

State of California—Health and Human Services Agency California Department of Public Health



February 28, 2021

Catherine Tolentino Laboratory Field Services 320 West 4th Street, Suite 890 Los Angeles, CA 90013

RE: STATE: CPH889339

OLA: 05D0407446

CUA: 05D2197416

Dear LFS Examiner, Catherine Tolentino

Attached for your review is the California Department of Public Health's (CDPH) and PerkinElmer's response to Laboratory Field Services (LFS) February 19, 2021 letter regarding deficinecies found at the CDPH (Valencia) Branch Laboratory (VBL) located at 28454 Livingston Ave, Valencia, CA 91355

Please let me know if you need any additional information.

Sincerely

Timothy Bow, Owner Represenatiive

Procurement Officer, Emergency Operations

cc: Mr. Robert Thomas, Chief Laboratory Field Services.

Elsa Eleco, Section Chief, On-Site Licensing Inspection

Dr. Adam Rosendorff, MD, CLIA Laboratory Director, CDPH Branch Lab.





PerkinElmer Genomics CDPH Branch Laboratory 28454 Livingston Avenue Valencia, CA 91355 USA

E-mail: adam.rosendorff@perkinelmer.com

CDPH-Laboratory Field Services 320 W. 4th Street, Suite 890 Los Angeles, CA 90013 Attention: Catherine Tolentino, Examiner II

Dear Catherine

Following the LFS site visit of February 17th, and the LFS report of February 19th entitled "Public Health Laboratory State Inspection- Condition Level Deficiencies-Immediate Jeopardy", please find our detailed official response document. We look forward to LFS comments and response following review.

Please do not hesitate to reach out to me with further questions or requests for clarification.

Sincerely,

Adam Rosendorff, MD Laboratory Director

Cc: Madhuri Hegde, PhD Cc: Lora Bean, PhD Cc: LeeAnn Dennewitz

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D3000	must meet the appl §§493.1101 through approves a procedu quality testing as sp. State Operations M (a) Reporting of SA the Public Health E 400.200 of this chap performs a test that SARS-CoV-2 or to COVID-19 (hereina "SARS-CoV-2 test" test results to the Smanner, and at such the Secretary may procedure the Condition is not a Based on the numb deficiencies cited here Condition for FA was not met as mar Title 42 of the Code Findings included: 1. The laboratory facontamination of painstruments, reager for the laboratory's Transcriptase-Polym (RT-PCR) was mini 2. The laboratory fa procedures to ensur chemical, biochemic materials (See D30).	at performs nonwaived testing icable requirements under h 493.1105, unless HHS ure that provides equivalent pecified in Appendix C of the anual (CMS Pub. 7). RS-CoV-2 test results During mergency, as defined in § poter, each laboratory that is intended to detect diagnose a possible case of fiter referred to as a orescribe. The many many many many many many many many	D3000	See D3003 See D3011 See D3027 See D3041		

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.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (XS) COMPLETION DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D3000 Continued From page 1 D3000 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). D3003 **FACILITIES** D3003 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).

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D3003	procedures (Policy and Quality Management 11/01/2020) stated thumidity monitoring monitoring. The laboration of the labo	aboratory's policies and a CA-QM-SOP-001, Title at Plan, Effective Date only the temperature and for environmental and so pratory failed to have writhe performance, freque of environmental aboratory's policies and assioning, heat inactivativativations, heat inactivativativativations, effective Date T-SOP-001, Title: Accession planes, Effective Date T-SOP-001, Title: Heat Swab Samples, Effective A-EXT-SOP-002, Title: Ch Preparation for Janus 3/2020; CA-EXT-SOP-006, A Extraction Using the ffective Date 11/03/2020; CA-EXT-SOP-006, CA-EXT-SOP-007, Title is known about this in the genetic characteristic RS-CoV suggest that the geneti	d safety sitten ency, on, PCR oning se s G3, 03, 04, 0) th and novel with safety sitten ency.		Appendix A - The Quality Plan has been revised and consolidated information a laboratory processes (CA-6 See Attachment 1: Summary: The laboratory decontamination (see CA-6 See Attachment 1: Summary: The use of 70% of the standard set by CDC. Heat effective method to inactive Disposal of MTM sample counter that have been subjected to in bleach is not necessary. The samples we adequately decontaminated the samples we adequately decontaminated the samples we are subjected to the samples we subject the samples we subject the samples we subject to the samples we subject the samples we	reorganized to about existing QM-SOP-001). Thas a plan for SAFE-POL-019). EtOH meets the inactivation is an ate SARS-CoV-2. collection tubes heat inactivation Therefore, the were handled was	

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED A. BUILDING IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION 02/17/2021 B. WING 05D2197416 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY **VALENCIA, CA 91355** (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D3003 Continued From page 3 D3003 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.

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D3011	declaration signed b 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1: 5. The Laboratory 12, 2021 at approximately failed to epatient specimens, ereagents, materials, FACILITIES CFR(s): 493.1101(d) Safety procedures m	00 SARS-CoV-2 test result 2/16/2020. Director affirmed (Februal nately 2:00 pm) the insure contamination of equipment, instruments, and supplies was minimized.	on lts ary ed.	03011			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION PRETIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY D3011 Continued From page 6 D3011 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: See Attachment 3: During the laboratory tour on December 8, In summary, the BSC 2020 at approximately 11:00 a.m., the laboratory staff stated that COVID-19 sample transfer manufacturer has confirmed that process is performed by one testing person per safety specifications to allow two one Class II Type A2 Biosafety Cabinet (BSC) for individuals to decap in BSC for safely working with materials contaminated with or potentially contaminated with infectious or this assay. The laboratory protocol biohazardous materials and for maintaining has been updated to reflect this. 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

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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.	PREFIX	(FACH DEFICIENCY N	JUST BE PRECEDED BY FULL F	REGULATORY	PREFIX	(EACH CORRECTIVE A) CROSS-REFERENCED TO	CTION SHOULD BE THE APPROPRIATE	COMPLETION DATE
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D3027	Test requisitions an records of test requiauthorizations, inclumedical record if us authorization, for at This Standard is no Based on interviewed director on Decemble test requisitions, an records covering the 12/08/2020, for 10 reviewed, it was defailed to retain reconsance SARS-CoV-2 patient Findings included: 1. The laboratory RT-PCR laboratory direct detection of Spatient samples un Health Officer.	d authorizations. Retain isitions and test uding the patient's charted as the test requisition the day as the test requisition that as evidenced by: I with staff and the labor of the	t or on or eatory e of t 20 to cords atory for 2 for the form te anket	D3027			

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D3027 Continued From page 10 D3027 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. D3041 RETENTION REQUIREMENTS D3041 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: 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. The laboratory issued test results for

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D3041 Continued From page 11 D3041 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. See Attachment 5: 4. CDPH Branch Laboratory has access with Summary: Original and amended the test results for SARS-CoV-2 but failed to provide the original test results reported on versions of report are retained 12/04/2020 and amended on 12/07/2020. and are available to the laboratory. 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 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PREFIX PROVIDER'S PLAN OF CORRECTION COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PREFIX TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY D3041 Continued From page 12 D3041 reports. D5300 PREANALYTIC SYSTEMS D5300 CFR(s): 493.1240 See D5301 Each laboratory that performs nonwaived testing See D3505 must meet the applicable preanalytic system(s) See D5311 requirements in §§493.1241 and 493.1242, unless HHS approves a procedure, specified in See D5313 Appendix C of the State Operations Manual See D5391 (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 Federal Regulation. 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).

