 2021 to determine availability and compliance with all required elements are performed by the quality organization. The availability of the requisition was confirmed for 10 samples via a routine tracer audit performed 26Feb2021. An audit (2021Audit-008) of an additional 25 samples was initiated to verify that requisitions are available and include all necessary requisition elements. See attachment 4 and appendix A (Quality Mgmt Plan) **Findings 1, 4-7** The CDPH Branch Laboratory receives the confirmation of a test requisition from registered collection sites operating under Dr. Pan's standing order for each sample by electronically requesting the data components during the accessioning process. This is completed by a system-to-system communication channel between the Color Genomics IT software system and the CDPH Branch Laboratory's LIMS software system. In the event that a test requisition is not available the response from the Color Genomics system indicates that the sample is not approved for processing and no collection date and time are provided. The Color API for External Labs [External] document outlines the process for data transmission and the data fields exchanged. **(1) Immediate Corrective Action:** Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and member of the Quality Assurance team received training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics, on demand. **(2) Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measures**: Through the use of CA-PER-FM-031, Pre/Post Analytical QA Training Checklist, the lab will continue to ensure the quality assurance and laboratory director staff at the CDPH Branch Laboratory has access to the Color Genomics system and can effectively and efficiently access the data stored by Color Genomics, on demand.	

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D5301	Continued From page 15 7. The laboratory director and testing personnel affirmed (December 8, 2020 at approximately 11:00 a.m.) that the laboratory did not have test requisitions for each patient or policies to address standing orders.	D5301	Continued from page 15 (4) **Monitoring Mechanism:** Monthly audits for FY 2021 to determine availability and compliance with all required elements are performed by the quality organization. The availability of the requisition was confirmed for 10 samples via a routine tracer audit performed 26Feb2021. An audit of an additional 25 samples was initiated on 11Mar2021. (see 2021AuditPlan-008)	
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This Standard is not met as evidenced by: Based on interviews with laboratory staff and the laboratory director on December 8, 2020, the absence of written policies and procedures (P/P) for ensuring test requisitions solicited required information, the absence of test requisitions for	D5305	Reference attachment 4 **Findings 1-6** All information, including Dr. Pan's information as the ordering provider, is collected on the electronic requisition form that is stored at Color Genomics (CLIA #05D2081492) at established collection sites (see D5311). Manual paper requisition forms are available for use in extreme emergent priority as requested by CHHS and documented as deviation from standard procedure. Data needed for testing is transferred to CDPH Branch Laboratory. Requisition data are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. The inspectors observed paper manifests (finding 2) accompanying the specimens. These are the shipping manifests from the collection sites and are date/time stamped at receipt and are recorded into the electronic Specimen Delivery Logs (CA-ACC-SOP-004 Day Shift and CA-ACC-SOP-005 Night Shift) from the computers located near the receiving area. Specimen count, time received, sending facility, verification of manifest, courier company, name of the Driver and any discrepancies are noted (cancelled specimens, unacceptable specimens). The shipping manifests are scanned electronically, emailed to the Operations Manager who stores the reports. All manifests are available for audit. The SOPS mentioned above are listed in Attachment 4. The required requisition elements as stipulated in CFR: 493.1241c are collected during the collection site registration process. (Refer to the documents in Attachment 4 titled (1) COLOR Registration Experience, (2) the CDPH Playbook to Collection Sites and Quality Management Plan (Section. 5.5.1.1) in Appendix A.	29Mar2021

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D5305	Continued From page 16 each patient tested, and random review of test records covering the period from 11/22/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to ensure test requisitions included necessary information for accurate reporting of test results for COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR). Findings included: 1. The laboratory utilized SARS-CoV-2 RT-PCR diagnostic laboratory developed test (LDT) forthe direct detection of SARS-CoV-2 virus RNA from patient samples. It utilizes Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. 2. During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory staff stated that CDPH Branch Lab has been working with another CLIA certified laboratory to help healthcare providers in ordering the test for patients diagnosed with possible Covid-19 infections. It was observed that along with the patient sample was only a "paper manifest" indicating the total number of samples received, site point of contact, tracking company number, collective date for sample collected, site name and address. 3. The laboratory failed to provide test requisitions for each patient sample received which included information, such as the name and address of the authorized person requesting the test, patient's name or unique identifier, sex, age, date of birth, tests to be performed, source of specimen, date and time of collection, and any additional information relevant to COVID-19 test	D5305	Continued from page 16 **(1)Immediate Corrective Action:** Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and member of the Quality Assurance team received training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics, on demand. **(2)Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3)Preventative Measures**: Through the use of the CA-PER-FM-031, Pre/Post Analytical QA Training Checklist, the lab will continue to ensure that current and future quality assurance staff and laboratory director(s) at CDPH Branch Lab have the knowledge and training to monitor, and produce when requested, a patient requisition from the Color Genomics database. **(4)Monitoring Mechanism**: Monthly audits for FY 2021 are conducted by the quality assurance organization to determine availability and compliance of the electronic requisition and the required elements. See attachment 4	

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D5305	Continued From page 17 to ensure accurate and timely testing and reporting of results. 4. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, but failed to provide test requisitions which included information necessary for accurate test result reporting. Accession Number [redacted] 5. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 6. The laboratory director and testing personnel affirmed December 8, 2020 at approximately 11:00 am, that the laboratory did not have test requisitions which included necessary information for accurate test results reporting.	D5305		
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written	D5311		29Mar2021

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D5311	Continued From page 18 policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This Standard is not met as evidenced by: Based on interviews with laboratory staff on December 8, 2020, review of policies and procedures (P/P) for specimen collection, storage, and shipping, and random review of test records covering the period from 11/02/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to ensure that written policies and procedures for specimen submission and handling were followed. Findings included: 1. The laboratory utilized SARS-CoV-2 RT-PCR diagnostic laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples. It utilizes Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. 2. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002, Title: Specimen Collection, Storage, and Shipping, Effective Date 12/07/2020) stated that "Collection kits with instructions for collection, packaging and shipping are provided to the collection sites through a third-party vendor. A specimen that is	D5311	Findings 1-6 Instruction for collection: During the initial planning and execution of the CDPH Branch Laboratory project the laboratory team provided feedback to the state of California on the collection process and media. Specifically, the team outlined the process for administering the nasal swab sample, the contents of the collection kit, packaging, infectious agents identification (UN3373) label, storage at room temperature, and shipping timeline. This information was then collated into the Testing Taskforce Playbook and the processes at the collection site and laboratory procedure CA-CLSRV-SOP-002. Instructions for obtaining sample kits (via Color Genomic for CDPH Branch Laboratory), collection and shipping of samples is provided to collection sites set up by the Testing Task Force. See attachment 6. Please note, Color Genomics provides COVID-19 testing through its own laboratory. Color assembles and distributes collection kits on the processes and methods developed in their laboratory. These activities are completely separate from the CDPH Branch Laboratory activities and have no bearing on the CDPH laboratory. Therefore, it is inappropriate to compare information on the Color website with procedures at the CDPH Branch Laboratory. As it relates to testing that occurs at the CDPH Branch Laboratory the state of California has contracted for two purposes: sample kit distribution and testing site operations. Color Genomics is contracted by CDPH Branch Laboratory to provide kits that are comprised of a sample collection tube prefilled with MTM and barcoded with two identifiers, one collection card for the patient with a matching barcode, and an absorbent pad. Any other type of sample kit received is not intended for the CDPH Branch Laboratory and is not tested. All samples tested to date were collected in Color collection kits containing MTM (see MTM Attestation Letter from Color; Purchase order from PrimeStore MTM in attachment 6)	

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D5311	Continued From page 19 not collected correctly will lead to inaccurate results." The laboratory failed to provide the instructions provided to all staff in the collection sites for their procurement process. a. Correct specimen collection using the appropriate technique and containers b. Specimen labeling, including patient name or unique identifier, and specimen source c. Proper storage and preservation d. Proper transportation e. Specimen acceptability, rejection and disposition 3. During the laboratory tour on 12/08/2020 at approximately 11:00 a.m., the laboratory staff stated that they only process samples collected in Molecular Transport Media (MTM), transported at room temperature, and stable for seven days. The laboratory coordinates with COLOR Laboratory for specimen collection and submission to CDPH Branch Lab. a. Review of COLOR website for specimen requirements only indicated VTM or UTM media transported at 2-8 Degrees Celsius within 24 hours, or -20 Degrees Celsius on dry ice if the specimen is to be submitted >24 hours. b. The laboratory failed to provide the client service manual that contains the reference laboratory's requirements for swab specimens transported in MTM.	D5311	Procedure CA-CLSRV-SOP-002 specifies use of MTM. Procedure CA-ACC-SOP-001 incorrectly used VTM (viral transport media) as a generic term. However, the rejection criteria in the procedure are sufficient since samples sent outside of the Color system are "Not Approved" and section 8.3.3 would be followed. The lab acknowledges that its written preanalytical policies and procedures and Quality Management Plan lacked the detail necessary to follow a specimen through the preanalytical phase of testing. **(1) Immediate Corrective Action:** • The Laboratory completed a major revision of its Quality Management Plan (CA-QM-SOP-001 v2), approved by the Lab Director and effective on 01MAR20201. Section 5.5.1 provides detailed overview of the preanalytical processes relating to test order management and specimen collection and acceptability of samples for testing. (Refer to Appendix A). • Created a new SOP, PreAnalytical QA Process (CA-ACC-SOP-003 v1), approved by the Lab Director on24Feb2021 defining current practice for tracking internal samples and clearly specifies the process in place of accepting samples received only through Color Genomics. (See D5391 for specific details). There is only one type of collection device and media (MTM) that is used for clinical lab testing of SARS-CoV-2. • CA-ACC-SOP-001 Sample Collection, Storage and Shipping, which incorrectly stated VTM (viral transport media) as a generic term, has been corrected to the MTM (molecular transport media); See Section 5.1 of version 4.1 approved 09Feb2021 by Lab Director. See Section 5.1. **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, there is no patient harm as there is no change in diagnosis, treatment, or recommended patient action (retesting) as the correct specimen collection device/ MTM was used for all testing.	

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D5311	Continued From page 20 4. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, but failed to ensure written policies and procedures for specimen submission and handling using MTM were available and followed. Accession Number [redacted] 5. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 6. The laboratory director affirmed (February 12, 2021 at approximately 2:00 pm) that the laboratory failed to ensure written policies and procedures for specimen submission and handling were available and followed.	D5311	Continued from page 20 **(3) Preventative Measures:** Lab Director and Quality staff to continue with timely document review following Document Management procedures and making revisions and edits when errors or changes in processes are identified. **(4) Monitoring Mechanism:** Continue to document and monitor unsatisfactory specimens (Unsatisfactory_1 Improper specimen transport medium) received and Accessioning Supervisor/ Manager to discuss any increased trends with COLOR and CHHS teams to determine if changes were made to collection kits. See attachment 6	
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This Standard is not met as evidenced by:	D5313		29Mar2021

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D5313	Continued From page 21 Based on interviews with laboratory staff on December 8, 2020, review of available policies and procedures (P/P), and random review of patient test records covering the period from 11/02/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the laboratory failed to ensure the date and time of specimen receipt in the laboratory for each specimen for SARS-CoV-2 patient testing was documented. Findings included: 1. The laboratory utilized SARS-CoV-2RT-PCR based diagnostic laboratory developed test (LDT) for the direct detection of SARS-CoV-2 virus RNA from patient samples. It utilizes Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. 2. During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory staff stated that CDPH Branch Lab has been working with another CLIA certified laboratory to help healthcare providers in ordering the test for patients possible with Covid-19 infections. It was observed that along with the patient sample was only a "paper manifest" indicating only the date for all the samples collected at the collection site. It did not indicate the date and time of collection for individual patient samples. 3. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002 Title: Specimen Collection, Storage, and Shipping, Effective Date 12/07/2020) did not include the requirement to document the date and time of collection for SARS-CoV-2 RT-PCR specimens.	D5313	**Findings 1-6** All information is collected, including date and time of collection, and is on the electronic requisition form that is stored at Color Genomics (CLIA #05D2081492). Data needed for testing is transferred to CDPH Branch Laboratory. Requisition data are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. The submission of a printed manifest with every sample s hipment is a requirement to ensure that the lab only recei ved activated samples that can be processed. Instructions provided to the collection sites by the Testing Task Force mandate the submission of a printed manifest. At the time of initial inspection on 08Dec2020, deliveries were d ocumented on an incoming log with noted date/time of receipt and the location of collection site. The lab had just implemented (first of December) documentation of handwritten date/time receipt on the manifest that contained the sample ID's. Specimens are not held at receiving, but are immediately unboxed and accessioned. At the time of accessioning the received data and time are logged. In the requisitions and reports file located in attachment 4, the 'Accession at' field represent the received date and time. As noted at the inspection on 08Dec2020, the process of handwriting the date/time of receipt on the manifest was not consistent. For additional information see D3027. **(1) Immediate Corrective Action:** • Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and member of the Quality Assurance team received training that allows them to effectively and efficiently access from the Color Genomics database the electronic requisitions that contains the specimen collection date/time. • An electronic date/time stamp was purchased and installed in the receiving area on 17Dec2020; all manifests are date/time stamped.	

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D5313	Continued From page22 4. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, but failed to ensure the date and time of specimen receipt was documented. Accession Number [redacted] 5. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 6. The laboratory director affirmed (February 12, 2021 at approximately 2:00 pm) that the laboratory failed to ensure the laboratory documented the date and time of specimen receipt.	D5313	**(2) Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measures**: • Through the use of CA-PER-FM-031, Pre/Post Analytical QA Training Checklist, the lab will continue to ensure the quality assurance and laboratory director staff at the CDPH Branch Laboratory has access to the Color Genomics system and can effectively and efficiently access the data stored by Color Genomics, on demand. • The Operations Manager and/or Accessioning Supervisors reviews the manifests (paper or scanned) prior to electronic storage. Any date/ time stamp omission is documented as exception on the Accessioning Exception log, monitored for trends, and enters the QER process if issues are identified. **(4) Monitoring Mechanism**: Monthly end to end tracer audit (FY2021) includes a lookback of at least 10 random samples; availability of the receipt manifest, verifying that manifest is scanned and date/time stamped and that a requestion replete with all required data elements is available are included in this monitoring mechanism. The availability of a complete requisition and date/time stamp of manifests was confirmed by the scheduled 26FEB2021 21AUDIT004, 10 specimens audit and unscheduled 11MAR2021 21AUDIT009 25 specimen audit. See Attachment 4 for examples of Collection Date/Tim on receipts (and reports) AND for examples of Specimen Receipt Date/Time stamped on the manifests.	
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at §493.1241	D5391	**D5391 Findings 1-5** As stated in D5300, the lab acknowledges that its written policies and procedures to monitor, asses, and when indicated, correct identified problems were not clearly defined in the original Quality Management Plan (1.0 , approved by Lab Director 20Oct2020) and were scattered through multiple procedural SOPs. D5311 and D5313 responses provide documentation that an electronic requisition and specimen collection date/time were available and that the interim step of documenting time of receipt on the paper manifest was not being performed consistently.	29Mar2021

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D5391	Continued From page 23 through 493.1242. This Standard is not met as evidenced by: Based on interview with the laboratory staff on December 8, 2020, review and the lack of documentation of policies and procedures (P/P) for Test Requisition, it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at CFR 493.1241 through 493.1242. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title: Quality Management Plan, Effective Date 11/01/2020) did not include an ongoing mechanism to perform and document quality issues regarding the lack of test requisition with complete information necessary to ensure accurate test results reporting (See D5301 and D5305); as well as specimen submission and handling (See D5311 and D5313). 2. The laboratory uses off-site collection facilities. The laboratory failed to establish policies and procedures to ensure proper accountability or tracking of specimens from time of collection to receipt in the laboratory. a. At the time of the on-site survey on December 8, 2020, the laboratory was only using Molecular Transport Media (MTM) to transport swab specimens, with a stated stability of seven days at room temperature. b. In the absence of documented specimen collection date and time, and specimen receipt	D5391	Continued from page 23 The corrective, preventative and monitoring actions to address those observations are not addressed again in this particular response that focuses on finding 2(b) – how to determine specimen acceptability based on sample stability of 7 days at room temperature. There was no clearly defined process for evaluating whether samples were tested within 7 days of collection. **(1) Immediate Corrective Action:** To ensure that the lab has an ongoing mechanism to perform and document quality issues in the preanalytical system • The Quality Management Plan has been revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 ver2.0 approved by Lab Director and effective 01Mar2021.The MediaLab Admin assigned the performing employee to read and acknowledge the changes to this document by 31Mar2021. • Created a new SOP, PreAnalytical QA Process (CA-ACC-SOP-003 v1), approved by the Lab Director on 24Feb2021 to capture processes already in use defining current practice for tracking internal samples and document quality issues in the preanalytical systems. • CA-ACC-SOP-001 revised (v4) and approved by Lab Director on 09Feb2021. o Added specimen rejection criteria for a maximum 72 hour window from specimen collection to Color test order approval and receipt at CDPH Branch Laboratory. See Section 8.3.3. Importantly this is NOT due to solely specimen stability, but based on decision by CHHS to balance clinical utility with sample stability. Note that this particular criteria has changed again and has been extended to ≤ 96 hours from time of collection (v6.0, approved by Lab Director on 24Mar2021). o If sample scans as NOT APPROVED, laboratory staff follow the algorithm specified in the Section 8.3.3. If sample registration date is ≥ 12 hours from current time sample is coded as UNAC2 (Inappropriate timing of collection relative to specimen receipt). If difference between collection date/ time and sample registration date/time is ≥96 hours, it remains coded UNAC2, and the client is notified.	