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PREFIX PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5300 Continued From page 13 D5300 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). **TEST REQUEST** D5301 D5301 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. During the initial stages of its application for a California clinical laboratory license, we asked the

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D5301	laboratory to submit that will be used. A the several requirem receiving a laborator the laboratory submitted will be used, the laboratory submitted will be used, the laboratory to policy on the use of no mechanism in plarequisition was generating at the 10 randomly revicovering the period to 12/08/2020, wherein SARS-CoV-2 tests at the provide test requisition was generated. 6. Based on the laboratory to policy on the use of no mechanism in plarequisition was generated. The following at the 10 randomly revicovering the period to 12/08/2020, wherein SARS-CoV-2 tests at the provide test requisition was generated. Accession Number the following at the 10 randomly revicovering the period to 12/16/2020, wherein SARS-CoV-2 tests at the provide test requisition was generated. Accession Number the following at the 12/16/2020, the laboratory to 12/16/2020, the laboratory	an example test requisitest requisition is only one test requisition is only one test requisition is only one test to be met, prior to ry license. On 10/20/20 itted a documented title tion Covid 19 Sample e Only v.3." Even though an example requisition or each patien failed to provide a writtestanding orders. There are to ensure a test erated for each patient. The the accession number item and reported results but sitions for each patient test record and reported results but sitions for each patient test record of the laboratory director and reported of the laboratory director and the laborator and the laborat	ne of 20, d, gh the h that t. en was ers of ds ed failed ested.	D5301	See Attachment 4: Summary: Individual s requisitions are obtain available for review an the CDPH Branch Lab years.	ed and are d auditing by	

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACHCORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) DATE TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5301 Continued From page 15 D5301 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. D5305 TEST REQUEST D5305 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION COMPLETION DATE PRETIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5305 Continued From page 16 D5305 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). See Attachment 4: Findings included: Summary: Individual sample 1. The laboratory utilized SARS-CoV-2RT-PCR requisitions are obtained via diagnostic laboratory developed test (LDT) for the electronic means with paper forms direct detection of SARS-CoV-2 virus RNA from available as back-up. Information patient samples. It utilizes Chemagic 360 for the captured in the requisition are isolation of the viral nucleic acids followed by the RT-PCR assay on Analytik Jena Thermal Cycler. available for review and auditing by the CDPH Branch Laboratory for 20 2. During the laboratory tour on 12/08/2020 at approximately 10:00 a.m., the laboratory staff years. 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

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATIONNUMBER: A. BUILDING AND PLAN OF CORRECTION 02/17/2021 05D2197416 B. WNG STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES COMPLETION DATE (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5305 Continued From page 17 D5305 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 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. D5311 SPECIMEN SUBMISSION, HANDLING, AND D5311 REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written

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D5311	policies and proce if applicable: (1) Patient prepar. (2) Specimen colle (3) Specimen labe unique patient ide specimen source. (4) Specimen stor (5) Conditions for (6) Specimen acc (8) Specimen acc (8) Specimen acc (8) Specimen refe This Standard is Based on intervie December 8, 202 procedures (P/P) storage, and ship records covering 12/08/2020, for 1 reviewed, it was failed to ensure t procedures for si handling were for Findings includes 1. The laborate diagnostic labora direct detection of patient samples. isolation of the v RT-PCR assay of 2. Review of th procedures (Poli Specimen Collee Effective Date 1. "Collection kits v packaging and s	edures for each of the fation. ection. eling, including patient rentifier and, when apprage and preservation. especimen transportation especimen collection especimen collection especimen collection especimen collection especimen the period from 11/02/00 out of 10 patient test determined that the lab that written policies and pecimen submission are allowed. d: Ory utilized SARS-CoV-atory developed test (LI of SARS-CoV-2 virus Roughlite especimen in the lab of SARS-CoV-2 virus Roughlite especimen submission are laboratory's policies in a laboratory's policies in the laboratory in th	name or opriate, on. oy: f on od n, ew oftest 2020 to records orratory I nd 2RT-PCR DT) for the RNA from 60 for the red by the nal Cycler. and 002, Title: pping, ection, o the	D5311				

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5311 D5311 Continued From page 19 not collected correctly will lead to inaccurate results." The laboratory failed to provide the instructions See Attachment 6: provided to all staff in the collection sites for their procurement process. Summary: The playbook a. Correct specimen collection using provided by the Testing the appropriate technique and containers Taskforce provides the collection sites sending to the b. Specimen labeling, including patient name or VBL all necessary information unique identifier, and specimen source to ensure sample collection and c. Proper storage and preservation transport meets the requirements of the VBL testing d. Proper transportation process. e. Specimen acceptability, rejection and disposition Our procedure for procuring During the laboratory tour on 12/08/2020 at and distributing kits has approximately 11:00 a.m., the laboratory staff ensured that only samples in stated that they only process samples collected MTM have been tested at the in Molecular Transport Media (MTM), transported CDPH Branch Laboratory. at room temperature, and stable for seven days. The laboratory coordinates with COLOR Color Genomics partnership Laboratory for specimen collection and with the VBL is only one part of submission to CDPH Branch Lab. their business. Other direct Review of COLOR website for specimen testing is done by Color requirements only indicated VTM or UTM media Genomics and is reflected in transported at 2-8 Degrees Celsius within 24 hours, or -20 Degrees Celsius on dry ice if the their corporate website. 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.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5311 Continued From page 20 D5311 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 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. SPECIMEN SUBMISSION, HANDLING, AND D5313 REFERRAL D5313 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:

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY IDENTIFICATIONNUMBER: A. BUILDING COMPLETED AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY D5313 Continued From page 21 D5313 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.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5313 Continued From page22 D5313 The following are the accession numbers of See D3027 and D5311 - sample the 10 randomly reviewed patient test records covering the period from 11/02/2020 to collection date and time are 12/08/2020, wherein the laboratory tested and received for all samples. reported SARS-CoV-2 RT-PCR patient test results, but failed to ensure the date and time of specimen receipt was documented. Accession Number 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. D5391 PREANALYTIC SYSTEMS QUALITY D5391 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

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D5391	through 493.1242. This Standard is not Based on interview December 8, 2020 documentation of procedures for an amonitor, assess, an problems identified specified at CFR 4. Findings included: 1. Review of the procedures (Policy Quality Manageme 11/01/2020) did not mechanism to perfissues regarding the complete informatic accurate test result D5305); as well as handling (See D53) 2. The laboratory facilities. The laboratory facilities. The laboratory facilities. The laboratory facilities and proceducountability or transposition of the complete informatic accountability or transposition of the complete informatic accountab	ot met as evidenced by: with the laboratory staft, review and the lack of policies and procedures in, it was determined that establish written policies ongoing mechanism to and when indicated, correct in the preanalytic system 93.1241 through 493.12 Ilaboratory's policies and # CA-QM-SOP-001, Tit ent Plan, Effective Date of include an ongoing form and document qual fiel lack of test requisition on necessary to ensure ts reporting (See D5301 specimen submission at 11 and D5313). If uses off-site collection ratory failed to establish dures to ensure proper acking of specimens from eight in the laboratory. The on-site survey on the laboratory was only with Media (MTM) to trans with a stated stability of site	ff on (P/P) t the s and ect ems 242. d tle: lity with and and n time using port seven	D5391	Appendix A - The Qualithas been revised and reor consolidated information laboratory processes (CA) See Attachment 7. Summary: As of 15F samples received aft canceled. A retrospfound that 129 / ~1. received more than collection; however, information from the indicates that the deto impact results. See also Attachment See also Attachment See also Attachment	ganized to about existing -QM-SOP-001). Geb2021, all er 96 hours are ective review 6 million were 7 days post additional the manufacturer lay was unlikely		

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY IDENTIFICATION NUMBER: A. BUILDING AND PLAN OF CORRECTION COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION DATE (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5391 Continued From page 24 D5391 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 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. ANALYTIC SYSTEMS D5400 D5400

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. W 3 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID ID PROVIDER'S PLAN OF CORRECTION COMPLETION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D540 D5400 Continued From page 25 CFR(s): 493.1250 See D5401 Each laboratory that performs nonwaived testing See D5403 must meet the applicable analytic systems See D5407 requirements in §§493.1251 through 493.1283, See D5411 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual See D5415 (CMS Pub.7), that provides equivalent quality See D5417 testing. The laboratory must monitor and See D5423 evaluate the overall quality of the analytic See D5433 systems and correct identified problems as specified in §493.1289 for each specialty and See D5791 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: 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). 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

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PRETIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE TAG OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY D5400 D5400 Continued From page 26 labeled as required (SeeD5415). The laboratory failed to ensure the decontamination solution used for SARS-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). 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). D5401 D5401 PROCEDURE MANUAL CFR(s): 493.1251(a) See D5403 See D5407 A written procedures manual for all tests, assays, See D5411 and examinations performed by the laboratory must be available to, and followed by, laboratory See D5415 personnel. Textbooks may supplement but not See D5417 replace the laboratory's written procedures for See D5423 testing or examining specimens. See D5433 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY IDENTIFICATIONNUMBER: A. BUILDING AND PLAN OF CORRECTION COMPLETED 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PRETIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY D5401 Continued From page 27 D5401 determined that 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 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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416	(X2) MULTIPLE A. BUILDING B. WING	ECONSTRUCTION	(X3) DATE SURVEY COMPLETED	
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	declaration signed to 12/16/2020, the lab approximately 430,0 from 11/02/2020 to 14. The Laboratory (February 12, 2021	2/16/2020. Director affirmed at approximately 2:00 ailed to ensure policies re established and				
	and procedures are D5403).	equired elements for policies enumerated in D5403, (Sec	e			
D5403	when applicable to t) ual must include the following	D5403			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued From page 29 D5403 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 (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 verified in §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,

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (XS) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5403 D5403 Continued From page 30 random review of patient test records covering the period from 11/22/2020 to 12/08/2020, for 60 See Attachment 6 and summary in out of 60 patient test records reviewed, it was determined that the laboratory's procedure failed D5311 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)

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued From page 31 D5403 c. Correct specimen collection using the appropriate technique and containers See Attachment 6 and Summary in D5311 (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 See Attachment 8 specimen collection and submission. Summary: procedure and process are (4) Review of COLOR website for designed to match the electronic specimen requirements indicated VTM or order to the sample tube received. UTM media transport. (5) The laboratory failed to specify and include in See also Attachment 4 and Summary its policies and procedures, the use ofMTM. in D3027 d. Specimen labeling, including patient Attachment 6 and Summary in name or unique identifier, and specimen D5311 (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 samplewas

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D5403	i. Total n ii. Site po iii. Trackii iv. collect sample v. Site na vi. Site ac (2) Review of the la CA-CLSRV-SOP-00 Storage and Shippin indicated the eleme electronic manifest, i. Trackii ii. Manife iii. Date iv. Site na vi. Site na vi. Site iii. Manife iii. Date iv. Site na vi. Si	umber of samples receipint of contact ing company number ive date for e collected ame didress aboratory's P/P (Policy# 02, Title Specimen Colle ing, Effective Date 12/07 ints for the paper and such as: ing company and number est number of sample collection name didress point of contact er, email address) number of samples ailed to ensure the police information for individual attent name or unique men source. e, preservation,	y staff MTM	D5403	See Attachment 4 and summary in D3027. See Attachment 6 and summary in D5311		

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION (X4) ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued From page 33 D5403 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued From page 34 D5403 09/16/2020 and 01/12/2021). (7) The laboratory failed to specify and include in its policies and procedures, the use of MTM. Specimen acceptability, rejection and disposition (1) Review of the laboratory's P/P (Policy # CA-CLSRV-SOP-002, Title Specimen See Attachment 6 and Collection, Storage and Shipping, Effective Date Summary D5311. 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.

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION (X4) ID PROVIDER'S PLAN OF CORRECTION PRETIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5403 Continued From page 35 D5403 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 See Attachment 9 interpretation of results. Summary: In summary, there is scientific and clinical debate regarding the best Findings included: interpretation of high Ct values. All At the time of inspection on 12/08/2020, the reports issues did match the analysis rules laboratory failed to provide an approved policy in place at the time of sample processing. and procedure for test calculations, and To manage this evolving field, a full-time, interpretation of test results utilized by the on-site Laboratory Director, who is laboratory staff interviewed performing onsite directly involved in day-to-day laboratory data analysis and interpretation. operations and result reporting has been hired so that decisions regarding data b. The laboratory also requested approval that interpretation area now made in a timely the quality metrics (including raw data) and manner, with consultation of CDPH curves generated from the PCR test be analyzed Leadership, the Testing Taskforce and at remote locations by CLIA qualified testing personnel for test results of positive, negative, other professionals as appropriate. invalid, or inconclusive in order to shorten the turn- around-time from specimen collection to For remote analysis response, see reporting of the test on 12/21/2020 without an Attachment 10 and Summary in D6102. 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

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: (X3) DATE SURVEY COMPLETED STATEMENT OF DEFICIENCIES A. BUILDING AND PLAN OF CORRECTION 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX TAG OR LSC IDENTIFYING INFORMATION) TAG Continued From page 36 D5403 D5403 procedure, including test calculations, and interpretation of results. Accession Number 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.

ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		R:	(X2) MULTIP A. BUILDING B. WING	LE CONSTRUCTION	(X3) DATE SU COMPLE				
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<u></u>	e. The La (February opm) the lab the step-by procedure, including te results. 3. Based laboratory or review of procedure of procedure of the period of the	on direct of staff on Description on direct of staff on Description of Description of Staff on Description of Staff on Description of Staff on Description of Staff on One of Staff on One of Staff on St	pirector at approximed to ensumance of the servation of	nately 2:00 sure include of the interpretation on, interviews and 9, 2020, res, quality co A) records covering 2/08/2020, fo eviewed, it was a procedure facent informationes). FU for PE New Ction Kit (Effec 6/2020 and cted results for Result interpret sars-cov-2 Not sars-cov-2 Dete	with introl ing in 60 is ailled in on w ctive in the	D5403	See Attachment 9 Summary: In summary, the and clinical debate regarding interpretation of high Ct vareports issues did match the in place at the time of samp. To manage this evolving fix on-site Laboratory Director directly involved in day-to-operations and result report hired so that decisions regainterpretation area now manner, with consultation Leadership, the Testing Taxother professionals as appropriate the summary of	ng the best alues. All ae analysis rules ple processing. eld, a full-time, r, who is day laboratory rting has been arding data ade in a timely of CDPH skforce and	
	/ One of the targets ≤ 42 SARS-CoV-2 Detected Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.								

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D5403	d. Based on the declaration signed 12/16/2020, the lat approximately 430, from 11/02/2020 to e. The Laborator 12, 2021 at approximately failed to and consistent info (normal values). 4. Based on with laboratory sta	laboratory's annual testile by the laboratory director of the laboratory director of the laboratory reported (12/16/2020). The property of the laboratory affirmed (February 2:10 pm) the laboratory ensure include complete mation on reference into the laboratory of	or on esults oruary te ervals views	D5403			
	with laboratory stareview of policies at (QC) and quality a random review of the period from 11 out of 60 patient to	direct observation, intendiff on December 8 and 9 and procedures, quality assurance (QA) records, patient test records cover/22/2020 to 12/08/2020 est records reviewed, it also approach to half a laboratory failed to half	control ering for 60				

AND PLAN OF CORRECTION IDENTIFICATIONNUM 05D219		(X1) PROVIDER/SUPPLIER/I IDENTIFICATIONNUMB	ER:	(X2) MULTIPL A. BUILDING B. WING	E CONSTRUCTION	(X3) DATE SU COMPLET	
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D5403	policies and proced Reporting. Findings included: a. At the time of in: 9, 2020, and until Fe laboratory failed to pand procedure for ling. b. The following at the 60 randomly revice covering the period 12/08/2020, wherein SARS-CoV-2 tests a failed to provide policy.	spection on December 8 between 12, 2021, the provide an approved po- fectious Diseases The the accession number fewed patient test recon- from 11/22/2020 to the laboratory performand reported results, but ficies to ensure it compliance Reporting required	and licy ers of rds ed t	D5403	See Attachment 16. Infectious disease info reported as required to		

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBI 05D21974	ER:		CONSTRUCTION	(X3) DATE S COMPLI	
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D5407	approved, signed, a laboratory director b This Standard is not 1. Based on direct laboratory staff on E) inges in procedures mu nd dated by the current	s with 2020,	D5407			

	OF DEFICIENCIE F CORRECTION		DER/SUPPLIER/CLIA FICATIONNUMBER: 05D2197416	A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPL	
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D5407	control (QC) random reviet the period frout of 32 pat determined to the procedur using the Period Reaction (RT approved, signification). Findings included a. During to 12/08/202 directors and requested for investigation increased number of the Emergiaboratory's a New Corona "Examination Specimen Rethe expected and negative in the period from the the	ew of patient test re om 12/04/2020 to ient test records re hat the laboratory e for reporting incorkin Elmer New Coon Kit Real Time P F-PCR) in vitro diagoned, and dated by uded: the first day of the coon of the laboratory of the laboratory of and corrective act mber of inconclusive wed the Instruction ency Use Authorizadopted test method in and Interpretation esults section should be control.	2/10/2020, for 32 eviewed, it was failed to ensure conclusive result connavirus Nucleic colymerase Chain gnostic was y the laboratory con-site inspection laboratory personnel, and ocumented ion regarding the ye patient results. Ins for Use (IFU) cation of the cod, Perkin Elmer Detection Kit. The in of Patient wed a table listing with valid positive Result interpretation SARS-CoV-2 Not Detected	D5407			
	/ Both targets ≤ 42 SARS-CoV-2 Detected / One of the targets ≤ 42 SARS-CoV-2 Detected Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.						