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D5391	Continued From page 24 date and time into the laboratory, laboratory staff will not be able to determine specimen acceptability based on sample stability of seven days at room temperature. 3. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, wherein the laboratory failed to ensure there was an ongoing mechanism to perform and document quality issues in the preanalytic systems. Accession Number [redacted] 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The laboratory director affirmed (February 12, 2021 at approximately 2:00 pm) that the laboratory failed to ensure they have an ongoing mechanism to perform and document quality issues in the preanalytic systems.	D5391	**Continued from page 24** • To determine if any delayed samples (>7 days from collection time) had been received and tested, a retrospective search of all samples received by the laboratory (~1.6 million) was conducted (28Oct2020 to 11Feb2021). o 129 specimens received more than 168 hours (7 days) post collection date/ time were identified. o To determine potential impact on these samples, the manufacturer of the MTM sample collection tubes, Longhorn Vaccines and Diagnostics, LLC provided data from multiple studies that demonstrated extended stability of RNA in MTM up to 30 days, room temperature, after collection. Of note, 107 / 129 were received on the 8th days. (Refer to MTM Attestation Letter from Color in Attachment7) o Only 1 specimen received (08Dec2020) more than 820 hours (30 days) post collection date/time (05Nov2020) was identified and tested with a report date of 11Dec2020. However due to aging of the initial order, Optum Serve made the decision to 'incomplete' the order and notified the patient to retest with 2nd collection on 09Nov2020 (D-2627446715) and a reported result 11Nov2020. Both samples tested negative. **(2) Patient Impact:** Referencing the look back above, per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm since the manufacturer has demonstrated stability of samples in MTM 30 days after collection, and the one patient whose sample was tested outside of demonstrated stability, was retested only 4 days after the initial specimen was collected.	
D5400	ANALYTIC SYSTEMS	D5400		8Mar2021

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D5391	Continued From page 24 date and time into the laboratory, laboratory staff will not be able to determine specimen acceptability based on sample stability of seven days at room temperature. 3. The following are the accession numbers of the 10 randomly reviewed patient test records covering the period from 11/02/2020 to 12/08/2020, wherein the laboratory tested and reported SARS-CoV-2 RT-PCR patient test results, wherein the laboratory failed to ensure there was an ongoing mechanism to perform and document quality issues in the preanalytic systems. Accession Number [redacted] 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The laboratory director affirmed (February 12, 2021 at approximately 2:00 pm) that the laboratory failed to ensure they have an ongoing mechanism to perform and document quality issues in the preanalytic systems.	D5391	**Continued from page 24** (3) **Preventative Measures:** • Lab Director, Technical & General Supervisors, and Quality staff to continue with timely document review following Document Management procedures and making revisions and edits when errors or changes in process are identified. • Worked with our partner, Color Genomics to institute an automated specimen rejection process. The first of February both CDPH Branch Lab and Color Genomics previewed a > 96-hour cancellation policy for CDPH Branch Laboratory samples, therefore, any sample accessioned at the Laboratory after 96 hours will register as canceled, automatically; no manual entry required. COLOR would implement first, scheduled for 15Feb2021 , followed by LIMC update estimated to release on 15Mar2021. As of the date of this response, implementation has been delayed. • Due to the delay, an additional lookback was taken 11Feb2021 to 15Mar2021. An additional 20 samples received >96 hours post-collection were identified (19/20 within 7 days and 1 on the 8th day). After discussion with Color, this was unexpected and CDPH Branch Laboratory will implement the automated cut-off instead (anticipated 07Apr2021). (4) **Monitoring Mechanism:** • Supervisors to document performing employees compliance with correct assignment of unsatisfactory specimens during specified 6 months, 12 month and annual competency observation and record reviews. • Quality staff conduct monthly audits of Delayed Receipt Cancellations (FY2021 Audit Schedule) to confirm that samples with delayed receipt are documented as unsatisfactory and are canceled by the Accessioning staff. • ACC-SOP-001 Specimen Accessioning • MTM/Longhorn Stability Study • ACC-SOP-003 PreAnalytical QA • Read Acknowledgement – CA-ACC-SOP-001 Specimen Accessioning • 2021 Audit Schedule – Delayed Receipt Cancellation Report • Data for > 7 days - Pivot table	
D5400	ANALYTIC SYSTEMS	D5400		8Mar2021

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D5400	Continued From page 25 CFR(s): 493.1250 Each laboratory that performs nonwaived testing 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 established, available to, and followed by laboratory personnel (See D5401). 2. The laboratory failed to ensure the procedure manuals met the requirements specified in 42 CFR 493. 1251 (b)(1)-(b)(14) (See D5403). 3. The laboratory failed to ensure procedure manuals were updated, approved, signed and dated by the current Laboratory Director (See D5407). 4. The laboratory failed to ensure it followed the adopted FDA EUA IFU, the subsequent revisions to the EUA, and changes made in the laboratory's policies and procedures (See D5411). 5. The laboratory failed to ensure reagents were	D5400	**Continued from page 25** (5401/5403/5407) During the initial planning and execution of the CDPH Branch Laboratory project the laboratory team provided feedback to the state of California on the collection process and media. Specifically, the team outlined the process for administering the nasal swab sample, the contents of the collection kit, packaging, infectious agents' identification (UN3373) label, storage at room temperature, and shipping timeline. This information was then collated into the Testing Taskforce Playbook and the processes at the collection site and laboratory procedure CA-CLSRV-SOP-002. Color Genomics provides COVID-19 testing through its own laboratory. References to their corporate site collection materials is specific to their laboratory. Color Genomics is contracted by CDPH Branch Laboratory to provide kits that are comprised of a sample collection tube prefilled with MTM and barcoded with two identifiers, one collection card for the patient with a matching barcode, and an absorbent pad. All samples tested to date were collected in Color collection kits containing MTM. Procedure CA-CLSRV-SOP-002 specifies use of MTM. Procedure CA-ACC-ACC-001 incorrectly used VTM (viral transport media) as a generic term. This has been corrected to MTM; however, the rejection criteria in the procedure are sufficient since samples sent outside of the Color system are "Not Approved". To determine if any delayed samples (> 7 days) had been received, a retrospective search of all samples received by the Laboratory (~1.6 million) was conducted. 129 samples received more than 168 hours (7 days) were identified. To determine potential impact on these samples, the manufacturer of the MTM sample collection tubes, Longhorn Vaccines and Diagnostics, LLC provided data from multiple studies that demonstrated extended stability of RNA in MTM up to 30 days after collection. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer issued set of credentials on a PerkinElmer issued laptop. During any remote session the data and system being accessed are located on the prior mentioned internal IT systems hardware. See sections 5401, 5403, 5407 for more details.	

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D5400	Continued From page 26 labeled as required (SeeD5415). 6. The laboratory failed to ensure the decontamination solution used forSARS-CoV-2 RT-PCR were not used past the labeled expiration dates (See D5417). 7. The laboratory failed to ensure it established and verified performance specifications prior to reporting patient test results using its modified FDA EUA IFU SARS-CoV-2 RT-PCR (See D5423). 8. The laboratory failed to the ensure the established maintenance protocol for centrifuges were performed and documented (SeeD5433). 9. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (D5791).	D5400	**Continued from page 26** **(5401/5407)** There is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. Contrary to Laboratory Director affirmation, LIMC User Specification and Acceptance Testing forms were signed. Both the User Specification and the User Acceptance forms signed by both Laboratory Directors is provided. The effective date 29Oct2020 is the date the blank form (template) was effective Delayed procedure approval: This timeline reflects the difficulty in coming to a scientific and clinical consensus on how low viral load (high Ct value – specifically > 37 - < 42) results should be interpreted. The VBL Playbook has been in use by the Task Force since the beginning of testing and was approved by the Lab Director. Test results are transmitted to from the LIMS API thorough the Color Platform to both CalREDIE and CalOES. CalREDIE transmits results to California county public health authorities and federal public health authorities as required by law. See section 5401 and 5407 for more details.	
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was	D5401	**(5401/5411/5417/5423/5791)** The laboratory has an Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/ degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and aseptic cleaning techniques all of work areas and equipment. The observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our procedure (see section 5.7.2). Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for decontamination is 60. Heat inactivation is a desirable method for ensuring that the infection risk associated with of SARS-CoV-2 clinical samples is as low as possible. Validation studies carried out prior the beginning of testing included LoD studies with both heat inactivated and non-heat inactivated samples (see validation report sent to LFS at 1:55pm PST on October the 24th). There was no performance impact on heat inactivation.	8Mar2021

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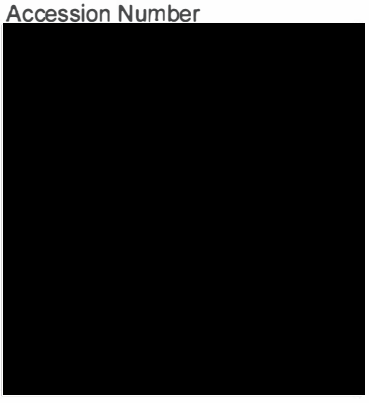
D5401	Continued From page 27 determined that the laboratory failed to ensure the procedure manuals for the Perkin Elmer New Coronavirus NucleicAcid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test were established and followed by the laboratory staff. Findings included: 1. The laboratory failed to establish and follow written P/P in all phases of clinical testing for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit RT-PCR in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler, when it started testing patient samples on 11/02/2020. 2. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory started performing SARS-CoV-2 tests and reported results, but failed to ensure policies and procedures were established and followed by laboratory staff. Accession Number 	D5401	Continued from page 26 Clinical performance in asymptomatic people: Per version 7 (06Jan2021) of The PerkinElmer® New Coronavirus Nucleic Acid Detection Kit IFU, the intended use for the kit is intended for: ...the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare provider (HCP), and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection. The CDPH Branch Laboratory is using this kit within the parameters of intended use. Thermocycler Parameters: The correct collection temperature is 65oC. A universal .trf file containing the PCR thermocycling conditions is generated by the PCR Janus program at the time a 384-well plate is set-up. The .trf file is imported to the AJ thermocycler. This file is correct. Records from the PCR output files for the 60 randomly chosen samples demonstrate that the correct temperature is being used (LFS Response Cycling Parameters). Appendix A of CA-PCR-SOP-002v1 contained a typographical error. This error was corrected in v2 (approved 26Jan2021). See sections 5401, 5411, 5417, 5423, 5791 for more details. **(5401/5415/5433/5791)** We acknowledge that labeling of some reagents was incomplete and are working to improve compliance. Non-compliance in reagent labeling and completion of instrument logs has been noted (QER-20-014, QER-20-015, QER-20-017, QER-20-036 and CAPA-20-007) and corrective action has been initiated. Supervisors and managers were instructed to review good documentation practices Instrument forms have been updated to make clear appropriate documentation for a shift when instrument is not in use. See sections 5401, 5415, 5433, 5479 for more details. **D5401** Please see responses to findings for D5403, D5407, D5411, D5415, D5417, D5423, and D5433 below.	

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D5401	Continued From page 28 [redacted] 3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to ensure policies and procedures were established and followed by laboratory staff. 5. Details of the required elements for policies and procedures are enumerated in D5403, (See D5403).	D5401		
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation;	D5403		29Mar2021

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D5403	Continued From page 29 specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verifiedin §493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This Standard is not met as evidenced by: 1. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records,	D5403	**Finding 1** Instruction for collection: During the initial planning and execution of the CDPH Branch Laboratory project the laboratory team provided feedback to the state of California on the collection process and media. Specifically, the team outlined the process for administering the nasal swab sample, the contents of the collection kit, packaging, infectious agents identification (UN3373) label, storage at room temperature, and shipping timeline. This information was then collated into the laboratory's Specimen Collection, Storage and Shipping (CA-CLSRV-SOP-002) SOP and the Testing Taskforce Playbook and website for the processes at the collection sites. (https://testing.covid19.ca.gov/valencia-branch-laboratory/#howtopartner) Instructions for obtaining sample kits (via Color Genomic for CDPH Branch Laboratory), collection and shipping of samples is provided to collection sites set up by the Testing Task Force. **Specimen collection (D5311 and D5403 parts a- f** Please note, Color Genomics provides COVID-19 testing through its own laboratory. Color assembles and distributes collection kits on the processes and methods developed in their laboratory. These activities are completely separate from the CDPH Branch Laboratory activities and have no bearing on the CDPH laboratory. Therefore, it is inappropriate to compare information on the Color website with procedures at the CDPH Branch Laboratory and described in laboratory procedure CA-CLSRV-SOP-002.	

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D5403	Continued From page 30 random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory's procedure failed to include the following requirements to ensure accurate and reliable test results: Specimen collection using the appropriate technique and containers Specimen labeling, including patient name or unique identifier, and specimen source Proper storage, preservation, and transportation Specimen acceptability, rejection and disposition Findings included: a. The laboratory failed to provide the procedure manual that met all the applicable requirements for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. b. During the on-site inspection on December 8 and 9, 2020, we noted discrepancies from these three sources, and are specified in "c" though "f" below: (1) Staff interviews (2) Perkin Elmer Emergency Use Authorization (EUA) Instructions for Use (IFU) (3) CDPH Branch Laboratory Policies and Procedures (P/P)	D5403	As it relates to testing that occurs at the CDPH Branch Laboratory the state of California has contracted for two purposes: sample kit distribution and testing site operations. Color Genomics is contracted by CDPH Branch Laboratory to provide kits that are comprised of a sample collection tube prefilled with MTM and barcoded with two identifiers, one collection card for the patient with a matching barcode, and an absorbent pad. Sample kits not intended for the CDPH Branch Laboratory are not tested. All samples tested to date were collected in Color collection kits containing MTM (see MTM Attestation Letter from Color; Purchase order from PrimeStore MTM) Procedure CA-CLSRV-SOP-002 specifies use of MTM. Procedure CA-SOP-ACC-001 incorrectly used VTM (viral transport media) as a generic term. This has been corrected to MTM (molecular transport media); however, the rejection criteria in the procedure are sufficient since samples sent outside of the Color system are "Not Approved" and section 8.3.3 would be followed. Procedure and process are designed to match the electronic order to the sample tube received. Use of MTM (5403 – a, c, e) The validation of this assay (approved by the Laboratory Director and submitted to LFS on 24Oct2020) was performed using MTM. Rejection Criteria (5403 -f) The CA-ACC-SOP-002 in effect at time of survey did not delineate all of the rejection criteria. See Attachment 4, 6, and 8 for additional information.	

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D5403	Continued From page 31 c. **Correct specimen collection using the appropriate technique and containers** (1) Based on interview with the laboratory staff on 12/08/2020, the laboratory only process samples collected in Molecular Transport Media (MTM). (2) Review of FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit stated the use of Viral Transport Media (VTM) (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021). There was no information provided regarding the use of MTM in the IFU. (3) Review of the laboratory's P/P (Policy# CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) indicated that CDPH Branch Lab Coordinates with COLOR laboratory for specimen collection and submission. (4) Review of COLOR website for specimen requirements indicated VTM or UTM media transport. (5) The laboratory failed to specify and include in its policies and procedures, the use of MTM. d. **Specimen labeling, including patient name or unique identifier, and specimen source** (1) During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory staff stated that CDPH Branch Lab has been working with another CLIA certified laboratory to help healthcare providers in ordering the test for patients possible with Covid-19 infections. It was observed that along with the patient sample was	D5403	Continued from page 31 **(1) Immediate Corrective Action:** • Through cooperation with Color Genomics and the CDPH Branch Lab, a method to present the data from electronic order in the form of a requisition was established. The Lab Director and the Quality Assurance Team received training that allows them to effectively and efficiently access the electronic requisition that includes the complete information for individual patients. • CA-ACC-SOP-001 revised (v4) and approved by Lab Director on 09Feb2021. o Accessioning Samples, which incorrectly stated VTM (viral transport media) as a generic term, has been corrected to the MTM (molecular transport media); See Section 5.1 of version 4.1 approved 09Feb2021 by Lab Director. o Clarified cancellation procedures and handling of misrouted samples. o Added specimen rejection criteria for a maximum 72 hour window from specimen collection to Color test order approval and receipt at CDPH Branch Laboratory. See Section 8.3.3.. Note this is NOT due to specimen stability, but based on decision by CHHS to balance clinical utility with sample stability. Note that this particular criteria has changed again and has been extended to < 96 hours from time of collection (v6.0, approved by Lab Director on 24Mar2021 o One more revision (5.0, approved by Lab Director on 26Feb2021) to align the rejection "no bar code on sample or bag" (Section 8.3.2.2.) with LIMC code UNSAT3 – "sample tube unlabeled". The Unsatisfactory (rejected) Sample table from the LIMC User Manual (CA-COMP-MAN-001) was added to the SOP (Section 8.3.3.)	

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D5403	Continued From page 32 only a "paper manifest" indicating the following: i. Total number of samples received ii. Site point of contact iii. Tracking company number iv. collective date for sample collected v. Site name vi. Site address (2) Review of the laboratory's P/P (Policy# CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) indicated the elements for the paper and electronic manifest, such as: i. Tracking company and number ii. Manifest number iii. Date of sample collection iv. Site name v. Site address vi. Site point of contact (name, phone number, email address) vii. Total number of samples (3) The laboratory failed to ensure the policy included complete information for individual patients, such as patient name or unique identifier, and specimen source. e. **Proper storage, preservation, and transportation** (1) Based on interview with the laboratory staff on 12/08/2020, the laboratory would receive MTM samples at room temperature, and good for seven days. (2) Review of FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit stated the	D5403	Continued from page 32 • Created a new SOP, PreAnalytical QA Process (CA-ACC-SOP-003 v1), approved by the Lab Director on 24Feb2021 to capture processes already in use defining current practice for tracking internal samples and clearly specifying the process in place of accepting samples received only through Color Genomics. (See D5391 for specific details). There is only one type of collection device and media (MTM) that is used for clinical lab testing of SARS-CoV-2. • To determine if any delayed samples (>7 days from collection time~) had been received and tested, a retrospective search of all samples received by the laboratory (~1.6 million) was conducted (28Oct2020 to 11Feb2021). o 129 specimens received more than 168 hours (7 days) post collection date/ time were identified. o To determine potential impact on these samples, the manufacturer of the MTM sample collection tubes, Longhorn Vaccines and Diagnostics, LLC provided data from multiple studies that demonstrated extended stability of RNA in MTM up to 30 days, room temperature, after collection. (Refer to MTM Attestation Letter from Color in Attachment7) o Only 1 specimen received (08Dec2020) more than 820 hours (30 days) post collection date/time (05Nov2020) was identified and tested with a report date of 11Dec2020. However due to aging of the initial order, Optum Serve made the decision to 'incomplete' the order and notified the patient to retest with 2nd collection on 09Nov2020 (D-2627446715) and a reported result 11Nov2020. Both samples tested negative. o Due to the delay, an additional lookback was taken 11Feb2021 to 15Mar2021. An additional 20 samples received >96 hours post-collection were identified (19/20 within 7 days and 1 on the 8th day). After discussion with Color, this was unexpected and CDPH Branch Laboratory will implement the automated cut-off instead (anticipated 07Apr2021).	

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

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5403	Continued From page 33 use of VTM, stored at 2-8 degrees Celsius for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens should be stored at -70 degrees Celsius (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021). (3) Review of the laboratory's P/P (Policy# CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date12/07/2020) indicated that CDPH Branch Lab Coordinates with COLOR laboratory for specimen collection and submission. (4) Review of COLOR website for specimen requirements indicated VTM or UTM media transport should be refrigerated at 2-8 degrees Celsius prior to and during transport within 24 hours. If the specimen is to be submitted >24 hours post collection, specimens should be freeze at -20 degrees Celsius or below, and then ship on dry ice. (5) Review of the laboratory's P/P (Policy# CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) stated under storage shipping and transport that specimens collected in MTM are stable at 2-25 degrees Celsius (room temperature) for 7 days. "Manufacturer's instruction for storage temperature storage and stability should be followed." (6) Review of the manufacturer's FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit stated the use of VTM, stored at 2-8 degrees Celsius for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens should be stored at -70 degrees Celsius (Effective Date 03/20/2020, Revised	D5403	**(2) Patient Impact:** Per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment or recommended patient action (retesting), and there would not be patient harm as all pertinent patient information is obtained in electronic format, the correct specimen collection device/MTM was used for all testing, manufacturer of MTM had demonstrated stability of samples in MTM 30 days after collection, and the one patient whose sample was tested outside of demonstrated stability, was retested only 4 days after the initial specimen was collected. **(3) Preventative Measures:** • Lab Director, Technical & General Supervisors, and Quality staff to continue with timely document review following Document Management procedures and making revisions and edits when errors or changes in process are identified. • An automated process to reject samples >96 hours old is being implemented in LIMC (anticipated 07Apr2021). For further details see D5391. **(4) Monitoring Mechanism:** • Supervisors to document performing employees compliance with correct assignment of unsatisfactory specimens during specified 6 months, 12 month and annual competency observation and record reviews. • Operations Manager and Leadership team to continue to summarize and monitor unsatisfactory specimen rates to evaluate for trends; daily volume and quality metric report delivered to COLOR, and CDPH teams to determine any changes in supply management of kits and/or potential issues at the collection sites. • Quality staff conduct monthly audits of Delayed Receipt Cancellations (FY2021 Audit Schedule) to confirm that samples with delayed receipt are documented as unsatisfactory and are canceled by the Accessioning staff.	