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY IDENTIFICATION NUMBER: A. BUILDING AND PLAN OF CORRECTION COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) 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 See Attachment 9 interpretation of patient specimen results. Summary: In summary, there is scientific and clinical debate regarding (i) A policy and procedure signed by the the best interpretation of high Ct laboratory was not available on December 8, values. All reports issues did match the 2020. analysis rules in place at the time of sample processing. To manage this (ii) Neither an unsigned policy and procedure evolving field, a full-time, on-site was available on December 8, 2020. Laboratory Director, who is directly Further interviews with the laboratory director involved in day-to-day laboratory on 12/08/2020, indicated there was a possibility operations and result reporting has that patient test results were reported in error as been hired so that decisions regarding a result of incorrect data analysis and data interpretation area now made in a interpretation. timely manner, with consultation of CDPH Leadership, the Testing e. The following day on 12/09/2020, we Taskforce and other professionals as conducted random sampling of an additional 32 appropriate. patient test records with specimens collected during the first week December until 12/08/2020. For remote analysis response, see Attachment 10 and Summary in D6102. On December 16, 2020, we wentback 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	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.		D5407	See Attachment 11: Summary: Contrary to Lab affirmation, User Specifica Acceptance Testing forms: Please note, the effective de the date the blank form (te effective. For evolution of the interprevalues, please see Attachment	tion and were signed. ate 29Oct2020 is mplate) was					
	i. Com laboratory specimen result cate	Not Detect FAM and instead of "Not IC Failure s No changes parative reg's adopted y's policy for results, she gory of In the was no interpretable. Was no interpretable to the second	Description rule for the new SOP: ted" Ct cutoff changed from 37 to 42 ROX >37 and <=12 will be called Detected". amples (HEX=0 or >40) will be release to no controls and "Detected" rules eview of the IFU for the di EUA method, and the or interpretting patient howed the laboratory add conclusive. dication that this docume equirement Specification	ed as "Invalid". ded a						

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY D5407 D5407 Continued From page 45 CA-COMP-FM-001 Version 1.0, was approved, signed, and dated by the Laboratory Director. See Attachment 9 This policy and procedure did not include the laboratory's signature. There was also no Summary: In summary, there is scientific and indication or verification that the laboratory clinical debate regarding the best director affixed a digital signature approving, signing and dating the document interpretation of high Ct values. All reports issues did match the analysis rules in place at the time of sample processing. To manage this 2. Based on direct observation, interviews with evolving field, a full-time, on-site Laboratory laboratory staff on December 8 and 9, 2020, Director, who is directly involved in day-toreview of policies and procedures, quality control day laboratory operations and result reporting (QC) and quality assurance (QA) records, has been hired so that decisions regarding data random review of patient test records covering interpretation area now made in a timely the period from 11/22/2020 to 12/08/2020, for 60 manner, with consultation of CDPH out of 60 patient test records reviewed, it was Leadership, the Testing Taskforce and other determined that the laboratory failed to provide professionals as appropriate. the updated and approved procedure manuals signed by the current laboratory director for the Perkin Elmer New Coronavirus Nucleic Acid For remote analysis response, see Attachment Detection Kit Real Time Polymerase Chain 10 and Summary in D6102. 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: Client procedure manual provided to all staff in the collection sites for patient preparation, See Attachment 6 and Summary for specimen collection, labeling, storage, D5311. preservation, transportation, processing, referral, and criteria for specimen acceptability.

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES A. BUILDING COMPLETED IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PRETIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D5407 0 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 Reference Intervals (normal values) See Attachment 16. iv. Infectious Diseases Reporting b. The following are the accession numbers of Infectious disease information is the 60 randomly reviewed patient test records being reported as required to state covering the period from 11/22/2020 to agencies. 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

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/S IDENTIFICATIONNUMB	ER:	(X2) MULTIPLE A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPLE	
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D5407	Continued From pa	ge 47		D5407			
	declaration signed by 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1 d. The Laboratory 12, 2021 at approximation from 12/2020 to 1 d. The Laboratory failed to proper instructions to step-by-step test calinterpretation of residuals.	2/16/2020. Director affirmed (Februately 2:10 pm) the provide policies to ensure to clients, accurate lculations, reference intuits, and it complied with Reporting required by lo	or on sults ruary e ervals,				
D5411	The testing must be manufacturer's instr provides test results	be selected by the labor performed following the uctions and in a manne within the laboratory's cations for each test sys	er that stated	D5411			
	Based on direct obs	t met as evidenced by: servation, interviews with December 8 and 9, 2020 and procedures (P/P), qu),				

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2197416 ME OF PROVIDER OR SUPPLIER		BER:	(X2) MULTIPLE A. BUILDING _ B. WING	CONSTRUCTION	(X3) DATE S COMPLI	
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D5411	control (QC) and querandom review of pathe period from 11/2 out of 60 patient test determined that the followed the adopted subsequent revision changes made in the procedures. Findings included: 1. Review of the lassecification studies (IFU) for Perkin Elme Acid Detection Kit, a procedures available inspection, the labor following: a. Decontamination ii. Review of the labor following: a. Decontamination iii. Review	ality assurance (QA) reatient test records cover 2/2020 to 12/08/2020, it records reviewed, it we laboratory failed to ensist FDA EUA IFU, the sto the EUA IFU, and a laboratory's policies a laboratory's policies a laboratory's performance, EUA Instructions for User New Coronavirus Nuclear New	fing for 60 as ure it Ind Seleic he New ective s and n tion. d the h a I or ect	D5411			

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D5411	iii Due to safety come Sodium Hypochlorite laboratory used ethativ. However, contrat concentration in the 70% ethanol, and not v. The laboratory farmanufacturer's instruction. The laboratory also performance specific ethanol is an effectiv 10% Sodium Hypoch centrifuge tubes and b. Heat Inactivation i. Review of the late Instructions for Use (Coronavirus Nucleic Date 03/20/2020, Re 01/12/2021) did not it procedures for swab ii. Review of the late procedures (Policy # Inactivation of Viral Sthe following: ii.a. Use of oviii.b. Pre-cool	lution. cerns with using 10% e solution with VTM, the solution with VTM, the anol. ry to the specified ethan IFU, the laboratory, used to 75% ethanol. illed to follow suctions specified in the laboratory specified in the laboration studies showing the decontaminant instead alorite solution for discard filter-tips. In of Swab Samples boratory's FDA EUA (IFU) for Perkin Elmer Nacid Detection Kit (Effectivised 09/16/2020 and include the heat inactiva	FU. 70% d of ded lew tive tion	D5411	See attachment 1: Summary: The use meets the standard Heat inactivation is method to inactivat CoV-2. Disposal of collection tubes that subjected to heat in bleach is not necess. Therefore, the area samples were handle adequately decontains.	set by CDC. s an effective te SARS- f MTM sample at have been factivation in sary. in which the led was	

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PRETIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5411 Continued From page 50 D5411 iii. The laboratory failed to provide performance specification studies for the heat inactivation of swab samples. Storage Conditions for nasopharyngeal, oropharyngeal, and anterior nasal swabs (Extracted RNA) 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 See Attachment 12. -15 degrees Celsius. Review of the laboratory's policies and Long-term storage temperature: The procedures (Title CA-EXT-SOP-004 Title Viral long-term storage at -84 - -76oC is RNA/DNA Extraction Using the Chemagic 360, intended for post-testing storage. This is Effective Date 11/03/2020 stated that, "Extracted not a change to the method described in the nucleic acids should be stored at -84 to -76 IFU and has no impact on the performance degrees Celsius for long term storage." of the assay. 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 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:

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION DATE (X4) ID PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY D5411 Continued From page 51 D5411 Step Temperature Time # of Cycles See Attachment 12. 37 degrees Celsius 2 minutes 2 50 degrees Celsius 5 minutes 1 42 degrees Celsius 35 minutes 1 3 Summary: A universal .trf file 10 minutes 1 94 degrees Celsius 4 containing the PCR thermocycling 10 seconds 94 degrees Celsius conditions is generated by the PCR 55 degrees Celsius 15 seconds 45 Janus program at the time a 384-65 degrees Celsius 45 seconds well plate is set-up. The .trf file is imported to the AJ thermocycler. *Collect fluorescence signal during the final 65 This file is correct. Records from degrees Celsius step the PCR output files for the 60 Review of the laboratory's policies and randomly chosen samples procedures (Policy # CA-PCR-SOP-002, Title demonstrate that the correct SARS-CoV-2-RT-PCR Using the Analytic, temperature is being used (LFS Effective Date 11/04/2020) stated the following Response Cycling Parameters). thermal cycler parameters: Appendix A of CA-PCR-SOP-002v1 contained a typographical error. # of Cycles Temperature Time Step that was later corrected. 25 degrees Not 1 2 minutes Celsius indicated 50 degrees 15 Not 2 indicated Celsius minutes Not 95 degrees 3 2 minutes Celsius indicated 95 degrees Not 4 3 seconds Celsius indicated 60 degrees 30 Not 5 indicated Celsius seconds

	FOF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB	ER:	(X2) MULTIPLE A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPLI	
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D5411	iii. Review of the sar Title SARS-CoV-2-F Jena, Effective Date following thermal cy Step Temperatur 1 25 degrees Cels 2 50 degrees Cels 3 95 degrees Cels 4 95 degrees Cels 5 60 degrees Cels 5 60 degrees Cels iv. The instruction to during the final 60 d specified in laborato (ii) and d (iii) is not tithe IFU, which indic signal during the final v. The laboratory manufacturer's instruction to the IFU, which indic signal during the final v. The laboratory manufacturer's instruction to the IFU, which indic signal during the final v. The laboratory manufacturer's instruction of the IFU in the above-described parameters. e. Interpretation of the IFC or on a virus Nucleic Date 03/20/2020, Re 01/12/2021) stated to kit with valid quality i.a.SA	me policies and procedu RT-PCR Using the Analy 11/04/2020, indicated clers dated 10/27/2020. The Time # of Cy isius 2 minutes 1 isius 15 minutes 1 isius 3 seconds 1 isius 30 seconds 45	ytic the cles cles 60 signal in d fon in ce tep."	D5411			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACHCORRECTIVE ACTIONS HOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5411 Continued From page 53 D5411 i.c.Invalid See Attachment 9 ii. Based on interview with the Laboratory Summary: In summary, there is Director on 12/08/2020 and 12/09/2020, the scientific and clinical debate regarding laboratory should be reporting the following: the best interpretation of high Ct values. All reports issues did match the analysis ii.a.SARS-CoV-2 Not Detected rules in place at the time of sample ii.b.SARS-CoV-2 Detected processing. To manage this evolving ii.c.Inconclusive field, a full-time, on-site Laboratory ii.d. Invalid Director, who is directly involved in dayto-day laboratory operations and result iii. At the time of inspection on 12/08/2020 and reporting has been hired so that 12/09/2020, the laboratory failed to provide performance specification studies to support the decisions regarding data interpretation updated interpretation of test results, to include area now made in a timely manner, with inconclusive result. consultation of CDPH Leadership, the Testing Taskforce and other 2. The following are the accession numbers of professionals as appropriate. 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

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D5411	3. Based on the la declaration signed by 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1: 4. The Laboratory 12, 2021 at approximatoratory's failure to instructions specified director also affirmed performance specific modification of the predoctor and the predoctor and the predoctor and the predoctor also affirmed performance specific modification of the predoctor also affirmed performance specific modification.	boratory's annual testing y the laboratory director oratory reported 00 SARS-CoV-2 test result 2/16/2020. Director affirmed (Februal nately 2:10 pm) the ofollow manufacturer's din the IFU. The laborated the absence of cation studies to support occedure not indicated in taboratory director also bry failed to establish its	on alts ary ory the	D5411			

STATEMENT OF DEFICIENCIES (X: AND PLAN OF CORRECTION				(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED	
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D5415	materials, calibration supplies, as appropriated the following (1) Identity and where or concentration. (2) Storage requirem (3) Preparation and experiment information. This Standard is not Based on direct obselaboratory staff on Directive of policies and control (QC) and quarandom review of pathe period from 11/2: out of 60 patient test determined that the I labeled the reagents. Findings included: 1. Review of the lat procedures (Policy # Labeling of Reagents Date 12/09/2020) star on labeling reagents:	, culture media, control materials, and other riate, must be labeled to g: a significant, titer, strenguents. expiration dates, mation required for property and the second of the secon	gth per use. ality ords, ing or 60 as ure it	D5415	See Attachment 2: See Attachment 2: Summary: In summary, expir	ad	
	 b. Expiration Date c. Initials of the per d. Date of preparat reconstituted by the le. e. Storage conditio exposure to light, etc manufacturer 	Expiration Date Initials of the person preparing the label Date of preparation, filtered, or constituted by the laboratory (if applicable) Storage conditions (e.g., temperature, coposure to light, etc. as specified by the anufacturer Any relevant biohazard or chemical			reagents, such as the 70% EtO only expired by a few days. Sir main concern of aging EtOH i evaporation and CDC states o EtOH is effective, the risk pose low. Corrective actions are bei taken.	H, were ace the as ver 60% ed is	

AND PLAN OF CORRECTION IDENTIFICATIONS		(X1) PROVIDER/SUPPLIER/OIDENTIFICATIONNUMB	ER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED 02/17/2021	
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D5415	2. During the laborate approximately 10:00 found with the follow properly: a. Elution Buffer x 1b. Magnetic Buffer c. Milli Q Water x 3 person, date pre 3. The following are the 60 randomly revisit covering the period find 12/08/2020, wherein	ory tour on 12/08/2020 a.m., the laboratory waing reagents not labeled a.m., the laboratory waing reagents not labeled a.m., the laboratory waing reagents not labeled a.m. 1- No initial of the person acceptance of the accession number of the accession number of the laboratory performent reported results but	ed on rson tial of the n.	D5415			

AND PLAN OF CORRECTION IDENTIFICAT				(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE 8 COMPU	
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D5415	declaration signed 12/16/2020, the lal approximately 430 from 11/02/2020 to 5. The Laborator (February 12, 202	laboratory's annual testi by the laboratory direct boratory reported ,000 SARS-CoV-2 test re 12/16/2020. ry Director affirmed 1 at approximately	or on	D5415			
D5417	(February 12, 2021 at approximately 2:10 pm) the laboratory's failure to label the reagents utilized for testing.		D5417				

AND PLAN OF CORRECTION IDENTIFICATION				A. BUILDIN	PLE CONSTRUCTION G	(X3) DATE SUI COMPLET	ED	
CDPH BRANCH LABORATORY 28454 L				DDRESS, CITY, STATE, ZIP CODE 4 LIVINGSTON AVE ENCIA, CA 91355				
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	approximately observed to ha Solution in disp expiration date a.1. Lot # 2670 12/03/2020 (2 dispe a.2. Lot # A100 12/07/2020 (2 dispe 2. Review of the laprocedures (Policy # Quality Managemen 11/01/2020) stated the should be used in teindicated expiration of the following arthe 60 randomly revicovering the period f 12/08/2020, wherein SARS-CoV-2 tests a	pratory tour on 12/08/20210:30 am., the laborator ve four 70% Ethanol Clebensing bottles beyond it. 15, ExpirationDate: nsing bottles) 12002B, ExpirationDate nsing bottles) aboratories policies and a CA-QM-SOP-001, title to Plan, Effective Date nat reagents and chemic sting process within their date. The the accession number lewed patient test recording to the patient test recording test test test recording test test recording test test test test recording test test test test test test test tes	y was eaning ts : als ir rs of ds	D5417	Appendix A - The Qualit Plan has been revised and consolidated information laboratory processes (CA-See Attachment 1: Summary: The laboratory decontamination (see CA-POL-019). See Attachment 2: Summary: In summary, e such as the 70% EtOH, we a few days. Since the main EtOH is evaporation and 60% EtOH is effective, the Corrective actions are being	reorganized to about existing -QM-SOP-001). Thas a plan for SAFE- expired reagents, ere only expired by a concern of aging CDC states over erisk posed is low.		