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D5403	Continued From page 34 09/16/2020 and 01/12/2021). (7) The laboratory failed to specify and include in its policies and procedures, the use of MTM. f. **Specimen acceptability, rejection and disposition** (1) Review of the laboratory's P/P (Policy # CA-CLSRV-SOP-002, Title Specimen Collection, Storage and Shipping, Effective Date 12/07/2020) indicated that CDPH Branch Lab Coordinates with COLOR laboratory for specimen collection and submission. (2) Review of COLOR website for specimen rejection indicated the following: i. insufficient, incompatible transport media. ii. Dry swabs that arrive >56 hours after collection iii. Improperly capped or labeled tubes iv. Swabs inverted in collection tubes (i.e. swab bud facing up) v.Missing physician order vi. Incomplete or missing patient information (3) Review of the laboratory's P/P (Policy # CA-ACC-SOP-00, Title Accessioning, Effective Date 12/05/2020) stated only the following rejection criteria: i. Broken/Damaged/QNS ii. No barcode (4) The laboratory failed to include in its policies and procedures, rejection criteria using use of MTM.	D5403	Continued from page 34 See Attachments 4, 6, and 7 • ACC-SOP-001 Specimen Accessioning • MTM/Longhorn Stability Study • ACC-SOP-003 PreAnalytical QA • Read Acknowledgement – CA-ACC-SOP-001 Specimen Accessioning • 2021 Audit Schedule – Delayed Receipt Cancellation Report • Data for > 7 days	

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D5403	Continued From page 35 2. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory's procedure failed to include the step-by-step performance of the procedure, including test calculations, and interpretation of results. Findings included: a. At the time of inspection on 12/08/2020, the laboratory failed to provide an approved policy and procedure for test calculations, and interpretation of test results utilized by the laboratory staff interviewed performing onsite data analysis and interpretation. b. The laboratory also requested approval that the quality metrics (including raw data) and curves generated from the PCR test be analyzed at remote locations by CLIA qualified testing personnel for test results of positive, negative, invalid, or inconclusive in order to shorten the turn- around-time from specimen collection to reporting of the test on 12/21/2020 without an approved policy and procedure on how to proceed with accurate remote reporting of patient test results. c. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results, but failed to include the step-by-step performance of the	D5403	**Finding 2** 1. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. 2. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. 3. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer issued set of credentials on a PerkinElmer issued laptop. During any remote session the data and system being accessed are located on the prior mentioned internal IT systems hardware. 4. The two data analysts who performed remote analysis were trained and qualified to do so: a. EV – Trained in data analysis and delegated the responsibilities of a General Supervisor b. MN – CLS trained in data analysis 5. CMS has made an exception to allow pathologist and other healthcare professionals to work remotely during the pandemic. CAP concurred with this exception. There is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. See Attachment 10 and Attachment 6 **(1) Immediate Corrective Action:** • SignOut Manager was instructed by Lab Director, Helen Farzanmehr, on 10Dec2020 that analysts may not analyze data remotely. • Human Resources informed potential qualified candidates and those awaiting onboarding/orientation that remote analysis was no longer a possibility; employment contingent upon on site analysis.	

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D5403	Continued From page 36 procedure, including test calculations, and interpretation of results. Accession Number [redacted] d. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.	D5403	Continued from page 36 **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Action:** A request to remove VPN access software from analyst computers was placed with the IT group by the project manager on 11Mar2020 and completed on 13Mar2020 by the IT group. **(4) Monitoring Mechanism:** A request to query for remote release of records made on 26Feb2021 could not be completed due to complexity. Removal of VPN access removes the need to monitor. As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es).	

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D5403	Continued From page 37 e. The Laboratory Director affirmed (February 12, 2021 at approximately 2:00 pm) the laboratory failed to ensure include the step-by-step performance of the procedure, including test calculations, and interpretation of results. 3. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory's procedure failed to include complete and consistent information on reference intervals (normal values). Findings included: a. Review of the FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) indicated the expected results for the kit with valid quality control as: i. SARS-CoV-2 Not Detected ii SARS-CoV-2 Detected iii Invalid	D5403	**Finding 3** There is scientific and clinical debate regarding the best interpretation of high Ct values. Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a timely manner. Although not approved, a consistent method of interpretation was used (see Analysis Timeline below). All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 - < 42) were interpreted as inconclusive • 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 37 - < 42) **(1) Immediate Corrective Action:** The specimens in question were resulted as per SOP (see D5800). **(2) Patient Impact**: See D5800 **(3) Preventive Action**: No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily shift to shift communication checklist (CA-RPT-FM-001, approved by Lab Director on 09Mar2021) for the data analysis team includes a written confirmation of the most recent updated version of the analysis and reporting SO (CA-RPT-SOP-002). **(4) Monitoring Mechanism**: Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. The February audit (see attachment 4) confirmed that the results matched the current SOP and process 100% of the time. See Attachment 9, Attachment 10, Analyst shift to shift communication checklist (CA-RPT-FM-001)	

IC (VIC/HEX)	N(FAM), ORF1ab ROX)	Result Interpretation
≤ 40	Both targets Undetermined or > 42	SARS-CoV-2 Not Detected
/	Both targets ≤ 42	SARS-CoV-2 Detected
/	One of the targets ≤ 42	SARS-CoV-2 Detected
>40 or Undetermined	Both targets Undetermined or > 42	Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.

/: No requirement on the Ct value.

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D5403	Continued From page 38	D5403		

- If the result for a specimen is SARS-CoV-2 RNA not detected, the Ct value of the internal control must be ≤ 40, otherwise the result of that specimen is invalid;

- If the result for a specimen is SARS-CoV-2 RNA not detected, the Ct value of the internal control must be ≤ 40, otherwise the result of that specimen is invalid;

b. At the time of inspection on 12/08/2020, the laboratory failed to provide an approved policy and procedure for test calculations, and interpretation of test results utilized by the laboratory staff interviewed performing onsite data analysis and interpretation, and reference intervals (normal values).

c. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to include complete and consistent information on reference intervals (normal values).

Accession Number

[redacted]

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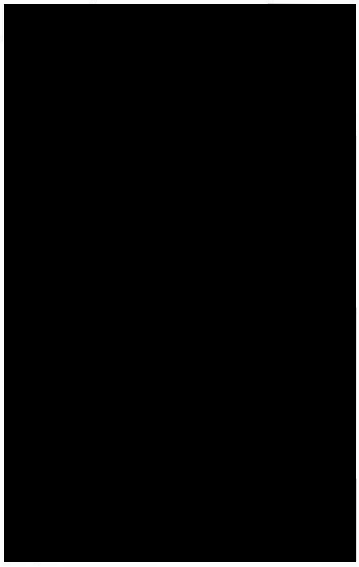
D5403	Continued From page 39	D5403		



d. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.

e. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to ensure include complete and consistent information on reference intervals (normal values).

4. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to have

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D5403	Continued From page 40 policies and procedures for Infectious Diseases Reporting. Findings included: a. At the time of inspection on December 8 and 9, 2020, and until February 12, 2021, the laboratory failed to provide an approved policy and procedure for Infectious Diseases Reporting. b. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results, but failed to provide policies to ensure it complied with Infectious Disease Reporting required by local, state, and federal authorities. Accession Number [redacted]	D5403	**Finding 4** Test results from CDPH Branch laboratory have been transmitted to CalREDIE since 28Oct202; Color Genomics transmits all CoVID test results to California's standalone Covid reporting (CCRS) database which is then transmitted to CalREDIE. The quality management plan (QMP-CA-SOP-001, Section 6.1.1.1 approved 01Nov2020) stated that results of positive infectious disease are reported to CDPH, but it did not specify the detail requested in this finding. **(1) Immediate Corrective Action:** Laboratory procedure CA-RPT-SOP-004 was created to capture policies and procedures for Infectious Disease Reporting specified in the contract between Color and PerkinElmer. **(2) Patient Impact:** Patient results have consistently been transferred to CalREDIE and CalOES by Color per their contract with PerkinElmer; therefore, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measure:** All future versions of CA-RPT-SOP-004 will specify how requirements for Infectious Disease Reporting are met. **(4) Monitoring Mechanism:** Transmission to CalREDIE and CalOES is monitored by Color via an API response codes. See attachment 16	

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D5403	Continued From page 41  c. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. d. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to provide policies to ensure it complied with Infectious Disease Reporting required by local, state, and federal authorities.	D5403		
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) 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: 1. Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P),quality	D5407		29Mar2021

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D5407	Continued From page 42	D5407	**Finding 1**	

control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure the procedure for reporting inconclusive result using the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic was approved, signed, and dated by the laboratory director.

Findings included:

a. During the first day of the on-site inspection on 12/08/2020, we interviewed laboratory directors and senior operations personnel, and requested for the laboratory's documented investigation and corrective action regarding the increased number of inconclusive patient results.

b. We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the laboratory's adopted test method, Perkin Elmer New Coronavirus Nucleic Acid Detection Kit. The "Examination and Interpretation of Patient Specimen Results" section showed a table listing the expected results for the kit with valid positive and negative control.

Cycle threshold		Result Interpretation
IC (VIC/HEX)	N(FAM), ORF1ab ROX)	
≤ 40	Both targets Undetermined or > 42	SARS-CoV-2 Not Detected
/	Both targets ≤ 42	SARS-CoV-2 Detected
/	One of the targets ≤ 42	SARS-CoV-2 Detected
>40 or Undetermined	Both targets Undetermined or > 42	Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.

Findings a-f
There is scientific and clinical debate regarding the best interpretation of high Ct values. Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a timely manner. Although not approved, a consistent method of interpretation was used (see Analysis Timeline below). All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate.
Please refer to the Analysis Timeline.

- 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive)
- 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU
- 11Dec2020 – 25Jan2021 – high Ct values (> 37 -< 42) were interpreted as inconclusive
- 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 37 -< 42)

(1) Immediate Corrective Action: The specimens in question were resulted as per SOP (see D5800).

(2) Patient Impact: See D5800.

(3) Preventive Action: No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily shift to shift communication checklist (CA-RPT-FM-001, approved by Lab Director on 09Mar2021) for the data analysis team includes a written confirmation of the most recent updated version of the analysis and reporting SOP (CA-RPT-SOP-002).

(4) Monitoring Mechanism: Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. Tracer audits initiated on 26Feb2021 (10 samples) and 11Mar2021(25 samples) confirmed that reported results matched the current SOP 100% of the time.

See Attachment 9 and Attachment 10

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	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5407	Continued From page 43	D5407		

c. In order to compare how the laboratory was calculating and interpreting patient results, we also asked the laboratory on December 8, 2020, to provide the LIMC Laboratory Information System (LIS) and its policy and procedure for interpretation of patient specimen results.

(i) A policy and procedure signed by the laboratory was not available on December 8, 2020.

(ii) Neither an unsigned policy and procedure was available on December 8, 2020.

d. Further interviews with the laboratory director on 12/08/2020, indicated there was a possibility that patient test results were reported in error as a result of incorrect data analysis and interpretation.

e. The following day on 12/09/2020, we conducted random sampling of an additional 32 patient test records with specimens collected during the first week December until 12/08/2020.

f. On December 16, 2020, we went back on-site at the laboratory to retrieve the additional patient test records. We also asked the laboratory to send via e-mail, the requested records and its policy and procedure for interpretation of patient specimen results.

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D5407	Continued From page 44	D5407	**Finding 1**	

g. The policy and procedure sent via e-mail on Dec. 16, 2020 showed the following:

(i) An annotation on the top portion of document indicated, "Effective Starting 10/29/2020" the document version history:

(ii) It was an Initial document, Version 1.0, with an effective date of December 13, 2020.

(iii) The Software Name was identified as LIMC, version 1.2

h. The Detailed User Requirements Specifications section of the document, showed the following policy for interpretation of patient specimen results.

User Requirement Number	Description
UR001	Update analysis rule for the new SOP: • "Not Detected" Ct cutoff changed from 37 to 42 • FAM and ROX >37 and <=42 will be called as "Inconclusive" instead of "Not Detected". • IC Failure samples (HEX=0 or >40) will be released as "Invalid". • No changes on controls and "Detected" rules

i. Comparative review of the IFU for the laboratory's adopted EUA method, and the laboratory's policy for interpreting patient specimen results, showed the laboratory added a result category of Inconclusive.

j. There was no indication that this document identified as User Requirement Specifications

Findings g-k

Contrary to Laboratory Director affirmation, User Specification and Acceptance Testing forms were signed.

LIMC documentation: Provided. Please note the following:

-Both the User Specification and the User Acceptance forms signed by both Laboratory Directors is provided.
-The effective date 29Oct2020 is the date the blank form (template) was effective

Delayed procedure approval: This timeline reflects the difficulty in coming to a scientific and clinical consensus on how low viral load (high Ct value – specifically > 37 - < 42) results should be interpreted.

Please refer to the Analysis Timeline.
• 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive)
• 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU
• 11Dec2020 – 25Jan2021 – high Ct values (> 37 -< 42) were interpreted as inconclusive
• 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 37 - < 42)

See Attachment 9, Attachment 10, and Attachment 11

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D5407	Continued From page 45 CA-COMP-FM-001 Version 1.0, was approved, signed, and dated by the Laboratory Director. k. This policy and procedure did not include the laboratory's signature. There was also no indication or verification that the laboratory director affixed a digital signature approving, signing and dating the document 2. Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures, quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to provide the updated and approved procedure manuals signed by the current laboratory director for the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. Findings included: a. At the time of inspection on 12/08/2020 and 12/09/2020, there was no updated P/P, approved, signed and dated by the laboratory director for the following: i. Client procedure manual provided to all staff in the collection sites for patient preparation, specimen collection, labeling, storage, preservation, transportation, processing, referral, and criteria for specimen acceptability.	D5407	**(1) Immediate Corrective Action:** The specimens in question were resulted as per SOP (see D5800). **(2) Patient Impact**: See D5800. **(3) Preventative Action**: No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily shift to shift communication checklist (CA-RPT-FM-001, approved by Lab Director on 09Mar2021), completed by the data analysis team, includes a written confirmation of the most recent updated version of the analysis and reporting SO (CA-RPT-SOP-002). **(4) Monitoring Mechanism**: Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. Tracer audits initiated on 26Feb2021 (10 samples) and 11Mar2021(25 samples) confirmed that reported results matched the current SOP 100% of the time. **Finding 2** The VBL Playbook has been in use by the Task Force since the laboratory opened and was moved to document control and approved for use by the Laboratory Director on 07Dec2021. In addition, CA-CLSRV-SOP-002 was used in draft version prior to Laboratory Director approval on 07Dec2020. Please see D5407 finding 1 regarding delays in approval of procedures. Test results are transmitted to from the LIMS API thorough the Color Platform to both CalREDIE and CalOES. CalREDIE transmits results to California county public health authorities and federal public health authorities as required by law.	

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D5407	Continued From page 46 ii. Step-by-step performance of the procedure, including test calculations, and interpretation of results. (1). Onsite Data Analysis (2). Remote Data Analysis iii. Reference Intervals (normal values) iv. Infectious Diseases Reporting b. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results, but failed to provide updated P/P, approved, signed and dated by the laboratory director. Accession Number [redacted]	D5407	**Continued from page 46:** Remote analysis: For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. This infrastructure configuration eliminates the ability for individuals to access the site and file repository from an external location on a general internet connection. Data is never transferred to the location of the remote (offsite) person. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer issued set of credentials on a PerkinElmer issued laptop. During any remote session the data and system being accessed are located on the prior mentioned internal IT systems hardware. Therefore, the experience of the analyst is the same and no separate training or procedure is used. Remote analysis is no longer allowed. See also D6082. **(1) Immediate Corrective Action:** • Sign Out Manager was instructed by the Lab Director, Haleh Farzanmehr, on 10Dec2020 that analysts may not analyze data remotely. • Human Resources informed potential qualified candidates and those awaiting onboarding/ orientation that remote analysis was no longer a possibility; employment contingent upon on site analysis • In addition to be being stipulated in the contract between Color Genomics and PKI, the process for infectious disease reporting has been detailed in Post-analytical QA Process (CA-RPT-SOP-004). **(2) Preventative Action:** No policy or procedure is placed into use until Dr. Rosendorff has signed off. Per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm.	

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D5407	Continued From page 47 [redacted] c. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. d. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to provide policies to ensure proper instructions to clients, accurate step-by-step test calculations, reference intervals, interpretation of results, and it complied with Infectious Disease Reporting required by local, state, and federal authorities.	D5407	Continued from page 47 **(3) Preventative Action:** A request to remove VPN access software from analyst computers was placed with the IT group by the project manager on 11Mar2020 and completed on 13Mar2020 by the IT group. **(4) Monitoring Mechanism:** Monthly internal audits are performed by the LIMC admin and Color Genomics. Additionally, at the beginning of each shift, data analysts confirm the version of the reporting SOP that is in use. See Attachment 16.	
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality	D5411	**D5411** Finding 1a: The laboratory has an Amplicon Contamination Prevention Plan, CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and aseptic cleaning techniques all of work areas and equipment. The observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our procedure (see section 5.7.2). Additionally, a default Safety statement was included in the technical SOPS (listed in the findings) that contradicted the current approved practice and the Laboratory Quality Management Plan (approved by the director and in effect at time of inspection (CA-QM-SOP-001 va effective 12OCT 2020) did not provide the robust environmental prevention and decontamination initiatives outlined in the Amplicon Contamination Prevention Plan. The FDA EUA instructions for use of the PKI nucelic Acid detection kit provided possible actions for preventing contamination; the decontamination prevention instructions do not impact performance	29Mar2021

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D5411	Continued From page 48 control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure it followed the adopted FDA EUA IFU, the subsequent revisions to the EUA IFU, and changes made in the laboratory's policies and procedures. Findings included: 1. Review of the laboratory's performance specification studies, EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, and current policies and procedures available during the on-site inspection, the laboratory failed to provide the following: a. Decontamination Protocol i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated under warnings and precautions #7 that, "Sterile centrifuge tubes and filter-tips should be disposed into a waste bin containing a 10% Sodium Hypochlorite solution. After the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared 10% Sodium Hypochlorite solution, and then cleaned with 75% Ethanol or pure water. Finally, turn on UV light to disinfect working surfaces for 30 minutes." ii. Based on direct observation and interview with the laboratory staff on 12/08/2020, the laboratory was utilizing 70% Ethanol as their general	D5411	Continued from page 48 characteristics of the test and it is the Laboratory Director who determines the contamination prevention and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work surface area and the instruments is not approved by the Laboratory Director and therefore not included in the contamination prevention plan. Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for decontamination is 60. **(1)Immediate Corrective Action:** • Reviewed and updated the Quality Management Plan as stipulated in the above summary. • Reviewed and updated all technical and Safety SOPS to reflect the practices currently in use and/or stipulated in the validation related to 70% ethanol, nonuse of UV light and bleach. Refer to Attachment 1 for updated SOPs and further discussion in D3003 Findings 1 and 2. **(2) Patient Impact:** Per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting) as the change in concentration of ethanol and nonuse of UV and bleach as decontamination measures would not cause patient harm. **(3) Preventative Measures:** • Lab Director, Technical & General Supervisors, and Quality staff to continue with timely document review following Document Management procedures and making revisions and edits when errors or changes in process are identified. • Performing employees were given immediate access to documents at time of director approval. **(4) Monitoring Mechanism:** As all documents impacted by this finding have been reviewed and all corrections have been made, there is nothing to monitor. As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es). See Attachment 1 The use of 70% EtOH meets the standard set by CDC. Heat inactivation is an effective method to inactivate SARS-CoV-2. Disposal of MTM sample collection tubes that have been subjected to heat inactivation in bleach is not necessary. Therefore, the area in which the samples were handled was adequately decontaminated.	

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D5411	Continued From page 49 decontamination solution. iii Due to safety concerns with using 10% Sodium Hypochlorite solution with VTM, the laboratory used ethanol. iv. However, contrary to the specified ethanol concentration in the IFU, the laboratory, used 70% ethanol, and not 75% ethanol. v. The laboratory failed to follow manufacturer's instructions specified in the IFU. vi. The laboratory also failed to provide performance specification studies showing 70% ethanol is an effective decontaminant instead of 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. b. Heat Inactivation of Swab Samples i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) did not include the heat inactivation procedures for swab samples. ii. Review of the laboratory's policies and procedures (Policy # CA-EXT-SOP-001 Heat Inactivation of Viral Swab Samples) indicated the following: ii.a. Use of oven to 70 degrees Celsius ii.b. Pre-cool centrifuge to 20 degrees Celsius iii.c. The use of centrifuge at 1200 RPM for 1 minute	D5411	**Finding 1b:** Heat inactivation is a desirable method for ensuring that the infection risk associated with SARS-CoV-2 clincial samples is as low as possible. Validation studies carried out prior to the beginning of testing included LoD studies with both heat inactivated and non-heat inactivated samples (see validation report sent to LFS at 1:55pm PST on 24Oct2020). There was no performance impact on heat inactivation. **(1) Immediate Corrective Action:** The validation report that included the heat inactivation process was sent to LFS on 24OCT2020 at 1:55pm PST. **(2) Patient Impact:** Per Lab Director, Dr. Rosendorff, as the validation was performed before the start of testing there is no change in the diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measure:** The quality organization will provide validation material to the inspection staff. **(4) Monitoring Mechanism:** On a yearly interval the quality organization ensures the validation study information is effectively and efficiently found and provided. **Finding 1c:** Storage condition: The long term storage -94--75oC is intended for post-testing storage. This is not a change to the method described in the IFU and has no impact on the performance of the assay. **(1) Immediate corrective action:** The stability of extracted RNA at -84 - -76oC was researched. Multiple sources indicate that RNA is stable at this temperature for at least one year (1. Technical Bulletin #159: Working with RNA, ThermoFisher.com [Accessed 10Mar2021]; 2. https://www.bioline.com/rna-hints-and-tips [Accessed 10Mar2021]) **(2) Patient Impact:** Per Lab Director, Dr. Rosendorff there is no change in the diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative action:** Any change in material storage temperature will be researched before a change is implemented. **(4) Monitoring mechanism:** As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es).	

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D5411	Continued From page 50 iii. The laboratory failed to provide performance specification studies for the heat inactivation of swab samples. c. Storage Conditions for nasopharyngeal, oropharyngeal, and anterior nasal swabs (Extracted RNA) i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated that, "Nasopharyngeal, oropharyngeal, and anterior nasal swabs with the extracted nucleic acids should be stored at -25 to -15 degrees Celsius. ii. Review of the laboratory's policies and procedures (Title CA-EXT-SOP-004 Title Viral RNA/DNA Extraction Using the Chemagic 360, Effective Date 11/03/2020 stated that, "Extracted nucleic acids should be stored at -84 to -76 degrees Celsius for long term storage." iii. The laboratory failed to follow manufacturer's instructions specified in the IFU. iv. The laboratory failed to provide performance specification studies showing the basis for changing the storage conditions requirement for extracted nucleic acids. d. Thermal Cycler Parameters i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the following thermal cycler set-ups:	D5411	**Finding 1d** Thermocycler Parameters: The correct collection temperature is 65oC. A universal .trf file containing the PCR thermocycling conditions is generated by the PCR Janus program at the time a 384-well plate is set-up. The .trf file is imported to the AJ thermocycler. This file is correct. Records from the PCR output files for the 60 randomly chosen samples demonstrate that the correct temperature is being used (LFS Response Cycling Parameters). Appendix A of CA-PCR-SOP-002v1 contained a typographical error. This error was corrected in v2 (approved 26Jan2021). **(1) Immediate Corrective Action:** CA-PCR-SOP-002 was updated and approved by the Lab Director on 26Jan2021 to correct the omitted step and the typographical error. **(2) Patient Impact:** Referencing the look back above, per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measure:** To reduce typographical errors and improve technical accuracy, the Lab Director has directed that a Technical Supervisor will conduct a secondary review of all technical (ACC, EXT, PCR, RPT and SAF) documents prior to approval request to the Lab Director. (4) Monitoring Mechanism: The lab performs one test at this time and there have been no changes to the thermocycler parameters since the validation; and none are expected for an established method that is in control and performing well. There is not one specific monitoring mechanism. However, As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). A confirmation that thermocycler parameters in Appendix A of the technical SOP have not changed without a concomitant validation is an item on this audit plan. See Attachment 12 **Finding 1e:** Delayed procedure approval: Please refer to the Analysis Timeline. This timeline reflects the difficulty in coming to a scientific and clinical consensus on how low viral load (high Ct value - specifically >36-<42) results should be interpreted. Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a timely manner. Although not approved, a consistent method of interpretation was used (see Analysis Timeline below)	

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Step Temperature Time # of Cycles
1 37 degrees Celsius 2 minutes 1
2 50 degrees Celsius 5 minutes 1
3 42 degrees Celsius 35 minutes 1
4 94 degrees Celsius 10 minutes 1
5 94 degrees Celsius 10 seconds
55 degrees Celsius 15 seconds 45
65 degrees Celsius 45 seconds

*Collect fluorescence signal during the final 65 degrees Celsius step

Review of the laboratory's policies and procedures (Policy # CA-PCR-SOP-002, Title SARS-CoV-2-RT-PCR Using the Analytic, Effective Date 11/04/2020) stated the following thermal cycler parameters:

Step	Temperature	Time	# of Cycles
1	25 degrees Celsius	2 minutes	Not indicated
2	50 degrees Celsius	15 minutes	Not indicated
3	95 degrees Celsius	2 minutes	Not indicated
4	95 degrees Celsius	3 seconds	Not indicated
5	60 degrees Celsius	30 seconds	Not indicated

- 28Oct2020 - 11Nov2020 - results were reported as per the IFU
- 11Nov2020 - 11Dec2020 - lower Ct cutoff was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU
- 11Dec2020 - present - high Ct values (>37 - <42) were interpreted as inconclusive

11Dec2020-25Jan2021 or presumptive positive (25Jan2021 -present)

Due to scientific discussion and disagreement, a final laboratory procedure was not approved by the laboratory directors until 08Dec2020. Additional versions were requested with delayed approval over the next week. Although the protocol in use should have been approved prior to use, mitigating circumstances to note include:

-Data analysts were trained using the draft protocol, which remained available to them
-Changes in the interpretation of results were handled in LIMC, not determined by data analysts
-An active discussion was held with

CDPH directors to bring the interpretation to resolution. See:

o 01Dec2020 Email CDPH Approval of v1
o 08Dec2020_Email Final SOP Definitions for v1 for Doc Control
o 11Dec2020 Email Changes to Ct

Reporting
o 14Dec2020 Email Changes to Ct
Reporting (v2)
o 16Dec2020 Email Changes to Ct
Reporting (v3.1)

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D5411	Continued From page 52 iii. Review of the same policies and procedures Title SARS-CoV-2-RT-PCR Using the Analytic Jena, Effective Date 11/04/2020, indicated the following thermal cyclers dated 10/27/2020. Step Temperature Time # of Cycles 1 25 degrees Celsius 2 minutes 1 2 50 degrees Celsius 15 minutes 1 3 95 degrees Celsius 2 minutes 1 4 95 degrees Celsius 3 seconds 1 5 60 degrees Celsius 30 seconds 45 *Collect fluorescence signal during the final 60 degrees Celsius step iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step" specified in laboratory procedures identified in d (ii) and d (iii) is not the same as the instruction in the IFU, which indicated "Collect fluorescence signal during the final 65 degrees Celsius step." v. The laboratory failed to follow manufacturer's instruction specified in the IFU. vi. The laboratory failed to provide the performance specification studies to support the above-described change in thermal cycler parameters. e. Interpretation of Test Results i. Review of the FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the expected results for the kit with valid quality control as: i.a. SARS-CoV-2 Not Detected i.b. SARS-CoV-2 Detected	D5411	Deviation from IFU outcomes: The clinical significance of high Ct values is a subject of scientific debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or no Ct values: - Negative (no virus detected) - Inconclusive / presumptive positive (high Ct value 37 - < 42) - Positive (virus detected with Ct value < 37) Note that is a post-analytical interpretative decision. This is not a change to the method described in the IFU and has no impact on the performance of the assay. **(1) Immediate Corrective Action:** A full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting. Decisions regarding data interpretation area now made in a timely manner. Interpretation of Ct values has been vetted by Dr. Rosendorff, the CDPH Leadership and the Testing Task Force **(2) Patient Impact**: Based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. Results were correctly reported as inconclusive pursuant to the lab SOP. However, the IFU v5 and the policies and procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these samples would now be considered Invalid. See also D5800. Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. A memorandum was provided to Color Genomics and OptumServe for the samples mentioned. They confirmed receipt. **(3) Preventative Action:** No revision is placed into use until Dr. Rosendorff has signed off. Monthly audits for data integrity are performed.	

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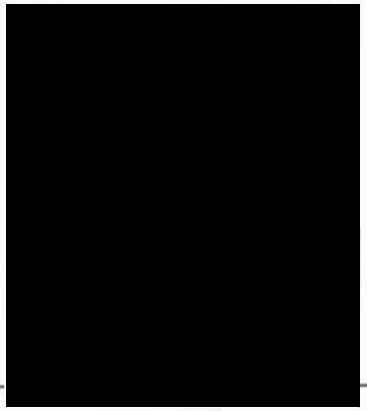
D5411	Continued From page 53 i.c.Invalid ii. Based on interview with the Laboratory Director on 12/08/2020 and 12/09/2020, the laboratory should be reporting the following: ii.a.SARS-CoV-2 Not Detected ii.b.SARS-CoV-2 Detected ii.c.Inconclusive ii.d. Invalid iii. At the time of inspection on 12/08/2020 and 12/09/2020, the laboratory failed to provide performance specification studies to support the updated interpretation of test results, to include inconclusive result. 2. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results, but failed to establish its RT-PCR in vitro diagnostic test P/P that included in the listed items "1a" through 1e", above. Accession Number 	D5411	Continued from page 53 **(4)Monitoring Mechanism:** Recent versions of CA-RPT-SOP-002 (v4, v5, and v6) were made and approved in a timely manner. To ensure data integrity between LIMC and Color, check of 10 random samples are performed each month going forward as part of quality review. An audit was conducted 26Feb2021 on 10 randomly selected samples from January 2021. Data integrity between LIMC and Color was confirmed for 10 samples via a routine tracer audit performed 26Feb2021. An audit of an additional 25 samples will be performed beginning 11Mar2021. **Finding 2-4**: Please see findings 1a - 1e above See Attachment 9	

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D5411	Continued From page 54 [redacted] 3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory's failure to follow manufacturer's instructions specified in the IFU. The laboratory director also affirmed the absence of performance specification studies to support the modification of the procedure not indicated in the FDA EUA IFU. The laboratory director also affirmed the laboratory failed to establish its RT-PCR in vitro diagnostic test P/P that included in the listed items "1a" through "1e", above.	D5411		
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)	D5415		29Mar2021

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D5415	Continued From page 55 Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. Other pertinent information required for proper use. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure it labeled the reagents as required. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-LABGEN-SOP-002 Labeling of Reagents and Solutions, Effective Date 12/09/2020) stated the following information on labeling reagents: a. Name of the reagent or solution b. Expiration Date c. Initials of the person preparing the label d. Date of preparation, filtered, or reconstituted by the laboratory (if applicable) e. Storage conditions (e.g., temperature, exposure to light, etc. as specified by the manufacturer f. Any relevant biohazard or chemical hazard information	D5415	**Finding 1-5:** We acknowledge that labeling of some reagents was incomplete and are working to improve compliance. Supervisors and managers were instructed to refamiliarize the staff with proper procedures for labeling reagents. Monitoring of labeling is ongoing. **(1) Immediate Corrective Action:** Procedures have been reviewed with staff and all technical staff have been re-assigned reading by the MediaLab Admin of CA-LABGEN-SOP-002 (Labeling of Reagents and Solutions) and acknowledge the changes to this document by 31Mar2021. **(2) Patient Impact:** Per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measure: I**mplemented a daily supervisor checklist and shift to shift communication hand-off; one of the action items for each shift requires supervisor to walk the floor and check reagents for proper labeling and expiration dates. This increases awareness and allows for timely correction/education, if needed. **(4) Monitoring Mechanism:** Each month (per the FY 2021 Audit Schedule) a walk-though audit, conducted by quality staff, confirms (or corrects) that all reagents on bench-tops and in refrigerated spaces meet the reagent labeling and expiration date requirements. Last audit conducted 25Feb2021 and reported 01Mar2021.	

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D5415	Continued From page 56 2. During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory was found with the following reagents not labeled properly: a. Elution Buffer x 1- No initial of the person b. Magnetic Buffer x1 - No initial of the person c. Milli Q Water x 3- No expiration date, initial of the person, date prepared, storage condition. 3. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed ensure reagents were labeled as required. Accession Number [redacted]	D5415		

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D5415	Continued From page 57  4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory's failure to label the reagents utilized for testing.	D5415		
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure reagents were not used past the labeled	D5417		29Mar2021

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D5417	Continued From page 58 expiration dates. Findings included: 1. During the laboratory tour on 12/08/2020 at approximately 10:30 am., the laboratory was observed to have four 70% Ethanol Cleaning Solution in dispensing bottles beyond its expiration date. a.1. Lot # 267015, ExpirationDate: 12/03/2020 (2 dispensing bottles) a.2. Lot # A10012002B, ExpirationDate: 12/07/2020 (2 dispensing bottles) 2. Review of the laboratories policies and procedures (Policy # CA-QM-SOP-001, title Quality Management Plan, Effective Date 11/01/2020) stated that reagents and chemicals should be used in testing process within their indicated expiration date. 3. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory performed SARS-CoV-2 tests and reported results but failed to ensure reagents were not used past the expiration dates. Accession Number 	D5417	**Finding 1- 5** We acknowledge the failure to discard some of the ethanol reagent bottles that were in use past their expiration; 2 bottles 5 days past expiration and 2 bottles 1 day past expiration date. See D3003 for additional details **(1) Immediate Corrective Action:** See D3003 Finding 2, 3, 4, 5 **(2) Patient Impact:** See D3003 Finding 2, 3, 4, 5 **(3) Preventative Measure:** See D3003 Finding 2, 3, 4, 5 **(4) Monitoring Mechanism:** See D3003 Finding 2, 3, 4, 5	

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D5417	Continued From page 59 [redacted] 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to monitor the expiration dates of its 70% Ethanol cleaning solution utilized in decontamination procedure.	D5417	Continued from page 59 (1)	
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval	D5423		29Mar2021

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D5423	Continued From page 60 (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of the laboratory's adopted FDA Approved EUA IFU Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to establish and verify performance specifications prior to reporting patient test results. Findings included: 1. Review of the laboratory's available performance specification studies, FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, and	D5423	**Finding 1a** Clinical performance in asymptomatic people: Per version 7 (06Jan2021) of The PerkinElmer® New Coronavirus Nucleic Acid Detection Kit IFU, the intended use for the kit is intended for: ...the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare provider (HCP), and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection. The CDPH Branch Laboratory is using this kit within the parameters of intended use. The IFU also states (page 27): 6. The PerkinElmer New Coronavirus Nucleic Acid Detection Kit may be used to test asymptomatic individuals, although performance has not been demonstrated in an asymptomatic population. This assay has been shown to exhibit high sensitivity when tested with the FDA reference panel. 7. Use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit in a general, asymptomatic screening population is intended to be used as part of an infection control plan, that may include additional preventative measures, such as a predefined serial testing plan or directed testing of high-risk individuals. Negative results should not be treated as definitive and do not preclude current or future infection obtained through community transmission or other exposures. Negative results must be considered in the context of an individual's recent exposures, history, and presence of clinical signs and symptoms consistent with COVID-19. Limitation in the IFU (page 26): 3. Nasal swab specimens self-collected under the supervision of or collected by a healthcare provider can be tested with the PerkinElmer New Coronavirus Nucleic Acid Detection Kit; however, performance with this specimen type has not been determined. 1. **Immediate Corrective Action:** Reviewed current IFU (version 6) to confirm that use in asymptomatic individual is appropriate. 2. **Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm.	

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D5423	Continued From page 61 current policies and procedures, the laboratory failed to provide documentation of established performance specifications for the performance characteristics listed in "a." through "f." as follows: a. Clinical Performance Evaluation for specimens collected from asymptomatic individuals. i. Review of the laboratory's FDA EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal and nasopharyngeal swab specimens collected by a HCP and anterior nasal swab specimens collected by a HCP or self- collected under the supervision of a HCP from ANY INDIVIDUAL, including without symptoms or other reasons to suspect COVID-19 infection." ii. Review of the same EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) also stated that, "Perkin Elmer MUST further evaluate the clinical performance from ASYMPTOMATIC individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this letter. Labeling updates must be made after submission to FDA." It was also stated under the kit limitations that, "nasal swab specimens self-collected under the supervision of or collected by a healthcare provider performance has not been determined." iii. The laboratory must provide its protocol and clinical performance evaluation from asymptomatic individuals, as stated by the FDA	D5423	3. **Preventative Action:** The laboratory will verify the current version of the IFU as part of the Quality Management Review process (at least every quarter) to determine if any changes that impact our current method have been made. **4. Monitoring Mechanism:** As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es). **Finding 1b:** The laboratory has an Amplicon Contamination Prevention Plan (CA-SAFE-POL-019 v 1.0, approved by Lab Director, in effect at time of inspection. This plan describes the measures put in place to prevent contamination that included laboratory design and construction of air lock doors, environmental controls with separate HVAC systems, unidirectional sample flow, secure PCR plate transport, use of PPE with defined gowning/degowning procedures, dedicated equipment and consumables in each room, aerosol-resistant pipette tips, dedicated refrigerators/freezers to separate reagents and samples, and aseptic cleaning techniques all of work areas and equipment. The observation made at time of inspection stated that the lab use of 70% ethanol did not match the EUA and our procedure (See Section 5.7.2). Additionally, a default Safety statement was included in the technical SOPS (listed in the findings) that contradicted the current approved practice and the Laboratory Quality Management Plan (approved by the director and in effect at time of inspection (CA-QM-SOP-001 va effective 01NOV2020) did not provide the robust environmental prevention and decontamination initiatives outlined in the Amplicon Contamination Prevention Plan.	