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D5417	Continued From pa	ge 59		D5417			
D5423	declaration signed by 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 12/5. The Laboratory 12, 2021 at approximate approximately 430,00 from 11/02/2020 to 12/5.	20 SARS-CoV-2 test result 2/16/2020. Director affirmed (Februal lately 2:10 pm) the conitor the expiration date laning solution utilized in dedure. ND VERIFICATION OF	lts	D5423			
		modifies an FDA-cleared n, or introduces a test sys earance or approval					

	AND PLAN OF CORRECTION IDENTIFICATION NU		. TO NOTE TO A STATE OF THE PARTY OF THE PAR		BER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE S COMPL	ETED
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D5423	(including methods standardized method procedures), or use performance specification manufacturer metest results, establist performance characteristics (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical set (2)(iv) Analytical set (2)(iv) Analytical set (2)(iv) Reportable results and the substances. (2)(v) Reportable results and the substance in (2)(vii) Any other perequired for test per This Standard is not Based on direct obsilaboratory staff on Dreview of the laboratic EUA IFU Perkin Elin Acid Detection Kit Findings included: 1. Review of the laboratic feed of the substance in (2)(8/2020, for 60 control of the substance in the substa	developed in-house and ods such as text book as a test system in which ications are not provided that, before reporting pash for each test system to ications for the following otherstics, as applicable: Instituty. Instituty. Instituty to include interference of test results for the tervals (normal values).	ering ering ne test c h o o c c h o o o o o o o o o o o o o	D5423					

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG **DEFICIENCY**) D5423 Continued From page 61 D5423 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 See Attachment 13. Detection Kit (01/12/2021) stated under the product authorization that, "Your product is a test for the qualitative detection of nucleic acid from Summary: The laboratory is using SARS-CoV-2 in human oropharyngeal and this kit within the limits of the nasopharyngeal swab specimens collected by a intended use. 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY COMPLETION PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) DATE TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5423 Continued From page 62 D5423 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. **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 See attachment 1: 09/16/2020 and 01/12/2021) stated under warnings Summary: The use of 70% EtOH and precautions #7 that, "Sterile centrifuge tubes and filter-tips should be disposed into a waste bin meets the standard set by CDC. containing a 10% Sodium Hypochlorite solution. After Heat inactivation is an effective the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared method to inactivate SARS-10% Sodium Hypochlorite solution, and then cleaned CoV-2. Disposal of MTM sample with 75% Ethanol or pure water. Finally, turn on UV light to disinfect working surfaces for 30 minutes." collection tubes that have been subjected to heat inactivation in ii. Based on direct observation and interview with bleach is not necessary. the laboratory staff on 12/08/2020, the laboratory was utilizing 70% Ethanol as their general Therefore, the area in which the decontamination solution. samples were handled was adequately decontaminated. 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING _ AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION (X4) ID PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5423 Continued From page 63 D5423 decontaminant instead of 10% Sodium Hypochlorite solution for discarded centrifuge tubes and filter-tips. Heat Inactivation of Swab Samples 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. See Attachment 1: Review of the laboratory's policies and procedures (Policy # CA-EXT-SOP-001 Heat Summary: The use of 70% EtOH Inactivation of Viral Swab Samples indicated the meets the standard set by CDC. following: Disposal of MTM sample collection tubes that have been subjected to heat ii.a.Use of oven to 70 degrees Celsius inactivation in bleach is not ii.b.Pre-cool centrifuge to 20 degrees Celsius ii.c. The use of centrifuge at 1200 RPM for 1 minute necessary. Therefore, the area in which the samples were handled was iii. The laboratory failed to provide studies about adequately decontaminated. the heat inactivation of swab samples. d. Storage Conditions for nasopharyngeal, oropharyngeal, and anterior nasal swabs (Extracted RNA) 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. Review of the laboratory's policies and procedures (Title CA-EXT-SOP-004 Title Viral

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	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			1				
		rees Celsius rees Celsius	15 minutes 2 minutes	1				
		ees Celsius	3 seconds	i				
	5 60 degr	ees Celsius	30 seconds	45				
	*Collect fluo degrees Ce	Marie Charles and Control of the Con	nal during the	final 60				
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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5423 Continued From page 66 D5423 f. Interpretation of Test Results 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 See Attachment 9. 12/08/2020 and 12/09/2020, the laboratory should be reporting the following: Summary: In summary, there is scientific ii.a. SARS-CoV-2 Not Detected and clinical debate regarding the best ii.b. SARS-CoV-2 Detected interpretation of high Ct values. All ii.c. Inconclusive reports issues did match the analysis ii.d. Invalid rules in place at the time of sample iii. The laboratory added "inconclusive" to the list of expected results. At the time of inspection on processing. To manage this evolving 12/08/2020 and 12/09/2020, the laboratory failed to field, a full-time, on-site Laboratory provide performance specification studies for updated Director, who is directly involved in dayinterpretation of test results. to-day laboratory operations and result reporting has been hired so that decisions The following are the accession numbers of regarding data interpretation area now the 60 randomly reviewed patient test records made in a timely manner, with covering the period from 11/22/2020 to consultation of CDPH Leadership, the 12/08/2020, wherein the laboratory modified the procedure listed in the IFU of the SARS-CoV-2 Testing Taskforce and other EUA, tested and reported results, but failed to professionals as appropriate. 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

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D5423	3. Based on the ladeclaration signed by 12/16/2020, the laboratory failed to papplicable performa	boratory's annual testing by the laboratory director oratory reported 00 SARS-CoV-2 test res 2/16/2020.	on ults uary r the	D5433				

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES IDENTIFICATIONNUMBER: A. BUILDING COMPLETED AND PLAN OF CORRECTION 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PRETIX PREFIX OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5433 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 Appendix A - The Quality Management Quality Management Plan, Effective Date Plan has been revised and reorganized to 11/01/2020) stated that, "Logs are annotated consolidated information about existing every day of laboratory operation. If the laboratory processes (CA-QM-SOP-001). instrument is not used during a regular laboratory workday, the log must indicate that the equipment was not used." During the laboratory tour on 12/08/2020 at approximately 11:00 a.m., the laboratory was

found with a centrifuge maintenance log which

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY COMPLETED AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING 05D2197416 B. WNG 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 (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5433 Continued From page 69 D5433 did not annotate every day of laboratory operation. See Attachment 2: a. Centrifuge SN # JBR20K009, not annotated on 12/02/2020, 12/03/2020, 12/04/2020, and 12/05/2020. Summary: In summary, issues with maintenance logs are primarily good 3. The following are the accession numbers of documentation practice and properly the 60 randomly reviewed patient test records completing logs when an instrument is covering the period from 11/22/2020 to not in use. A corrective action plan is in 12/08/2020, wherein the laboratory failed to place. ensure the established maintenance protocol were performed and documented. Accession Number

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D5791	Continued From pa	ge 73		D5791			
D5800	declaration signed b 12/16/2020, the labor approximately 430,00 from 11/02/2020 to 13 4. The Laboratory 12, 2021 at approxim laboratory failed to e mechanism to monitor indicated, correct pro systems. POSTANALYTIC SY CFR(s): 493.1290 Each laboratory that	200 SARS-CoV-2 test res 2/16/2020. Director affirmed (Febru- nately 2:10 pm) the nsure there was an ong or, assess and when oblems in the analytic	r on sults uary noing	D5800			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5800 Continued From page 74 D5800 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: See Attachment 9 Summary: In summary, there is scientific The laboratory failed to ensure the electronic and clinical debate regarding the best system(s) it used, accurately and reliably interpretation of high Ct values. All reports transmitted patient-specific data from the point of issues did match the analysis rules in place at data entry to final report destination. (See the time of sample processing. To manage D5801). this evolving field, a full-time, on-site Laboratory Director, who is directly 2. The laboratory failed to ensure its test results involved in day-to-day laboratory operations provided the correct interpretation for SARS-CoV-2 (See D5805). and result reporting has been hired so that decisions regarding data interpretation area The laboratory failed to ensure its accurate now made in a timely manner, with reference intervals determined by the laboratory consultation of CDPH Leadership, the were available for the authorized person, or Testing Taskforce and other professionals as individual responsible for using the test results appropriate. (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).