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D5423	Continued From page 62 .under the "Conditions of Authorization." v. The laboratory must provide the performance evaluation for nasal swab specimens self-collected under the supervision of or collected by a healthcare provider. b. Decontamination Protocol i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated under warnings and precautions #7 that, "Sterile centrifuge tubes and filter-tips should be disposed into a waste bin containing a 10% Sodium Hypochlorite solution. After the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared 10% Sodium Hypochlorite solution, and then cleaned with 75% Ethanol or pure water. Finally, turn on UV light to disinfect working surfaces for 30 minutes." ii. Based on direct observation and interview with the laboratory staff on 12/08/2020, the laboratory was utilizing 70% Ethanol as their general decontamination solution. iii Due to safety concerns in using 10% Sodium Hypochlorite solution with VTM, the laboratory used ethanol. iv. However, contrary to the specified ethanol concentration in the IFU, the laboratory used 70% ethanol, and not 75% ethanol. v. The laboratory failed to follow manufacturer's instructions specified in the IFU. vi. The laboratory also failed to provide performance specification studies showing 70% ethanol is an effective	D5423	Continued from page 62 The FDA EUA instructions for use of the PKI nucelic Acid detection kit provided possible actions for preventing contamination; The decontamination prevention instructions do not impact the performance characteristics of the test and it is the Laboratory Director who determines the contamination prevention and decontamination procedures to be used at the Laboratory. Use of UV light to disinfect the work surface area and the instruments is not approved by the Laboratory Director and therefore not included in the contamination prevention plan. **(1)Immediate Corrective Action:** • Updated all technical protocols to reflect the current disinfectant in use, 70% Ethanol and remove the (See Attachment X for list of documents, approval date). AS 70% was already the disinfectant used in the lab, re-training was not required. • Updated the Quality Management Plan (CA-QM_SOP-001, Sections 6.3.4.7, 6.5.1, 6.8.1, approved by Lab Director and effective 01Mar2021) to reflect contamination prevention and monitoring that is in place, following current Amplicon Contamination Prevention Plan (SAFE-POL-019., v1.1, approved by Lab Director and effective 14Dec202). Staff were assigned to read and acknowledge the changes to this document. **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. Appropriate quality control reactions are helpful in determining whether contamination has occurred. A patient lookback (from 28OCT2020 to 08DEC2020) and a patient lookforward (09DEC2020 to 28FEB2021) was conducted to review all positive and negative controls to look for the presence of viral targets that could indicate contamination. There was no evidence of contamination as values were well below 2% threshold. (See Attachment 1) The trend downward noted is due to a software change allowing for color compensation and better resolution and not attributable to EtOH or % of EtOH used. Per Dr. Rosendorff, the current Lab Director, there is no contamination of patient samples or test results.	

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5423	Continued From page 63 decontaminant instead of 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. c. Heat Inactivation of Swab Samples i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) did not include the heat inactivation procedures for swab samples. ii. Review of the laboratory's policies and procedures (Policy # CA-EXT-SOP-001 Heat Inactivation of Viral Swab Samples indicated the following: ii.a.Use of oven to 70 degrees Celsius ii.b.Pre-cool centrifuge to 20 degrees Celsius ii.c. The use of centrifuge at 1200 RPM for 1 minute iii. The laboratory failed to provide studies about the heat inactivation of swab samples. d. Storage Conditions for nasopharyngeal, oropharyngeal, and anterior nasal swabs (Extracted RNA) i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated that, "Nasopharyngeal, oropharyngeal, and anterior nasal swabs with the extracted nucleic acids should be stored at -25 to -15 degrees Celsius. ii. Review of the laboratory's policies and procedures (Title CA-EXT-SOP-004 Title Viral	D5423	**(3) Preventative Measure:** On 18Mar2021 Quality Specialists scanned the document control management (MediaLab) for additional references to VTM and 75% EtOH; none were found. Staff were provided access via MediaLab to the updated SOPs on the day the Lab Director approved the documents (refer to the SOPs in attachment 1). As this was a correction that reflected the current practice, no additional training was required. **(4) Monitoring Mechanism:** the sign out manager is actively monitoring positive and negative controls and laboratory supervisors are conducting weekly Contamination Wipe Tests. There has been no evidence of contamination on the instruments, work areas, lab instrumentation, equipment, and computers (see Attachment 1 for examples of last 4 Wipe tests). Appendix A: The Quality Management Plan has been revised and reorganized to consolidate information about existing laboratory processes, CA-QM-SOP-001 ver 2.0 approve by Lab Director and effective on 01Mar2021. See Attachment 1 The use of 70% EtOH meets the standard set by CDC. Heat inactivation is an effective method to inactivate SARS-CoV-2. Disposal of MTM sample collection tubes that have been subjected to heat inactivation in bleach is not necessary. Therefore, the area in which the samples were handled was adequately decontaminated. **Finding 1c**: Heat inactivation is a desirable method for ensuring that the infection risk associated with of SARS-CoV-2 clinical samples is as low as possible. Validation studies carried out prior the beginning of testing included LoD studies with both heat inactivated and non-heat inactivated samples (see validation report sent to LFS at 1:55pm PST on October the 24th). There was no performance impact on heat inactivation. **(1) Immediate Corrective Action:** The validation report that included the heat inactivation process was sent to LFS on 24OCT2020 at 1:55pm PST. **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, as the validation was performed before the start of testing there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measure:** The quality organization will provide validation material to the inspection staff. **(4) Monitoring Mechanism:** On a yearly interval the quality organization is ensuring the validation study information is effectively and efficiently found and provided. As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es).	

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D5423	Continued From page 64 RNA/DNA Extraction Using the Chemagic 360, Effective Date 11/03/2020 stated that, "Extracted nucleic acids should be stored at -84 to -76 degrees Celsius for long term storage." iii. The laboratory failed to provide performance specification studies to support the storage conditions requirement for extracted nucleic acids. e. Thermal Cycler Parameters i. Review of the laboratory's FDA EUA Instructions for Use (IFU) for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the following thermal cycler set-ups: Step Temperature Time # of Cycles 1 37 degrees Celsius 2 minutes 1 2 50 degrees Celsius 5 minutes 1 3 42 degrees Celsius 35 minutes 1 4 94 degrees Celsius 10 minutes 1 5 94 degrees Celsius 10 seconds 55 degrees Celsius 15 seconds 45 65 degrees Celsius 45 seconds *Collect fluorescence signal during the final 65 degrees Celsius step ii. Review of the laboratory's policies and procedures (Policy # CA-PCR-SOP-002, Title SARS-CoV-2-RT-PCR Using the Analytik Jena, Effective Date 11/04/2020) stated the following thermal cycler parameters:	D5423	Finding 1d See D5411 finding 1b for additional information. **(1) Immediate Corrective Action:** See D5411 finding 1b **(2) Patient Impact:** See D5411 finding 1b **(3) Preventative Measure:** See D5411 finding 1b **(4) Monitoring Mechanism:** See D5411 finding 1b **Finding 1e:** Thermocycler Parameters: The correct collection temperature is 65oC. A universal .trf file containing the PCR thermocycling conditions is generated by the PCR Janus program at the time a 384-well plate is set-up. The .trf file is imported to the AJ thermocycler. This file is correct. Records from the PCR output files for the 60 randomly chosen samples demonstrate that the correct temperature is being used (LFS Response Cycling Parameters). Appendix A of CA-PCR-SOP-002v1 contained a typographical error. This error was corrected in v2 (approved 26Jan2021). **(1) Immediate Corrective Action:** CA-PCR-SOP-002 was updated and approved by the Lab Director on 26Jan2021 to correct the omitted step and the typographical error. **(2) Patient Impact:** Referencing the look back above, per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Measure:** To reduce typographical errors and improve technical accuracy, the Lab Director has directed that a Technical Supervisor will conduct a secondary review of all technical (ACC, EXT, PCR, RPT and SAF) documents prior to approval request to the Lab Director. **(4) Monitoring Mechanism:** The lab performs one test at this time and there have been no changes to the thermocycler parameters since the validation; and none are expected for an established method that is in control and performing well. There is not one specific monitoring mechanism. However, As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). A confirmation that thermocycler parameters in Appendix A of the technical SOP have not changed without a concomitant validation is an item on this audit plan. **Finding 1f:** Delayed procedure approval: Please refer to the Analysis Timeline. This timeline reflects the difficulty in coming to a scientific and clinical consensus on how low viral load (high Ct value – specificallyRefer to Analysis >37 - <42 results should be interpreted.	

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D5423	Continued From page 65	D5423		

Step	Temperature	Time	# of Cycles
1	25 degrees Celsius	2 minutes	Not indicated
2	50 degrees Celsius	15 minutes	Not indicated
3	95 degrees Celsius	2 minutes	Not indicated
4	95 degrees Celsius	3 seconds	Not indicated
5	60 degrees Celsius	30 seconds	Not indicated

iii. Review of the same policies and procedures Title SARS-CoV-2-RT-PCR Using the Analytik Jena, Effective Date 11/04/2020, indicated the following thermal cyclers dated 10/27/2020.

Step	Temperature	Time	# of Cycles
1	25 degrees Celsius	2 minutes	1
2	50 degrees Celsius	15 minutes	1
3	95 degrees Celsius	2 minutes	1
4	95 degrees Celsius	3 seconds	1
5	60 degrees Celsius	30 seconds	45

*Collect fluorescence signal during the final 60 degrees Celsius step

iv. The instruction to "Collect fluorescence signal during the final 60 degrees Celsius step "specified in laboratory procedures identified in d(ii) and d(iii) is not the same as the instruction in the IFU, which indicated "Collect fluorescence signal during the final 65 degrees Celsius step."

v. The laboratory failed to provide performance specification studies to support the above-described change in thermo cycler parameters.

Timeline. Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a timely manner. Although not approved, a consistent method of interpretation was used (see Analysis Timeline below).

- 28Oct2020 – 11Nov2020 – results were reported as per the IFU
- 11Nov2020 – 11Dec2020 – a lower Ct cutoff was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU
- 11Dec2020 – 25Jan2021 – high Ct values (> 37 - < 42) were interpreted as inconclusive
- 25Jan2021 – present – high Ct values (> 37 - < 42) were interpreted as presumptive positive

Due to scientific discussion and disagreement, a final laboratory procedure was not approved by the laboratory directors until 08Dec2020. Additional versions were requested with delayed approval over the next week. Although the protocol in use should have been approved prior to use, mitigating circumstances to note include:

- Data analysts were trained using the draft protocol, which remained available to them
- Changes in the interpretation of results were handled in LIMC, not determined by data analysts

- An active discussion was held with CDPH directors to bring the interpretation to resolution. See:

o 01Dec2020 Email CDPH Approval of v1
o 08Dec2020_Email Final SOP Definitions for v1 for Doc Control
o 11Dec2020 Email Changes to Ct Reporting
o 14Dec2020 Email Changes to Ct Reporting (v2)
o 16Dec2020 Email Changes to Ct Reporting (v3.1)

Deviation from IFU outcomes: The clinical significance of high Ct values is a subject of scientific debate. Although the IFU gives only a positive or negative interpretation, the decision was made to interpret high Ct values differently from negative or no Ct values:
- Negative (no virus detected)
- Inconclusive / presumptive positive (high Ct value – > 37 - < 42)
- Positive (virus detected with Ct value < 37)

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D5423	Continued From page 66 f. Interpretation of Test Results i. Review of the FDA EUA IFU for PE New Coronavirus Nucleic Acid Detection Kit (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) stated the expected results for the kit with valid quality control as: i.a. SARS-CoV-2 Not Detected i.b. SARS-CoV-2 Detected i.c. Invalid ii. Based on interview with the Laboratory Director on 12/08/2020 and 12/09/2020, the laboratory should be reporting the following: ii.a. SARS-CoV-2 Not Detected ii.b. SARS-CoV-2 Detected ii.c. Inconclusive ii.d. Invalid iii. The laboratory added "inconclusive" to the list of expected results. At the time of inspection on 12/08/2020 and 12/09/2020, the laboratory failed to provide performance specification studies for updated interpretation of test results. 2. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory modified the procedure listed in the IFU of the SARS-CoV-2 EUA, tested and reported results, but failed to demonstrate it established performance specifications for the performance characteristics enumerated in "1 a. through f." above, including step-by-step performance of the procedure, test calculations, and interpretation of results. Accession Number [redacted]	D5423	Continued from page 66 Note that is a post-analytical interpretative decision. This is not a change to the method described in the IFU and has no impact on the performance of the assay. **(1) Immediate Corrective Action:** A full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting. Decisions regarding data interpretation area now made in a timely manner. Interpretation of Ct values has been vetted by Dr. Rosendorff, the CDPH Leadership and the Testing Task Force **(2) Patient Impact:** Based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. Results were correctly reported as inconclusive pursuant to the lab SOP. However, the IFU v5 and the policies and procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these samples would now be considered Invalid. See also D5800. Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. A memorandum was provided to Color Genomics and OptumServe for the samples mentioned. They confirmed receipt.	

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D5423	Continued From page 67 [redacted] 3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to provide documentation for the applicable performance specification studies.	D5423	**(3) Preventative Action**: No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily checklist is being completed at shift change by the Data Analyst staff and verified by the Sign Out Manager. **(4) Monitoring Mechanism**: Recent versions of CA-RPT-SOP-002 (v4, v5, and v6) were made and approved in a timely manner. To ensure data integrity between LIMC and Color, check of 10 random samples is performed each month going forward as part of quality review. An audit was conducted 26Feb2021 on 10 randomly selected samples from January 2021. Data integrity between LIMC and Color was confirmed for 10 samples via a routine tracer audit performed 26Feb2021. An audit of an additional 25 samples will be performed beginning 11Mar2021. **Finding 2-4**: Please see responses to Findings 1a - 1f above See Attachment 9	
D5433	MAINTENANCE AND FUNCTION CHECKS	D5433		29Mar2021

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D5433	Continued From page 68 CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the laboratory failed to ensure the established maintenance protocol for centrifuges were performed and documented. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Title Quality Management Plan, Effective Date 11/01/2020) stated that, "Logs are annotated every day of laboratory operation. If the instrument is not used during a regular laboratory workday, the log must indicate that the equipment was not used." 2. During the laboratory tour on 12/08/2020 at approximately 11:00 a.m., the laboratory was found with a centrifuge maintenance log which	D5433		

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D5433	Continued From page 69 did not annotate every day of laboratory operation. a. Centrifuge SN # JBR20K009, not annotated on 12/02/2020, 12/03/2020, 12/04/2020, and 12/05/2020. 3. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory failed to ensure the established maintenance protocol were performed and documented. Accession Number [redacted]	D5433	**Findings 1-5** 1. CA-DC-SOP-002 (Good Documentation Practices) was re-assigned for all Managers, Supervisors, and technical to re-read. 2. Instrument forms have been updated to make clear appropriate documentation for a shift when instrument is not in use (see centrifuge log as example). See Attachment 2 **(1) Immediate Corrective Action:** • See CAPA-20-007 • Procedures referenced in CAPA-20-007 have been reviewed with staff and all technical staff have been reassigned reading by the MediaLab Admin of CA-DC-SOP-002 (Good Documentation Practices) with acknowledgment expected by 31Mar2021. **(2) Patient Impact:** Per Lab Director, Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Action:** Supervisors have checklists that include daily review of instrument logs for compliance with GDP and documentation of maintenance are now in use. **(4) Monitoring Mechanism:** In addition to the daily supervisor review of equipment maintenance logs, a monthly walk-through audit reviewing all equipment logs is conducted by the quality staff (see FY2021 audit schedule).	

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D5433	Continued From page 70 [redacted] 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to ensure centrifuge maintenance was performed and documented.	D5433	**D5791 Finding 1a - 1d, 2-4:** Appendix A - The Quality Management Plan has been revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 ver. 2.0 approved by Lab Director and effective 01Mar2021. The Amplicon Contamination Prevention Plan, CA-SAFE-POL-019 v 1.0, approved by the Lab Director was in effect in affect at the time of inspection and specifies the use of 70% EtOH. The observation made at the time of inspection stated that the lab use of 70% ethanol did not match the EUA procedure; however, the instructions for use were meant to be possible actions and do not impact the performance characteristics of the assay. Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for decontamination is 60. Heat inactivation was included in the validation studies submitted to LFS at 1:55pm PST on 24Oct2020. The storage of extracted RNA at -84 - -76oC is a post-test process that does not impact the performance of the assay. The thermocycler parameters have been the same as described in the IFU for all tests performed, despite a typographical error in CA-PCR-SOP-002 (corrected 26Jan2021).	
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 through493.1283. (c) The laboratory must document all analytic systems assessment activities. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8 and 9, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 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	D5791	Delayed procedure approval: Please refer to the Analysis Timeline. This timeline reflects the difficulty in coming to a scientific and clinical consensus on how low viral load (high Ct value – specifically > 37 - < 42) results should be interpreted. Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 -< 42) were interpreted as inconclusive • 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 37 - < 42)	29Mar2021

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D5791	Continued From page 71 analytic systems specified in CFR 493.1251 through 493.1254. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 11/01/2020) failed to include an ongoing mechanism to perform or document quality issues regarding the following: a. The laboratory failed to ensure the procedure manuals for the Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test were established, available, and followed by the laboratory staff (See D5401). b. The laboratory failed to ensure the procedure manuals for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler met all the requirements specified in 42 CFR 493.1251(b)(1) - (b)(14) (See D5403). c. The laboratory failed to ensure the updated procedure manuals for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit Real Time Polymerase Chain Reaction (RT-PCR) in vitro diagnostic test utilizing Chemagic 360 for the isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler, were approved, signed and dated by the current Laboratory Director (See D5407). d. The laboratory failed to ensure it followed the adopted FDA EUA IFU, the subsequent revisions	D5791	Due to scientific discussion and disagreement, a final laboratory procedure was not approved by the laboratory directors until 08Dec2020. Additional versions were requested with delayed approval over the next week. Although the protocol in use should have been approved prior to use, mitigating circumstances to note include: - Data analysts were trained using the draft protocol, which remained available to them - Changes in the interpretation of results were handled in LIMC, not determined by data analysts - An active discussion was held with CDPH directors to bring the interpretation to resolution. See: o 01Dec2020 Email CDPH Approval of v1 o 08Dec2020_Email Final SOP Definitions for v1 for Doc Control o 11Dec2020 Email Changes to Ct Reporting o 14Dec2020 Email Changes to Ct Reporting (v2) o 16Dec2020 Email Changes to Ct Reporting (v3.1) The Amplicon Contamination Prevention Plan, CA-SAFE-POL-019 v 1.0, approved by the Lab Director was in effect in affect at the time of inspection and specifies the use of 70% EtOH. The observation made at the time of inspection stated that the lab use of 70% ethanol did not match the EUA procedure; however, the instructions for use were meant to be possible actions and do not impact the performance characteristics of the assay. Based on CDC guidelines and the letter from our corporate quality organization the minimum percent ethanol required for decontamination is 60. Heat inactivation was included in the validation studies submitted to LFS at 1:55pm PST on 24Oct2020. The storage of extracted RNA at -84 - -76oC is a post-test process that does not impact the performance of the assay. The thermocycler parameters have been the same as described in the IFU for all tests performed, despite a typographical error in CA-PCR-SOP-002 (corrected 26Jan2021). See Attachment 9 for additional information For additional details please see D5401, D5403, D5407, D5411 and D5800. **(1) Immediate Corrective Action:** Please see D5401, D5403, D5407, D5411 and D5800. **(2) Patient Impact:** Please see D5401, D5403, D5407, D5411 and D5800. **(3) Preventative Action:** Please see D5401, D5403, D5407, D5411 and D5800. **(4) Monitoring Mechanism:** Please see D5401, D5403, D5407, D5411 and D5800.	

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 72 to the EUA IFU, and changes made in the laboratory's policies and procedures (See D5411). e. The laboratory failed to ensure it labeled reagents as required (See D5415). f. The laboratory failed to ensure it monitored decontamination solution used for SARS-CoV-2 RT-PCR have not exceeded the expiration date (See D5417). g. The laboratory failed to ensure it established, verified, and documented the performance specification characteristics for its modified FDA approved SARS-CoV-2 RT-PCR (See D5423). h. The laboratory failed to ensure the established maintenance protocol for centrifuges were performed and documented (SeeD5433). 2. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, 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 Accession Number [redacted]	D5791	**Finding 1e - 1f, 2-4**: See Attachment 2 and D5415 and D5417: Summary: In summary, expired reagents, such as the 70% EtOH, were only expired by a few days. Since the main concern of aging EtOH is evaporation and CDC states over 60% EtOH is effective, the risk posed is low. Corrective actions are being taken. **(1) Immediate Corrective Action:** Please see D5415 and D5417 **(2) Patient Impact:** Please see D5415 and D5417 **(3) Preventative Action**: Please see D5415 and D5417 **(4) Monitoring Mechanism:** Please see D5415 and D5417. **Findings 1g, 2-4**. See Attachment 13 and D5423: Summary: The laboratory is using this kit within the limits of the intended use. **(1) Immediate Corrective Action:** Please see D5423. **(2) Patient Impact:** Please see D5423. **(3) Preventative Action**: Please see D5423. **(4) Monitoring Mechanism**: Please see D5423. **Findings 1h, 2-4**: See Attachment 2 and D5433: Summary: In summary, issues with maintenance logs are primarily good documentation practice and properly completing logs when an instrument is not in use. A corrective action plan is in place. **(1) Immediate Corrective Action:** Please see D5433. **(2) Patient Impact**: Please see D5433. **(3) Preventative Action**: Please see D5433. **(4) Monitoring Mechanism**: Please see D5433.	

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	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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D5791	Continued From page 73 [redacted] 3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to ensure there was an ongoing mechanism to monitor, assess and when indicated, correct problems in the analytic systems.	D5791		
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves	D5800		8Mar2021

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D5800	Continued From page 74 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: 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 the electronic system(s) it used, accurately and reliably transmitted patient-specific data from the point of data entry to final report destination. (See D5801). 2. The laboratory failed to ensure its test results provided the correct interpretation for SARS-CoV-2 (See D5805). 3. The laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results (See D5807). 4. The laboratory failed to ensure it updated their clients regarding changes in the interpretation of results (See D5809). 5. The laboratory failed to ensure it updated clients when the laboratory failed to release patient test results on time (See D5815).	D5800	**(5801/5805/5807/5809/5821)** In regard to the 32 samples in question (D5801), we have verified that the samples were handled in accordance with the standard operating procedure (SOP) in place on December 10, 2020 (CA-SOP-RPT-002). Based on the input from the CDPH laboratory directors', it was determined that results with IC dropout were better characterized as Invalid results (19) and the negative samples with high Ct values were better characterized as inconclusive (13). This change in classification was implemented via the onsite CDPH lab directors' discretion on December 11, 2020 with the SOP approved on December 13, 2020. During these two days, results were manual reported and staff were trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a LIMC update was implemented into production to automated result code calculation thereby reducing any manual intervention by the data analyst staff. It was observed that the LIMC result of Not Detected was listed on the Color patient report as Negative (Not Detected). This has been changed so that in the green banner (Not Detected) has also been placed there as well. It was observed that the Color patient report showed CT values for N and ORF1ab. The CT values have been removed and are no longer present on the Color report as of December 16, 2020. A memorandum was provided to Color Genomics and OptumServe for the samples mentioned. They confirmed receipt. Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 - < 42) were interpreted as inconclusive • 25Jan2021 – present – high Ct values (> 37 - < 42) were interpreted as presumptive positive The laboratory maintains duplicate original reports in addition to issuing amended reports with original results. **(5815)** The only client of the CDPH Branch Laboratory is the State of California. The laboratory reports the status of samples to the Testing Test Force, CDPH Leadership, and Dr. Pan nightly (see VBL Updates). Per the laboratory contract with the state, the expectation is to meet the 48hr TAT in 95% of cases **(5891)** The inconclusive rate for this assay is monitored daily. Summaries are sent to the Testing Task Force daily. Currently, inconclusive samples include only those with internal control failures (invalid) or samples that were unsatisfactory for testing. The current rate has been consistently ~0.5%. Several factors contribute to this including:	

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D5800	Continued From page 75 6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821) 7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)	D5800	Continued from page 75 a. Staff "superuser" training b. Improvement to Janus Reformatter and Chemagic protocols c. Evidence provided at on-site inspection as part of CAPA-20-002 Both the LIMC User Specification and the User Acceptance forms were signed by both Laboratory Directors is provided. The effective date 29Oct2020 is the date the blank form (template) was effective. In summary, there is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce	
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure	D5801	**The below details are for D5801, D5805, D5807, D5809, D5821** In regard to the 32 samples in question (D5801), we have verified that the samples were handled in accordance with the standard operating procedure (SOP) in place on December 10, 2020 (CA-SOP-RPT-002). Based on the input from the CDPH laboratory directors', it was determined that results with IC dropout were better characterized as Invalid results (19) and the negative samples with high Ct values (37-42) were better characterized as inconclusive (13). This change in classification was implemented verbally via the onsite CDPH lab directors' discretion on December 11, 2020 with the SOP approved on December 13, 2020. During these two days, results were manual reported and staff were trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a LIMC update was implemented to automate result code calculation thereby reducing any manual intervention by the data analyst staff. It was observed that the LIMC result of Not Detected was listed on the Color patient report as Negative (Not Detected). This has been changed so that in the green banner (Not Detected) has also been placed there as well. It was observed that the Color patient report showed CT values for N and ORF1ab. The CT values have been removed and are no longer present on the Color report as of December 16, 2020. A memorandum was provided to Color Genomics and OptumServe for the 32 samples mentioned. They confirmed receipt. The original report and letter of correction for the 19 samples with a change in terminology was provided to Dr. Pan.	29Mar2021

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D5801	Continued From page 76 the electronic system(s) it used accurately and reliably transmitted patient-specific data, from the point of data entry to final report destination. Findings included: 1. The laboratory subcontracts the preanalytic and postanalytic phases of testing to an outside entity, COLOR. 2. The following 13 final patient test reports emailed by the laboratory on 01/06/2021 were reported as "Negative" for SARS-CoV-2. a. The laboratory LIMC LIS report sent by the laboratory to the examiners via e-mail on 12/22/2020 showed a result of "Not Detected" for SARS-CoV-2. b. The final test result generated by COLOR showed a final result of "Negative"	D5801	Continued from page 76 Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 -< 42) were interpreted as inconclusive • 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 37 - < 42) The laboratory maintains duplicate original reports in addition to issuing amended reports with original results. Test results are transmitted to from the LIMS API thorough the Color Platform to both CalREDIE and CalOES. CalREDIE transmits results to California county public health authorities and federal public health authorities as required by law. **(1) Immediate Corrective Action:** The specimens in question were resulted as per SOP. A look forward from December 13, 2020 to December 31, 2020 verified that all samples were reported per SOP versions 2 and 3.1. The CT values were removed from the Color patient report on December 16, 2020. **(2) Patient Impact:** Based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. Results were correctly reported as inconclusive pursuant to the lab SOP. However, the IFU v5 and the policies and procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these samples would now be considered Invalid. For this reason a memorandum was provided to the public healthcare providers responsible for receiving results explaining the change in interpretation to remain on file in the event that these 19 patients contacted them to explain any questions regarding their results. Of the 19 samples reported as invalid, 14 patients were retested (74%) per Color and all tested negative.	

NOT DETECTED	LIMC Report	Final Test Report
[redacted]	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2

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D5801	Continued From page 77 3. Review of the e-mail communication sent by the Director of Clinical Informatics on 12/13/2020, and review of the 32 patient test records obtained by the examiners on December 16, 2020 showed: a. Thirteen (13) patient results were reported as "Not Detected" when it should have been reported "Inconclusive" on December 10, 2020. Reported as Not Detected, but should be reported as Inconclusive [redacted] b. Nineteen (19) patient results were reported as "Inconclusive" when it should have been reported as "Invalid" on December 10, 2020.	D5801	Continued from page 77 Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting). **(3) Preventative Action:** No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily checklist is being completed at shift change by the Data Analyst staff and verified by the Sign Out Manager. **(4) Monitoring Mechanism:** Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. A 23Feb2021 Tracer audit of 10 samples confirmed that the results matched the current SOP 100% of the time. An audit of an additional 25 samples will be performed beginning 11Mar2021. **Appendix B** Sample Look Back and Look Forward 2021 Audit Schedule End to End Audit Plan 2021Audit-004 Report Color Genomics - Memorandum to File OptumServe - Memorandum to File Dr_Pan_Receipt_of_Corrected_Letters Corrected Letters Draft Corrected Reports Original Reports Dr_Pan_Receipt_of_Draft_Corrected_Reports OptumServe_Receipt_Memorandum Color Genomics_Receipt_Memorandum	

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D5801	Continued From page 78 Reported as Inconclusive but should be reported as Invalid. [redacted] 4. The laboratory failed to show the electronically transmitted results between its LIMC LIS, and the outside entity subcontracted by the laboratory, were periodically verified for accuracy. 5. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 6. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the electronic system(s) used by the laboratory, accurately and reliably transmitted	D5801		

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D5801	Continued From page79 patient-specific data, from the point of data entry to final report destination.	D5801		
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure its test report provided the correct interpretation for SARS-CoV-2. Findings included: 1. Based on interview with the laboratory director on 12/08/2020, there were several patient test results reported in error as a result of incorrect data analysis and interpretation, such as: a. "Not Detected" for SARS-Cov-2 should have	D5805	**See response started in D5801**	29Mar2021

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D5805	Continued From page 80	D5805		

been "Inconclusive"
b. "Inconclusive" for SARS-CoV-2 should have been true "Invalid"

2. Based on review of CDPH Branch Lab LIMC LIS reports emailed on 12/22/2020 and SARS-CoV-2 final patient test reports emailed by the laboratory director on 01/06/2021 from COLOR, the laboratory failed to provide the correct interpretation of results to the patients, and how the laboratory conveyed this information to its clients.

a. In an e-mail communication with the laboratory director on 01/12/2021, the examiners asked if corrected reports were issued for the affected patients. The laboratory director indicated that reports were not amended to provide the correct interpretation of results because COLOR did not have the current system to issue corrected reports.

NOT DETECTED	Reported	Correct Interpretation
[redacted]	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive

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D5805	Continued From page 81	D5805		

INCONCLUSIVE	Reported	Correct Interpretation
[redacted]	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid

3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.

4. The Laboratory Director affirmed (01/12/2021 at approximately 11:58 a.m.) through email communication that the laboratory failed to ensure its test results provided the correct interpretation for SARS-CoV-2.

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.	D5807	See response started in D5801	29Mar2021

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D5807	Continued From page 82 This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results. Findings included: 1. Based on review of patient test reports for SARS-CoV-2, the laboratory indicated under the test result and specific genes cycle threshold (Ct) value, "To learn more about the technical details of the test, please see the test methodology and limitation section." 2. Review of the test reports methodology and limitation section did not indicate how the laboratory determined its results (Positive, Negative, Inconclusive, and Invalid). The report also indicated its reference, "Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, 2019-nCOv-PCR AUS Instructions for Use (IFU)." Review of Perkin Elmer New Coronavirus Nucleic Acid Detection Kit FDA Approved EUA IFU for PE New Coronavirus Nucleic Acid (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) indicated only the interpretation for the following: a. Detected b. Not Detected c. Invalid	D5807		

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D5807	Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations a. Detected b. Not Detected c. Inconclusive d. Invalid 3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results.	D5807		

NOT DETECTED (Should be Inconclusive)	INCONCLUSIVE (Should be Invalid)
[redacted]	[redacted]

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D5807	Continued From page 84 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed on (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results.	D5807		
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients regarding changes in the interpretation of results. Findings included: 1. Based on email communication with the	D5809	**See response started in D5801**	29Mar2021

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D5809	Continued From page 85	D5809		

laboratory director on 01/12/2021, and review of patients reported on 12/10/2020:

a. Results were reported as "Not detected" or "Negative" but should have been reported as "Inconclusive"

b. Results were reported as "Inconclusive "but should have been true "Invalid"

2. The laboratory failed to ensure it updated their clients regarding change in the interpretation of results. The laboratory's outside entity subcontractor, failed to issue corrected reports because the current system it used is not capable of issuing corrected reports.

3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure it updated their clients regarding changed in the interpretation of results.

a. Below are test results that were reported as "Negative", but the correct result should have been "Inconclusive"

NOT DETECTED	LIMC Report	Final Test Report
[redacted]	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2

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D5809	Continued From page 86	D5809		

b. Below are test results that were reported as "Inconclusive", but the correct result should have been "Invalid"

INCONCLUSIVE	Reported	Correct Interpretation
[redacted]	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid

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D5809	Continued From page 87 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (01/12/2021 at 11:58 a.m.) through email communication that the laboratory failed to ensure it updated its clients regarding changes in the interpretation of results because the laboratory failed to issue corrected reports.	D5809	Finding 1-5: 1. The only client of the CDPH Branch Laboratory is the State of California. The laboratory reports the status of samples to the Testing Test Force, CDPH Leadership, and Dr. Pan nightly (see VBL Updates). 2. Per the laboratory contract with the state, the expectation is to meet the 48hr TAT in 95% of cases. **(1) Immediate Corrective Action:** The daily status report is sent by the CDPH Branch Laboratory project manager to key stakeholders. A review of daily update emails shows that this summary was given to the client each day from 4Dec2020 – 10Dec2020. Due to the mission and scope of testing performed, our clients, the Task Force, Dr. Pan and the State of California have not requested a list of individual barcodes exceeding 48 hours. **(2) Patient Impact:** Our TAT time for November and December averaged 37.39 hours which is within the 24-48 hour target with continued trend towards faster TAT. Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Action:** The routine daily email sent by the project manager allows the provider and other stakeholders to monitor sample status. **(4) Monitoring Mechanism:** The daily summary is generated each day and emailed by the project manager to the key stakeholders. This report is stored by the laboratory. Turnaround time is monitored as indicated in the Quality Management Plan (CA-QM-SOP-001). This process has been added to the Post-analytical QA Process (CA-RPT-SOP-004). See Attachment 14	
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002, Title Specimen Collection, Storage, and Shipping, Effective Date 12/07/2020) stated, "The turnaround time (TAT) for the results is within 24-	D5815		29Mar2021

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D5815	Continued From page 88 48 hours." 2. Based on email communication with the laboratory director on 01/08/2021, that the laboratory start counting for TAT when the samples get to the laboratory. 3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported 5 out of 32 SARS-CoV-2 patient test results with no documentation of delay in reporting patient test results.	D5815		

Accession #	Collected	Received	Reported	Result
D-6195896854	12/04/2020	12/05/2020	12/10/2020	Inconclusive
D-6195255010	12/04/2020	12/05/2020	12/10/2020	Inconclusive
D-6199026441	12/04/2020	12/05/2020	12/10/2020	Inconclusive
D-6192530811	12/04/2020	12/05/2020	12/10/2020	Inconclusive
D-4669414825	12/04/2020	12/05/2020	12/10/2020	Inconclusive

	4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure it documented delay in reporting patient test results.			
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	See response started in D5801	29Mar2021

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D5821	Continued From page 89 (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 on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory director, the laboratory through COLOR failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results, and maintained duplicates of the original report. Findings included: 1. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, the laboratory through COLOR failed to perform the following: a. Notification and Issuance of Corrected Reports i. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, "Not detected" but should have been "Inconclusive," and "Inconclusive" but should have been true "Invalid. " The laboratory failed to ensure it notified and issued amended reports to the individual using the test results.	D5821		

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D5821	Continued From page 90	D5821		

ii. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported 13 out of 13 "Not Detected" but should have been "Inconclusive" and 19 out of 19 "Inconclusive" but should have been "Invalid" for SARS-CoV-2 patient test results.

NOT DETECTED	Reported	Correct Interpretation
[redacted]	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive

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D5821	Continued From page 91	D5821		

INCONCLUSIVE	Reported	Correct Interpretation
[redacted]	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid

b. Maintain duplicates of the original report

i. Based on review of patients test records emailed by the laboratory director on 12/24/2020, the laboratory through COLOR issued amended reports on 12/07/2020 for reported SARS-CoV-2 results on 12/04/2020 without providing the original report.

ii. The following 10 out of 10SARS-CoV-2 patient test results were amended:

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D5821	Continued From page 92	D5821		

Accession #	Original Report 12/04/2020	Amended 12/07/2020
[redacted]	Detected	*
	Detected	*
	Detected	*
	Not Detected	*
	Detected	*
	Detected	*
	Detected	*
	Detected	*
	Detected	*
	Detected	*

*Unable to return results for this sample.

Please disregard any previous reports as they were issued in error.

Amended Report: The previously reported result (detected/not detected) is not valid due to a lab process error (Accession #s), Covid-19 Test.

Report Test Date: December 4, 2020

Recommendation: This patient should be retested.

2. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.

3. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report.

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D5891	Continued From page 93 POSTANALYTIC SYSTEMS QUALITY ASSESSMENT 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: 1. Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure there was a mechanism to periodically verify calculated results, results sent to interfaced systems, and patient specific data for SARS-CoV-2. Findings included: a. Prior to the scheduled on-site inspection, Laboratory Field Services (LFS) sent an e-mail communication on November 13, 2020, wherein we informed the laboratory that we will be looking into the report of increased number of inconclusive patient test results, published in a news article on November 10, 2020. Below is the excerpt of the e-mail communication: "Please refer to the following media report: https://www.newsweek.com/spike-bad-test-results-californias-new-120m-covid-19-testing-lab-comes-amid-tighter-restrictions-1546522	D5891	**Finding 1a** 1. The inconclusive rate for this assay is monitored daily. Summaries are sent to the Testing Task Force daily. Currently, inconclusive samples include only those with internal control failures (invalid) or samples that were unsatisfactory for testing. The current rate has been consistently ~0.5%. Several factors contribute to this including: a. Staff "superuser" training b. Improvement to Janus Reformatter and Chemagic protocols c. Evidence provided at on-site inspection as part of CAPA-20-002 **(1) Immediate Corrective Action:** CAPA-20-002 provided at on-site inspection provides the immediate corrective actions that were taken. Including increasing the internal control from 5ul to 20ul per reaction, as allowed by the EUA, updating instrument protocols and providing additional training for staff. Including increasing the internal control from 5ul to 20ul per reaction, as allowed by the EUA, updating instrument protocols and providing additional training for staff. **(2) Patient Impact:** Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting). **(3) Preventative Action:** Since the immediate corrective actions were effective process improvements, no further preventative action is needed. IC dropout rate is included on the daily report to allow monitoring for trends. **(4) Monitoring Mechanism:** Recent versions of CA-RPT-SOP-002 (v4, v5, and v6) were made and approved in a timely manner. A daily report of inconclusive and invalid samples is shared with the Testing Task Force, OptumServe, and CDPH partners . The quality organization is responsible for timely review and signoff of future SOPs.	29Mar2021

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D5891	Continued From page 94	D5891	**Finding 1b-m**	

LFS expects full documentation of:
* Evaluation of reported patient tests results during the affected time period. Patient look-back.
* How the lab identified the problem and the corresponding solution.
* What is the corrective action?
* How the lab is monitoring the corrective action. Is it the fix working?"

b. During the first day of the on-site inspection on 12/08/2020, we interviewed laboratory directors and senior operations personnel, and requested for the laboratory's documented investigation and corrective action regarding the increased number of inconclusive patient results.
c. We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the laboratory's adopted test method, Perkin Elmer New Coronavirus Nucleic Acid Detection Kit. The "Examination and Interpretation of Patient Specimen Results" section showed a table listing the expected results for the kit with valid positive and negative control.

Cycle threshold		Result Interpretation
IC (VIC/HEX)	N(FAM), ORF1ab ROX)	
≤ 40	Both targets Undetermined or > 42	SARS-CoV-2 Not Detected
/	Both targets ≤ 42	SARS-CoV-2 Detected
/	One of the targets ≤ 42	SARS-CoV-2 Detected
>40 or Undetermined	Both targets Undetermined or > 42	Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.

LIMC v1.0 was validated and accepted by the Laboratory Director on 27Oct2020 (note that 28Aug2019 is the date the PerkinElmer form used to document the validation was effective). This validation included acceptance of LIMC User Requirements, LIMC Installation Qualification and LIMC Operational Qualification. The updated LIMC version 1.2 was approved by the Laboratory Director on 13Dec2020 and (note that the form, called CA-COMP-FM-003, is a form used for user acceptance testing and was approved on 28Oct2020 as a CDPH Branch Laboratory form). The data showing validation of "inconclusive" at Ct values between 37 and 42 is shown on pages 8 and 9. The Director approval of the data is shown on page 12. These digital signatures were obtained via DocuSign software.