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY IDENTIFICATIONNUMBER: AND PLAN OF CORRECTION A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5800 Continued From page 75 D5800 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) D5801 TEST REPORT D5801 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

	AND PLAN OF CORRECTION IDENTIFICA		OVIDER/SUPPLIER/O ENTIFICATIONNUMBE 05D21974	ER:	(X2) MULTIF A. BUILDING B. WING	PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
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D5801	the electronic sys reliably transmitte point of data entry. Findings included 1. The laborator and postanalytic pentity, COLOR. 2. The following emailed by the lab reported as "Nega a. The laborator laboratory to the electronic laboratory to the electronic systems."	tem(s) it u d patient-s d to final re s y subcont chases of 13 final p coratory or ative" for S y LIMC LI examiners ed a result result gen	expecific data, from the precipitation of the preci	m the llytic side ts re the	D5801	See Attachment 9 Summary: In summary, and clinical debate regard interpretation of high Ct issues did match the analat the time of sample promanage this evolving fiel site Laboratory Director, involved in day-to-day la operations and result rephired so that decisions reinterpretation area now manner, with consultation Leadership, the Testing Testi	ding the best values. All reports ysis rules in place cessing. To d, a full-time, on- who is directly boratory orting has been garding data nade in a timely n of CDPH	
	NOT DETECTED	Not Detected Not Detected	Final Test Fleport Negative for SARS-CoV-2			professionals as appropri		

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/G IDENTIFICATION NUMB 05D21974	ER:	(X2) MULTIPLE A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPLI	
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D5801	3. Review of the e the Director of Clinic and review of the 32 by the examiners on a. Thirteen (13) pa as "Not Detected" w reported "Inconclusive Reported as Not Der reported as Inconclusive b. Nineteen (19) p reported as "Inconclusive b. Nineteen (19) p	-mail communication set al Informatics on 12/13 patient test records ob December 16, 2020 shoutent results were reported it should have been ve" on December 10, 20 tected, but should be	/2020, tained owed: tted 120.	D5801			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING_ COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D5801 Continued From page 78 D5801 Reported as Inconclusive but should be reported as Invalid. 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

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PRETIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5801 Continued From page 79 D5801 patient-specific data, from the point of data entry to final report destination. TEST REPORT D5805 D5805 CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. 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: "Not Detected" for SARS-Cov-2 should have

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION TAG TAG DEFICIENCY) D5805 D5805 Continued From page 80 been "Inconclusive" b. "Inconclusive" for SARS-CoV-2 should have been true "Invalid" 2. Based on review of CDPH Branch Lab See Attachment 9: LIMC LIS reports emailed on 12/22/2020 and SARS-CoV-2 final patient test reports emailed by Summary: In summary, there is scientific the laboratory director on 01/06/2021 from and clinical debate regarding the best COLOR, the laboratory failed to provide the interpretation of high Ct values. All correct interpretation of results to the patients, reports issues did match the analysis rules and how the laboratory conveyed this information in place at the time of sample processing. to its clients. To manage this evolving field, a full-time, on-site Laboratory Director, who is a. In an e-mail communication with the directly involved in day-to-day laboratory laboratory director on 01/12/2021, the examiners asked if corrected reports were issued for the operations and result reporting has been affected patients. The laboratory director hired so that decisions regarding data indicated that reports were not amended to interpretation area now made in a timely provide the correct interpretation of results manner, with consultation of CDPH because COLOR did not have the current system Leadership, the Testing Taskforce and to issue corrected reports. other professionals as appropriate. NOT DETECTED **Correct Interpretation** Reported Negative Inconclusive Negative Inconclusive Negative Inconclusive Negative Inconclusive Inconclusive Negative Negative Inconclusive Inconclusive Negative Inconclusive Negative Inconclusive Negative Negative Inconclusive Negative Inconclusive Negative Inconclusive Inconclusive Negative

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	3. Based on the declaration signed 12/16/2020, the lab approximately 430, from 11/02/2020 to	by the labora coratory repo 000 SARS-C	tory director on				
1	4. The Laborator (01/12/2021 at app through email comfailed to ensure its correct interpretation TEST REPORT	roximately 11 munication th test results p	i:58 a.m.) lat the laboratory rovided the	D5807			
D5807	CFR(s): 493.1291(Pertinent "reference	e intervals" o					
a te	as determined by the tests, must be avail who ordered the te individual responsible.	lable to the a sts and, if ap	uthorized person plicable, the				

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY IDENTIFICATIONNUMBER: A. BUILDING AND PLAN OF CORRECTION COMPLETED 05D2197416 B. WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY D5807 Continued From page 82 D5807 This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual See Attachment 9 responsible for using the test results. Summary: In summary, there is scientific Findings included: and clinical debate regarding the best interpretation of high Ct values. All 1. Based on review of patient test reports for reports issues did match the analysis rules SARS-CoV-2, the laboratory indicated under the in place at the time of sample processing. test result and specific genes cycle threshold (Ct) To manage this evolving field, a full-time, value, "To learn more about the technical details on-site Laboratory Director, who is of the test, please see the test methodology and directly involved in day-to-day laboratory limitation section." operations and result reporting has been 2. Review of the test reports methodology and hired so that decisions regarding data limitation section did not indicate how the interpretation area now made in a timely laboratory determined its results (Positive, manner, with consultation of CDPH Negative, Inconclusive, and Invalid). Leadership, the Testing Taskforce and other professionals as appropriate. 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: Detected Not Detected b. c. Invalid

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIE IDENTIFICATIONNU 05D219	JMBER:	(X2) MULTIPLE A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPLE	
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D5807	Review of the update for analysis and report (last final version on following interpretations. Detected b. Not Detected c. Inconclusive d. Invalid	ed policies and proceed porting of SARS-CoV-12/16/2020) indicate ons sampling covering the 12/10/2020, the labor out 32 out of 32SAR which the laboratory freference intervals aboratory were available, or individual respondits.	-2 Assay ed the he period bratory RS-CoV-2 failed to bable for bonsible	D5807			
	(Should be inconci	and the same of th	Marine Contract Contr				

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE **DEFICIENCY**) D5807 Continued From page 84 D5807 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. **TEST REPORT** D5809 D5809 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

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D580	laboratory director reported on 12/10 a. Results were "Negative" but se "Inconclusive" b. Results were "but should have their clients regard fresults. The laboration of results. The last subcontractor, for the subcontractor, fo	or on 01/12/2020: The reported as 'hould have be reported as 'hould have be re reported as 'e been true "In ory failed to er ording change is aboratory's out ailed to issue of rent system it of the reports. It is sampling to 12/10/2020 to	"Inconclusive valid" "Inconclusive valid" "Insure it update in the interpretation and reported reported is not cap covering the p D, the laborator of 32SARS-Caboratory faile regarding chaits were reported in the reported to the covering the p D, the laboratory faile regarding chaits were reported to the covering the p D.	ed ation orts pable eriod gry cov-2 d to inged das e Report SARS-Cov-2 SARS-Cov-2	D5809	See Attachment 9 Summary: In summary, and clinical debate regard interpretation of high Ctreports issues did match tin place at the time of san To manage this evolving on-site Laboratory Direct directly involved in day-to operations and result repehired so that decisions reginterpretation area now manner, with consultation Leadership, the Testing Tother professionals as appropriate the summary of the professionals as appropriate the summary of the sum	ding the best values. All the analysis rules inple processing. field, a full-time, tor, who is o-day laboratory orting has been garding data inade in a timely in of CDPH caskforce and		

AND PLAN C			PER/SUPPLIER/C FICATION NUMBE 05D21974	ER:		CONSTRUCTION	(X3) DATE SURVEY COMPLETED 02/17/2021	
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D5809	b. Below are tes "Inconclusive", be been "Invalid"	at results that wat the correct re	esult should l	have	D5809			
	INCONCLUSIVE	Reported Inconclusive	Correct Intel Inval	id i				