See Attachment 11.

(1) Immediate Corrective Action: The specimens in question were resulted as per SOP. A look forward from 13Dec2020 to 31Dec2020 verified that LIMC transmitted results to Color accurately.

(2) Patient Impact: Based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. Results were correctly reported as inconclusive pursuant to the lab SOP. However, the IFU v5 and the policies and procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these samples would now be considered Invalid. For this reason a memorandum was provided to the public healthcare providers responsible for receiving results explaining the change in interpretation to remain on file in the event that these 19 patients contacted them to explain any questions regarding their results. Of the 19 samples reported as invalid, 14 patients were retested (74%) per Color and all tested negative.

Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm.

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D5891	Continued From page 95 d. In order to compare how the laboratory was calculating and interpreting patient results, we also asked the laboratory on December 8, 2020, to provide the LIMC Laboratory Information System (LIS) and its policy and procedure for interpretation of patient specimen results. a. A policy and procedure signed by the laboratory was not available on December 8, 2020. b. Neither an unsigned policy and procedure was available on December 8, 2020. e. Further interviews with the laboratory director on 12/08/2020, indicated there was a possibility that patient test results were reported in error as a result of incorrect data analysis and interpretation. f. The following day on 12/09/2020, we conducted random sampling of an additional 32 patient test records with specimens collected during the first week December until 12/08/2020. g. On December 16, 2020, we went back on-site at the laboratory to retrieve the additional patient test records. We also asked the laboratory to send via e-mail, the requested records and its policy and procedure for interpretation of patient specimen results. h. The policy and procedure sent via e-mail on Dec. 16, 2020 showed the following: (i) An annotation on the top portion of document indicated, "Effective Starting 10/29/2020" the document version history : (ii) It was an Initial document, Version 1.0, with	D5891	**(3) Preventative Action:** No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily checklist is being completed at shift change by the Data Analyst staff and verified by the Sign Out Manager. Daily updates will continue to be distributed to clients and key stakeholders including CHHS, CDPH Leadership, Dr. Erica Pan, OptumServe and Color. **(4) Monitoring Mechanism:** Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. A 23Feb2021 Tracer audit of 10 samples confirmed that the results matched the current SOP 100% of the time. An audit of an additional 25 samples will be performed beginning 11Mar2021.	

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D5891	Continued From page 96	D5891	**Finding 1o-p**	

an effective date of December 13, 2020.

(iii) The Software Name was identified as LIMC, version 1.2

i. The Detailed User Requirements Specifications section of the document showed the following policy for interpretation of patient specimen results.

User Requirement Number	Description
UR001	Update analysis rule for the new SOP: • "Not Detected" Ct cutoff changed from 37 to 42 • FAM and ROX >37 and <=42 will be called as "Inconclusive" instead of "Not Detected". • IC Failure samples (HEX=0 or >40) will be released as "Invalid". • No changes on controls and "Detected" rules

j. Comparative review of the IFU for the laboratory's adopted EUA method, and the laboratory's policy for interpreting patient specimen results, showed the laboratory added a result category of Inconclusive.

k. There was no indication that this document identified as User Requirement Specifications CA-COMP-FM-001 Version 1.0, was approved, signed, and dated by the Laboratory Director.

l. This policy and procedure did not include the laboratory's signature. There was also no indication or verification that the laboratory director affixed a digital signature approving, signing and dating the document.

m. In addition to failing to have available, a signed policy and procedure for interpreting

In regard to the 32 samples in question (D5801), we have verified that thesamples were handled in accordance with the standard operating procedure (SOP) in place on December 10, 2020 (CA-SOP-RPT-002). Based on the input from the CDPH laboratory directors', it was determined that results with IC dropout were better characterized as Invalid results **(19)** and the negative samples with high Ct valu better characterized as inconclusive (13). This change in classification was implemented via the onsite CDPH lab directors' discretion on December 11, 2020 with the SOP approved on December 13, 2020. During these two days, results were manual reported and staff were trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a LIMC update was implemented into production to automated result code calculation thereby reducing any manual intervention by the data analyst staff.

It was observed that the LIMC result of Not Detected was listed on the Color patient report as Negative (Not Detected). This has been changed so that in the green banner (Not Detected) has also been placed there as well. It was observed that the Color patient report showed CT values for N and ORF1ab. The CT values have been removed and are no longer present on the Color report as of December 16, 2020.

A memorandum was provided to Color Genomics and OptumServe for the samples mentioned. They confirmed receipt. Please refer to the Analysis Timeline.

- 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive)
- 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU
- 11Dec2020 – 25Jan2021 – high Ct values (> 37 - < 42) were interpreted as inconclusive
- 25Jan2021 – present – high Ct values (> 37 - < 42) were interpreted as presumptive positive

The laboratory maintains duplicate original reports in addition to issuing amended reports with original results.

(5815) The only client of the CDPH Branch Laboratory is the State of California. The laboratory reports the status of samples to the Testing Test Force, CDPH Leadership, and Dr. Pan nightly (see VBL Updates). Per the laboratory contract with the state, the expectation is to meet the 48hr TAT in 95% of cases

(5891) The inconclusive rate for this assay is monitored daily. Summaries are sent to the Testing Task Force daily. Currently, inconclusive samples include only those with internal control failures (invalid) or samples that were unsatisfactory for testing. The current rate has been consistently ~0.5%. Several factors contribute to this including:

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D5891	Continued From page 97 patient sample results, the laboratory also failed to show it validated its LIS to include a result category of "Inconclusive" prior to reporting patient test results on 11/02/2020. (See D5423). o. Review of the 32 patient test records retrieved on December 16, 2020 showed: (i) Thirteen (13) patient results were reported as "Not Detected" when it should have been reported "Inconclusive" on December 10, 2020. Reported as Not Detected, but should be reported as Inconclusive [redacted] (ii) Nineteen (19) patient results were reported as "Inconclusive" when it should have been reported as "Invalid" on December 10, 2020. Reported as Inconclusive, but should be reported as Invalid. [redacted]	D5891	Continued from page 97 a. Staff "superuser" training b. Improvement to Janus Reformatter and Chemagic protocols c. Evidence provided at on-site inspection as part of CAPA-20-002 Both the LIMC User Specification and the User Acceptance forms were signed by both Laboratory Directors is provided. The effective date 29Oct2020 is the date the blank form (template) was effective. In summary, there is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce **(1) Immediate Corrective Action:** The specimens in question were resulted as per SOP. A look forward from December 13, 2020 to December 31, 2020 verified that all samples were reported per SOP versions 2 and 3.1. **(2) Patient Impact:** Based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. Results were correctly reported as inconclusive pursuant to the lab SOP. However, the IFU v5 and the policies and procedures were communicated but not finalized in a revised SOP until December 13, 2020 indicating these samples would now be considered Invalid. For this reason a memorandum was provided to the public healthcare providers responsible for receiving results explaining the change in interpretation to remain on file in the event that these 19 patients contacted them to explain any questions regarding their results. Of the 19 samples reported as invalid, 14 patients were retested (74%) per Color and all tested Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Action:** No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily checklist is being completed at shift change by the Data Analyst staff and verified by the Sign Out Manager. Daily updates will continue to be distributed to clients and key stakeholders including CHHS, CDPH Leadership, Dr. Erica Pan, OptumServe and Color.	

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D5891	Continued From page 98 [redacted] o. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. p. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure was a mechanism to periodically verify calculated results, results sent to interfaced systems, and patient specific data for SARS-CoV-2. 2. Based on interview with the laboratory director on 12/08/2020, 12/09/2020 and 12/16/2020 and email communication on 12/22/2020, 12/24/2020, 01/06/2021 and 01/12/2021, review of policies and procedures, quality control (QC) and quality assurance (QA) records, 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	D5891	Continued from page 98 **(4) Monitoring Mechanism:** As a follow-up to the inspection process, a post inspection audit, conducted by the quality staff, is added to the FY2021 Audit Schedule at a time to be determined by Lab Director (3 and/or 6 months post inspection). All identified findings with corresponding corrective, preventative and monitoring activities are evaluated to determine if findings have been resolved and/or are being monitored effectively. Any items determined to be out of compliance will move into the QER, and if needed, CAPA process(es). Monthly tracer studies will confirm that electronic transmission of results is accurate.	

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D5891	Continued From page 99 problems identified in the postanalytic systems specified in CFR 493.1291 (a)-(k). Findings included: a. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 11/01/2020)showed the laboratory failed to include an ongoing mechanism to perform or document quality issues regarding the following: b. The laboratory failed to ensure the electron system(s) it used, accurately and reliably trans patient-specific data from the point of data entry to fi report destination (See D5801). c. The laboratory failed to ensure its test result provided the correct interpretation for SARS-CoV-2 (See D5805). d. The laboratory failed to ensure its accurate reference intervals determined by the laboratory based on LOD were available for the authorized person, or individual responsible for using the test results (See D5807). e. The laboratory failed to ensure its clients were updated regarding changes in the interpretation of results (See D5809). f. The laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time (See D5815). g. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821).	D5891	**Finding 2** See Attachment 9 and D5411 In summary, there is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. Appendix A - The Quality Management Plan has been revised and reorganized to consolidate information about existing laboratory processes (CA-QM-SOP-001 ver. 2.0 approved by Lab Director and effective 01Mar2021. (1) **Immediate Corrective Action:** Please see D5411, D5800 (2) **Patient Impact**: Please see D5411, D5800 (3) **Preventative Action**: Please see D5411, D5800 (4) **Monitoring Mechanism**: Please see D5411, D5800	

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D5891	Continued From page 100 h. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, showed that for 32 out of 32 results records reviewed, the laboratory tested and reported SARS-CoV-2 results, but failed to ensure there was an ongoing mechanism to identify issues in the postanalytic systems. [redacted]	D5891		

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D5891	Continued From page 101 i. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. j. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to monitor, assess, and when indicated, correct problems identified in the postanalytic systems	D5891		
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart. This Condition is not met as evidenced by: Based on the severity of the deficiencies cited herein, it was determined that the condition Laboratories Performing High Complexity Testing, Laboratory Director was not met: Findings included: 1. The Laboratory Director failed to demonstrate quality of service provided in the postanalytic system when the laboratory failed to provide documentation of training, competency assessment, and consultation electronically or by telephone, as necessary; delegated to qualified personnel specific responsibilities which can be reapportioned to technical supervisor, general supervisor, and clinical consultant. The Laboratory Director was not aware that data	D6076	To manage the laboratory effectively, a full-time, on-site Laboratory Director, has been hired who is directly involved in day-to-day laboratory operations and result reporting. The Laboratory Director is an MD, Board Certified in Clinical Pathology. The Laboratory Director is responsible for the below items in response to the findings in D6076 and its related subsections. • (6082) Ensure data analysis continues to happen only onsite at the CDPH Branch Laboratory • (6083) Ensure environmental conditions that are established at the CDPH Branch laboratory are appropriate for testing • (6084) Ensure testing personnel continue to be safe from physical, chemical and biological hazards • (6093) Ensure quality control programs that are established continue to be maintained and to identify failures in quality as the occur • (6094) Ensure quality assurance activities that have been established continue to be maintained and to identify failures in quality as they occur • (6101) Ensure the laboratory continues to have the adequate number of personnel with appropriate training to perform testing • (6102) Ensure the laboratory staff continues to demonstrate competency prior to reporting patient results	8Mar2021

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D6076	Continued From page 102 analysis and reporting of patient test results was taking place at a location outside of the listed and known physical location of the laboratory in its State and CLIA applications (See D6082). 2. The Laboratory Director failed to ensure that environmental conditions of the laboratory are appropriate for the testing performed (See D6083). 3. The Laboratory Director failed to ensure that testing personnel were safe from physical, chemical and biological hazards (See D6084). 4. The Laboratory Director failed to ensure quality control programs were established and maintained to assure the quality of services provided, and to identify failures in quality as they occur (See D6093). 5. 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). 6. The Laboratory Director failed to ensure it utilized adequate number of laboratory personnel for high complexity testing with appropriate training to provide supervision accordingly (See D6101). 7. The Laboratory Director failed to ensure the laboratory staff demonstrated competency prior to reporting patient test results (See D6102).	D6076	**Continued from page 102** **(1) Immediate Corrective Action:** As the newly delegated Lab Director (27JAN2021), all documents and processes for sample workflow (preanalytical, analytical, and postanalytical as well as the quality system essentials that support them are under review to determine if they are in compliance with regulatory requirements and reflect actual lab practice. The Quality Management Plan underwent a major reorganization following initial review; now a deliberate review of the policies and procedures that support that plan are being carefully reviewed. Given that there are 243 documents, this process is ongoing. To date, 153 documents (63%) have been reviewed in Media Lab, with 40 documents revised/approved. **(2) Patient Impact:** Based on the deficiencies listed under D6076 we believe that the impact to patient care had the potential to be significant. In particular items 1,4,6,5,7 could have negatively impacted the volumes of invalid/cancelled specimens, and potentially impacted turnaround times, thereby causing a delay in identification of patients at risk of COVID and timely treatment. However, our TAT time for November and December averaged 37.39 hours which is within the 24-48 hour target with continued trend towards faster TAT. Based on lookback audit of laboratory results generated 28Oct2020 - 31Dec2020 and a post inspection lookback at results generated 01Jan2021 – 28Feb2021, QC values were within acceptable ranges (see attached report (therefore we do not believe that these deficient practices impacted the accuracy of patient testing or a delay in timely treatment. **(3) Preventative Action:** Dr Rosendorff, Lab Director, to continue to review and approve documents and understand processes in place and revise as he deems necessary to ensure that regulatory guidelines are followed, that quality assurance activities are measurable and timely and the corrective actions are documented, resolved in timely manner and effective. **(4) Monitoring Mechanism:** Include % of Review/ Approval of Documents as a reportable Quality Metric. Continue to monitor existing quality indicators	
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test	D6082		29Mar2021

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D6082	Continued From page 103 performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This Standard is not met as evidenced by: 1. Preanalytic System (Test Requisition) Based on interviews with staff and the laboratory director on December 8, 2020, the absence of test requisitions, and random review of test records covering the period from 11/22/2020 to 12/08/2020, for 10 out of 10 patient test records reviewed, it was determined that the Laboratory Director failed to ensure the quality of service provided in the preanalytic system when records of test requisitions for SARS-CoV-2 patient testing was not retained. Findings included: a. The Laboratory Director failed to ensure it retained records of test requisitions of all patients tested for SARS-CoV-2, for at least two years (See D3027). 2. Postanalytic System (Test Report) Based on email communication with the laboratory director on 12/24/2020, the absence of original test reports, and review of test records covering the period from 12/02/2020 to 12/04/2020, for 10 out of 10 patient test records reviewed, it was determined that the Laboratory Director failed to ensure the quality of service provided in the postanalytic system when records of original test reports for SARS-CoV-2 patient testing were not retained. Findings included: a. The Laboratory Director failed to ensure it	D6082	**Finding 1-2:** See Attachment 4 and D3207, D5301 All information is collected on the electronic requisition form that is stored at Color Genomics (CLIA #05D2081492) at established collection sites (see D5311). Data needed for testing is transferred to CDPH Branch Laboratory. Requisition data and laboratory reports are retained by Color Genomics for 20 years per their policies and procedures. These documents are accessible to CDPH Branch Laboratory for auditing purposes. (1) **Immediate Corrective Action:** Please see D3027, D5301 (2) **Patient Impact**: Please see D3027, D5301 (3) **Preventative Action**: Please see D3027, D5301 (4) **Monitoring Mechanism**: Please see D3027, D5301	

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D6082	Continued From page 104 retained records of original test reports of all patients tested for SARS-CoV-2, for at least two years (See D3041). 3. Postanalytic System (Training, Competency Assessment, Consultation, and Delegation of Duties to Qualified Personnel in Remote Data Analysis) Based on email communication with the Director of Informatics on 12/16/2020 , interviews with the laboratory staff on 12/08/2020, review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, the Laboratory Director failed to demonstrate quality of service provided in the postanalytic system when the laboratory failed to provide documentation on training, competency assessment, and consultation electronically or by telephone, as necessary; or delegated to qualified personnel specific responsibilities which can be reapportioned to technical supervisor, general supervisor, and clinical consultant during the time data analysis and remote reporting of patient test results were taking place at a location outside of the laboratory facility. Findings included: a. Based on interview with the laboratory staff on 12/08/2020, a laptop computer was issued to nine data analysis laboratory personnel which would enable access to the laboratory's information system and facilitate patient test reporting remotely. Data Analysis Staff — Perkin Elmer Computer VPN a. SS — VALLL015 b. RR — VALLL014 c. AE — VALLL020 d. SM — VALLL013	D6082	**Finding 3** 1. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. 2. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. a. This infrastructure configuration eliminates the ability for individuals to access the site and file repository from an external location on a general internet connection. b. Data is never transferred to the location of the remote (offsite) person. 3. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer issued set of credentials on a PerkinElmer issued laptop. During any remote session the data and system being accessed are located on the prior mentioned internal IT systems hardware. 4. The two data analysts who performed remote analysis were trained and qualified to do so: a. EV – Trained in data analysis and delegated the responsibilities of a General Supervisor b. MN – CLS trained in data analysis 5. CMS has made an exception to allow pathologist and other healthcare professionals to work remotely during the pandemic. CAP concurred with this exception. See Attachment 10. **(1) Immediate Corrective Action:** • SignOut Manager was instructed by Lab Director, Helen Farzanmehr, on 10Dec2020 that analysts may not analyze data remotely. • Human Resources informed potential qualified candidates and those awaiting onboarding/orientation that remote analysis was no longer a possibility; employment contingent upon on site analysis. **(2) Patient Impact**: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm.	

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D6082	Continued From page 105 e. FJ VALLL017 f. MW VALLL021 g. YZ VALLL002 h. WT VALLL033 i. MN VALLL023 b. Based on email communication with the Director of Clinical Informatics on 12/16/2020, remote workers need to connect to VPN to be able to login to LIMC (LIS), so their IP addresses are Perkin Elmer IP address. The CDPH Branch Laboratory Valencia lab IP address range is 165.88.16.###. Non-Valencia IP Addresses Login 1. By EV 2. By MN 165.88.255.136 165.88.254 165.88.176.91 165.88.254 165.88.192.131 165.88.176.64 165.88.254.202 c. Review of the laboratory's policies and procedures (Policy # CA-RPT-SOP-002, Title: Analysis and Reporting of SARS-CoV-2 Assay, Version 1 Effective Date 12/8-13/2020, Version 2.0 Effective Date 12/13-16/2020, Version 3.0 Effective Date 12/16/2020, and Version 3.1 Effective Date 12/16/2020), the Laboratory Director failed to demonstrate quality of service provided in the postanalytic system when the laboratory failed to provide documentation on training, competency assessment, and consultation electronically or by telephone, as necessary; or delegate to qualified personnel specific responsibilities which can be reapportioned to technical supervisor, general supervisor, and clinical consultant during the time data analysis and remote reporting of patienttest	D6082	**(3) Preventative Action:** A request to remove VPN access software from analyst computers was placed with the IT group by the project manager on 11Mar2020 and completed on 13Mar2020 by the IT group. **(4) Monitoring Mechanism:** A request to query for remote release of records made on 26Feb2021 could not be completed due to complexity. Removal of VPN access removes the need to monitor.	

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D6082	Continued From page 106 results were taking place at a location outside of the laboratory facility. d. Random review of test records covering the period from 11/22/2020 to 12/08/2020, the laboratory tested and reported 60 out of 60 SARS-CoV-2 patient test results, showed two laboratory personnel to perform data analysis and remote reporting outside the location of CDPH Branch laboratory in Valencia without documentation of training, competency assessment, and consultation electronically or by telephone. e. Below are 30 representative examples each for EV and MN, wherein data were remotely analyzed, and patient test results were released remotely. **See table below for data analyzed by EV:**	D6082		

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D6082		D6082		

Continued From page 107

Data Analyzed by EV:

Accession Number	Date Reported	IP Address
[redacted]	11/22/2020	165.88.255.136
	11/22/2020	165.88.255.136
	11/22/2020	165.88.255.136
	11/22/2020	165.88.255.136
	11/23/2020	165.88.176.91
	11/23/2020	165.88.176.91
	11/23/2020	165.88.176.91
	11/23/2020	165.88.176.91
	11/24/2020	165.88.192.131
	11/24/2020	165.88.192.131
	11/24/2020	165.88.192.131
	11/24/2020	165.88.192.131
	11/25/2020	165.88.176.64
	11/25/2020	165.88.176.64
	11/25/2020	165.88.176.64
	11/25/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/28/2020	165.88.254.202
	11/28/2020	165.88.254.202
	11/28/2020	165.88.254.202
	11/28/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/30/2020	165.88.254.202
	11/30/2020	165.88.254.202

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D6082	Continued From page 108	D6082		

See table below for data analyzed by MN:

Data Analyzed by MN:

Accession Number	Date Reported	IP Address
[redacted]	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200

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D6082	Continued From page 109 The total number of results reported by MN from 12/07/2020 to 12/08/2020 was 1,974. g. The total number of results reported byEV from 11/22/2020 to 11/30/2020 was 13, 291. h. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. i. The Laboratory Director affirmed(12/17/2020 at 12:15 p.m.) through email communication that the two data analysis personnel analyzed and reported the SARS-CoV2 amplification test results which the laboratory failed to provide documentation of training, competency assessment, and consultation electronically or by telephone, as necessary; or delegated to qualified personnel specific responsibilities which can be reapportioned to technical supervisor, general supervisor, and clinical consultant, during the time data analysis and remote reporting of patient test results were taking place at a location outside of the laboratory.	D6082		

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	Continued From page 110			
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, interviews conducted with the laboratory staff on 12/08/2020 and 12/09/2020, review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the Laboratory Director failed to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was minimized. Findings included: 1. The laboratory failed to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was minimized (See D3003).	D6083	**D6083 Finding 1:** Reference D3003 for our response to the finding. **(1) Immediate Corrective Action:** See D3003 **(2) Patient Impact:** See D3003 **(3) Preventative Measure:** See D3003. Additionally, the Laboratory Director has instituted the below items. • Weekly quality meetings that includes a review of QERs and CAPAs • Meet with TS/GS on any type of schedule? • Request review (documented by signature) of what? He doesn't have to review QC monthly, but he is. What else does he want to review/sign as an active presence in the lab. • How is Adam coordinating his procedure/ document review process. Should this be a coordinated plan wherein all documents are reviewed in a timely cycle by category by a team of employees (Director, Quality, supervisors): o Personnel documents reviewed against the QMP in Feb o Equipment documents reviewed against the QMP in April o Safety documents reviewed against the QMP in July o Technical documents reviewed against the QMP in September o Quality documents reviewed against the QMP in Nov **(4) Monitoring Mechanism:** See D3003	29Mar2021
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and	D6084	**D6084 Finding 1:** Reference D3011 for our response to the finding. **(1) Immediate Corrective Action:** See D3011 **(2) Patient Impact:** See D3011 **(3) Preventative Measure:** See D3011 **(4) Monitoring Mechanism:** See D30113	29Mar2021

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D6084	Continued From page 111 biological hazards. This Standard is not met as evidenced by: Based on interview with laboratory staff on December 8, 2020, review of policies and procedures (P/P) for General Facilities Safety Plan, and review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the Laboratory Director failed to ensure safety procedures were in place to protect employees from physical, chemical, biochemical, and biohazardous materials. Findings included: 1. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials (See D3011).	D6084		
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 direct observation, interviews conducted with the laboratory staff on 12/08/2020 and 12/09/2020, and review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed , it was determined that the Laboratory Director failed to ensure quality control 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 D5400).	D6093	**Finding 1-8:** See Attachment 9 and ID D5411 In summary, there is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. See full responses in D5415, D5417, D5423, D5433	8Mar2021

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D6093	Continued From page 112 Findings included: 1. The laboratory failed to ensure procedure manuals were established, available to, and followed by laboratory personnel (See D5401). 2. The laboratory failed to ensure the procedure manuals met the requirements specified in 42 CFR 493. 1251 (b)(1)-(b)(14) (See D5403). 3. The laboratory failed to ensure procedure manuals were updated, approved, signed and dated by the current Laboratory Director (See D5407). 4. The laboratory failed to ensure it followed the adopted FDA EUA IFU, the subsequent revisions to the EUA, and changes made in the laboratory's policies and procedures (See D5411). 5. The laboratory failed to ensure reagents were labeled as required (See D5415). 6. The laboratory failed to ensure the decontamination solution used forSARS-CoV-2 RT-PCR were not used past the labeled expiration dates (See D5417). 7. The laboratory failed to ensure it established and verified performance specifications prior to reporting patient test results using its modified FDA EUA IFU SARS-CoV-2 RT-PCR (See D5423). 8. The laboratory failed to the ensure the established maintenance protocol for centrifuges were performed and documented (SeeD5433).	D6093	**(1) Immediate Corrective Action:** Please see D5411, D5415, D5417, D5423, D5433. **(2) Patient Impact:** Please see D5411, D5415, D5417, D5423, D5433. **(3) Preventative Action:** Please see D5411, D5415, D5417, D5423, D5433 **(4) Monitoring Mechanism**: Please see D5411, D5415, D5417, D5423, D5433	
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)	D6094		8Mar2021

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D6094	Continued From page 113 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 direct observation, interviews conducted with the laboratory staff on 12/08/2020 and 12/09/2020, and review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the Laboratory 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 ensure it establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems (See D5391). 2. 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). 3. 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 postanalytic systems (See D5891)	D6094	**Finding 1-3**: See Attachment 9 In summary, there is scientific and clinical debate regarding the best interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. See full responses in IDs D5391, D5791, D5891 **(1) Immediate Corrective Action:** Please see D5391, D5791, D5891. **(2) Patient Impact**: Please see D5391, D5791, D5891. **(3) Preventative Action**: Please see D5391, D5791, D5891. **(4) Monitoring Mechanism:** Please see D5391, D5791, D5891.	
D6101	LABORATORY DIRECTOR RESPONSIBILITIES	D6101		8Mar2021

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D6101	Continued From page 114 CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This Standard is not met as evidenced by: Based on direct observation, interviews conducted with the laboratory staff on 12/08/2020, 12/09/2020, and 12/16/2020, and review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the Laboratory Director failed to ensure there was an adequate number of supervisors for high complexity testing, with appropriate education, training and experience in order to provide accurate and reliable test performance and reporting. Findings included: 1. Analytic Testing Supervision a. Based on interview with the laboratory staff designated as Perkin Elmer Genomics GM Global Laboratory Operations who was providing supervision to the analytic testing laboratory staff, and observation of laboratory personnel on 12/16/2020, lack of training documents, lack of written delegation of duties, it was determined that there was inadequate supervision of the analytic phase of testing. b. Review of CMS 209, signed and dated by the Laboratory Director on 10/15/2020, did not	D6101	**Finding 1-5** 1. Supervisory staff onsite on 12Dec2020 included: a. [redacted] b. c. d. Note – the hiring process for much these staff were not complete at the time CMS 209 was submitted on 15Oct2020. 2. PerkinElmer is contracted by the state to provide testing services. The CDPH Branch Laboratory has extensive support from the wider PerkinElmer team (see org chart). There was no request for updated CMS209 to be submitted prior to the inspection; staff were being onboarded every week in anticipation of the testing demands. The Supervisory staff onsite on 16Dec2020 had not started working at the lab at the time of submission of initial application. It was the expectation , and responsibility, to provide this to the inspection team at time of inspection. a. The PerkinElmer Genomics GM Global Laboratory Operations, who is an experienced ACSP-certified molecular geneticist, does function in an advisory capacity for the laboratory (as he did on 16Dec2020); HOWEVER, he is not a laboratory supervisor and does not perform this function for the clinical laboratory staff. The GM Global Lab Ops may provide oversight and instruction for R&D / development work being done in the laboratory that is separate from clinical activities. b. The Principal Scientist Molecular and Special Diagnostic team member is not a supervisor. As part of the PerkinElmer team, this individual deployed to CDPH Branch Laboratory, submitted credentials, and completed training. She has functioned as a technologist in the analysis area. Technologists may participate in training of staff and sharing knowledge pertaining to the work being performed. **(1) Immediate Corrective Action:** An updated CMS209 with staff current as 04Dec2020 was provided to the inspection team on the first day of inspection 08Dec2020. It included all staff (general and technical supervisors, clinical consultants, and technologists) that had been hired since the initial submission date.	29MAR2021

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D6101	Continued From page 115 indicate the name of the interviewed general supervisor, who was providing supervision to the analytic testing laboratory staff on 12/16/2020. 2. Data Analysis Supervision a. Based on direct observation and interview with the laboratory staff designated as Principal Scientist Molecular and Special Diagnostics Supervisor who was providing supervision to a Clinical Laboratory Scientist performing data analysis on 12/08/2020, lack of training documents, lack of written delegation of duties, it was determined that there was inadequate supervision of laboratory personnel performing data analysis. b. Review of CMS 209, signed and dated by the Laboratory Director on 10/15/2020, did not indicate the name of the general supervisor interviewed providing supervision to the data analysis personnel. c. Based on interview with the Laboratory Director on 12/16/2020, the Principal Scientist Molecular and Special Diagnostics Supervisor interviewed on 12/08/2020 was no longer available on site because the person was only requested to help during the inspection on 12/08/2020. The two general supervisors listed on CMS 209 were also not available onsite. 3. Random patient sampling covering the period from 11/22/2020 to 12/08/2020, showed the laboratory tested and reported 60 out of60 SARS-CoV-2 patient test results, when there was inadequate supervision of laboratory personnel performing data analysis. Accession Number	D6101	Continued from page 115 **(2) Patient Impact:** The lookback shows adequate supervision at the time of the inspection. As a look forward the CDPH Branch Laboratory has added more supervisors and managers to the testing process. Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Action:** An Inspection Work Instruction has been drafted for the CDPH Branch Laboratory to ensure that laboratory personnel understand their role in managing an efficient and appropriate inspection process. This process includes a pre-meeting, assigned roles for the day inspection, and debrief following the inspection. This new process was followed for the LFS on-site visit 11Mar2021 with improved outcome. As part of this process, laboratory personnel are reminded to state their role in the laboratory when introduced to laboratory visitors. A list of current personnel including Laboratory Director, Technical Supervisor, General Supervisor, as well as Mentors has been created to assist in the inspection process (CA-PER-GUIDE-001). Initiated the Roster feature of the MediaLab software, updating all personnel with their designated CLIA roles and utilized as part of the onboarding and separation processes, allowing rapid availability of a current CMS209 at all times. **(4) Monitoring Mechanism:** All monthly scheduled (FY 2021 Audit Schedule) end to end tracer audits and wet lab walkthrough audits, conducted by quality staff, include a review of MediaLab personnel documentation related to qualifications, training and competency for employees involved in specimen handling, testing (reagents and equipment), and result reporting of samples selected for audit.	

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D6101	Continued From page 116 [redacted]	D6101		

4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.

5. The Laboratory Director affirmed (12/16/2020 at 1:00 p.m.) the laboratory failed to ensure it utilized adequate number of laboratory personnel

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	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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

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D6101	Continued From page 117 for high complexity testing with appropriate training to provide supervision accordingly.	D6101	**Finding 1** **Findings a-f** There is scientific and clinical debate regarding the best interpretation of high Ct values. Due to discussion among Laboratory Directors, the procedure used in analysis was not approved in a timely manner. Although not approved, a consistent method of interpretation was used (see Analysis Timeline below). All reports issues did match the analysis rules in place at the time of sample processing. To manage this evolving field, a full-time, on-site Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been hired so that decisions regarding data interpretation area now made in a timely manner, with consultation of CDPH Leadership, the Testing Taskforce and other professionals as appropriate. Please refer to the Analysis Timeline. A single data analysis policy was in place on 08Dec2020. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (<37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 -< 42) were interpreted as inconclusive • 25Jan2021 – present were interpreted as presumptive positive – high Ct values (> 37 -< 42) **(1) Immediate Corrective Action:** The specimens in question were resulted as per SOP (see D5800). **(2) Patient Impact**: See D5800. **(3) Preventive Action**: No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily shift to shift communication checklist (CA-RPT-FM-001, approved by Lab Director on 09Mar2021) for the data analysis team includes a written confirmation of the most recent updated version of the analysis and reporting SOP (CA-RPT-SOP-002). **(4) Monitoring Mechanism**: Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. Tracer audits initiated on 26Feb2021 (10 samples) and 11Mar2021(25 samples) confirmed that reported results matched the current SOP 100% of the time. See Attachment 9 and Attachment 10	
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 direct observation, interviews conducted with the laboratory staff on 12/08/2020, 12/09/2020 and 12/16/2020, and review of test records covering the period from 11/22/2020 to 12/08/2020, for 60 out of 60 patient test records reviewed, it was determined that the Laboratory Director failed to ensure all laboratory staff received appropriate training prior to reporting patient test results. Findings included: 1. Data Analysis Performed at CDPH Branch Lab a. Based on direct observation and interview with the Clinical Laboratory Scientist (CLS) performing data analysis on 12/08/2020, it was determined that the CLS was not updated on the laboratory's current data analysis policies and procedures. b. Review of policies and procedures for data analysis, it was determined at the time of inspection on 12/08/2020, the laboratory has been utilizing two existing data analysis policies	D6102		29Mar2021

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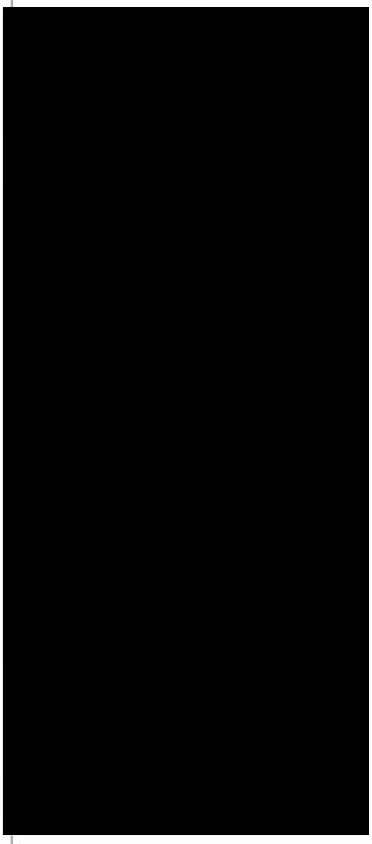
D6102	Continued From page 118 and procedures. c. The following are the accession numbers of the 60 randomly reviewed patient test records covering the period from 11/22/2020 to 12/08/2020, wherein the laboratory tested and reported 60 out of 60 SARS-CoV-2 patient test results, but failed to ensure all laboratory staff received appropriate training prior to reporting patient test results. Accession Number 	D6102		

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D6102	Continued From page 119 [redacted] 2. Data Analysis Performed Outside CDPH Branch Lab (Remote Reporting) a. Based on review of test records, it was determined that the two laboratory staff who performed data analysis from the location outside the CDPH Branch Lab did not have training documentation on how to handle remote reporting, direction and consultation electronically or by telephone when the Laboratory Director and delegated personnel were not with them during remote data analysis. b. Review of policies and procedures (Policy # CA-PER-SOP-002, Title Competency Assessment) failed to include training for remote reporting. c. Random review of test records covering the period from 11/22/2020 to 12/08/2020, the laboratory tested and reported 60 out of 60 SARS-CoV-2 patient test results, showed two laboratory personnel to perform data analysis outside the location of CDPH Branch laboratory in Valencia without documented training for remote reporting. d. Below are 30 representative examples each for EV and MN, wherein data were remotely analyzed, and patient test results were released remotely.	D6102	**D6102 - Finding 2** 1. For the purposes of data analysis, the staff members use a (1) secure data repository and (2) a PerkinElmer LIMS web based application. 2. Both of these are hosted within the PerkinElmer network and are secured behind a firewall. a. This infrastructure configuration eliminates the ability for individuals to access the site and file repository from an external location on a general internet connection. b. Data is never transferred to the location of the remote (offsite) person. 3. The only method to access the systems remotely is through a secured VPN tunnel using a PerkinElmer issued set of credentials on a PerkinElmer issued laptop. During any remote session the data and system being accessed are located on the prior mentioned internal IT systems hardware. 4. The two data analysts who performed remote analysis were trained and qualified to do so: a. EV – Trained in data analysis and delegated the responsibilities of a General Supervisor b. MN – CLS trained in data analysis 5. CMS has made an exception to allow pathologist and other healthcare professionals to work remotely during the pandemic. CAP concurred with this exception. The data analysts are trained based on the current version of CA-RPT-SOP-002 (v6, effective date M/D/Y) See Attachment 10.	

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D6102	Continued From page 120	D6102	**Continued from page 121**	

Data Analyzed by EV:

Accession Number	Date Reported	IP Address
[redacted]	11/22/2020	165.88.255.136
	11/22/2020	165.88.255.136
	11/22/2020	165.88.255.136
	11/22/2020	165.88.255.136
	11/23/2020	165.88.176.91
	11/23/2020	165.88.176.91
	11/23/2020	165.88.176.91
	11/23/2020	165.88.176.91
	11/24/2020	165.88.192.131
	11/24/2020	165.88.192.131
	11/24/2020	165.88.192.131
	11/24/2020	165.88.192.131
	11/25/2020	165.88.176.64
	11/25/2020	165.88.176.64
	11/25/2020	165.88.176.64
	11/25/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/27/2020	165.88.176.64
	11/28/2020	165.88.254.202
	11/28/2020	165.88.254.202
	11/28/2020	165.88.254.202
	11/28/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/29/2020	165.88.254.202
	11/30/2020	165.88.254.202
	11/30/2020	165.88.254.202

(1) Immediate Corrective Action:

- SignOut Manager was instructed by Lab Director, Helen Farzanmehr, on 10Dec2020 that analysts may not analyze data remotely.
- Human Resources informed potential qualified candidates and those awaiting onboarding/ orientation that remote analysis was no longer a possibility; employment contingent upon on site analysis.

(2) Patient Impact: Per Lab Director Dr. Rosendorff, there is no change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm.

(3) Preventative Action: A request to remove VPN access software from analyst computers was placed with the IT group by the project manager on 11Mar2020 and completed on 13Mar2020 by the IT group.

(4) Monitoring Mechanism: Query performed 26Feb2021 demonstrated no remote release of results. Removal of VPN access removes the need to monitor.

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D6102	Continued From page 121	D6102		

Data Analyzed by MN:

Accession Number	Date Reported	IP Address
[redacted]	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/07/2020	165.88.254.222
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200
	12/08/2020	165.88.254.200

e. The total number of results reported by MN from 12/07/2020 to 12/08/2020 was 1,974.

f. The total number of results reported byEV from 11/22/2020 to 11/30/2020 was 13,291.

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D6102	Continued From page 122 3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (12/16/2020 at 1:00 p.m.) the laboratory failed to ensure the laboratory staff have appropriate training prior to reporting patient test results.	D6102		