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER IDENTIFICATIONNUM		(X2) MULTIPLE A. BUILDING	CONSTRUCTION	(X3) DATE S	
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D5809	4. Based on the la declaration signed b 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 15. 5. The Laboratory (01/12/2021 at 11:58 communication that the interpretation of laboratory failed to is the interpretation of laboratory failed to is TEST REPORT CFR(s): 493.1291(h) When the laboratory results within its estal aboratory must deter of the patient test(s) if the appropriate indivitesting. This Standard is not in Based on direct obseand procedures, qual assurance (QA) reconconducted with the la laboratory failed to enwhen the laboratory fresults on time. Findings included: 1. Review of the laborocedures (Policy # 6 Specimen Collection, Effective Date 12/07/2	boratory's annual testicy the laboratory director artery reported 20 SARS-CoV-2 test research 2/16/2020. Director affirmed a.m.) through email the laboratory failed to clients regarding changes and the sue corrected reports. cannot report patient to blished time frames, through email the sue corrected reports. cannot report patient to blished time frames, through ease don the unrequested, the need to dual(s) of the delayed met as evidenced by: rivation, review of policity control (QC) and quirds, and interviews boratory staff, the issure it updated their called to release patient coratory's policies and CA-CLSRV-SOP-002, Storage, and Shipping	est ne gency notify	D5809			

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER 05D21974		BER:	A. BUILDING B. WING	LE CONSTRUCTION	(X3) DATE SU COMPLET	
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D5815	2. Based on email the laboratory direct the laboratory start of the samples get to the sa	l communication with tor on 01/08/2021, that counting for TAT when the laboratory. It sampling covering the 12/10/2020, the laboratory 5 out of 32 SARS-CoV with no documentation of attent test results. It sampling covering the 12/10/2020, the laboratory 12/10/2020 in 12/10/2020 i	Result Inconclusive Inconclusiv	D5815	See Attachment 14 In summary, the CDP Laboratory has been in the Testing Task Force CDPH partners regard testing. A daily report client has requested sar	close contact with , OptumServe, and ing the status of is provided. No	

	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/IDENTIFICATION NUMBER 05D21974	BER:	(X2) MULTIPLE A. BUILDING B. WING	CONSTRUCTION	(X3) DATE S COMPLE	
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D5821	ordering the test and using the test results (k)(2) Issue corrected authorized person or applicable, the individual (k)(3) Maintain duplic well as the corrected This Standard is not Based on direct obseand procedures, qual assurance (QA) reconducted with the lalaboratory through C promptly notified and the authorized person results, and maintain report. Findings included: 1. Based on email laboratory director on patients reported on through COLOR failed. a. Notification and I Reports i. Based on email laboratory director or patients reported on but should have been "Inconclusive" but she "Invalid." The laboratory director or patients reported on but should. "The laboratory director or patients reported on but should." The laboratory director or patients reported on but should have been "Inconclusive" but she "Invalid." The laboratory director or The laboratory director or patients reported on but should have been "Inconclusive" but she "Invalid." The laboratory director or The laboratory director or The laboratory director or patients reported on but should have been "Inconclusive" but she "Invalid." The laboratory director or The la	y the authorized person, if applicable, the individual using the test and, if dual using the test resurates of the original report. met as evidenced by: ervation, review of policility control (QC) and quards, and interviews aboratory director, the OLOR failed to ensure issued corrected report or individual using the ed duplicates of the original report.	vidual ne ults. port, as cies uality it ts to test ginal e w of tory ing:	D5821			

	ATEMENT OF DEFICIENCIES D PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		ER:	(X2) MULTIPL A. BUILDING B. WNG	E CONSTRUCTION	(X3) DATE SURVEY COMPLETED 02/17/2021		
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D5821	ii. Random patier from 12/04/2020 to tested and reported but should have be of 19 "Inconclusive" Invalid" for SARS-	nt sampling of 12/10/2020 d 13 out of 1 en "Inconclu" but should	the laborate Not Detectionsive" and 19 have been	ory ted" out	D5821	See Attachment 9 Summary: In summary, the scientific and clinical debate the best interpretation of hi All reports issues did match	e regarding gh Ct values.	
		2.77				rules in place at the time of		
	NOT DETECTED	Reported	Correct Inte			processing. To manage this		
		Negative	Inconc	THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS NAMED IN COL		field, a full-time, on-site Lal	0	
		Negative	Inconc			Director, who is directly inv		
		Negative	Inconc					
		Negative	Inconc	THE PERSON NAMED IN COLUMN TWO IS NOT THE OWNER.		day-to-day laboratory opera result reporting has been hi		
		Negative	Inconc	***************************************				
		Negative	Inconc			decisions regarding data int		
		Negative	Inconc			area now made in a timely r		
	0	Negative	Inconc	CONTRACTOR OF STREET		consultation of CDPH Lead		
		Negative	Inconc	and the same of th		Testing Taskforce and other		
		Negative	Inconc	Delate designation of the large beautiful to		professionals as appropriate		
	-	Negative	Inconc	-				
		Negative	Inconcl	THE PERSON NAMED IN COLUMN 2 I				
		Negative	Inconcl	usive				

	OF DEFICIENCIES F CORRECTION		ER/SUPPLIER/CLIA CATIONNUMBER: 05D2197416	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 02/17/2021	
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D5821	Continued From p	eage 91		D5821			
	INCONCLUSIVE	Reported	Correct Interpretation				
	audited dit	Inconclusive	Invalid				
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	100	Inconclusive	Invalid				
	 b. Maintain dupli i. Based on revie emailed by the laboratory throuse reports on 12/07/20 results on 12/04/20 original report. ii. The following patient test results 	ew of patients bratory director ugh COLOR is 020 for reporte 020 without pro	test records on 12/24/2020, sued amended of SARS-CoV-2 oviding the				
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		IDENTIFICATION	PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 02/17/2021	
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D5821	Continued From page 92			D5821				
	Accession #	Original Report 12/04/2020	Amended 12/07/2020		See Attachment 5.			
	Detected *		Summary: Original and amended versions of report are retained and are					
		Detected	*		available to the laboratory.			
	4	Detected	*					
	4	Not Detected	*					
		Detected	*					
	4	Detected	*					
Pis	4	Detected	*					
		Detected						
		Detected Detected	*					
	Please disregard and subsequently served in error. Amended Report: 1	esults for this sample my previous reports The previously reported) is not valid due	as they were					
	error (Accession #s), Covid-19 Test.						
	Report Test Date: [
R	 Based on the declaration signed 12/16/2020, the la approximately 430 from 11/02/2020 to The Laborato 	,000 SARS-CoV-2 to 12/16/2020. ry Director affirmed	testing frector on est results (February					
	laboratory failed to and issued correct person or individua	cimately 2:10 pm) the ensure it promptly rated reports to the audit using the test resistes of the original re-	notified uthorized ults and					

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		BER:	(X2) MULTIPLE A. BUILDING _ B. WING	CONSTRUCTION	(X3) DATE (COMPL		
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D5891	policies and procedumechanism to monitindicated, correct prostanalytic systems. This Standard is not a same of policies and control (QC) and querandom review of policies and control (QC) and querandom review of pathe period from 12/0 out of 32 patient test determined that the there was a mechanicalculated results, resystems, and patient CoV-2. Findings included: a. Prior to the schellaboratory Field Ser communication on New informed the laboratory field ser communication on New excerpt of the e-mail	YSTEMS QUALITY a) It establish and follow wures for an ongoing tor, assess and, when oblems identified in the sepecified in §493.129 It met as evidenced by: the observation, interview december 8, 9, and 16, and procedures (P/P), quality assurance (QA) reception that test records cover 4/2020 to 12/10/2020, at records reviewed, it was laboratory failed to ensist to periodically verifies that sent to interface of the second of the	s with 2020, pality cords, ring for 32 ras sure fy d S- on, mail erein oking in a is the	D5891				

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ID FIX G		UMMARY STATEMENT O IENCY MUST BE PRECE OR LSC IDENTIFYING II	DED BY FULL REGULATORY	ID PREFIX TAG	ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH CORRECTIVE ACTION SHOULD BE			
b. on din recinving c. the late san	LFS expects * Evaluation during the a look-back. * How the la correspondi * What is the * How the la action. Is it to b. During on 12/08/20 directors and requested for investigation increased nuc. We review the Emerger laboratory's New Corona "Examination Specimen R the expected and negative	Thow 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? 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. We reviewed the Instructions for Use (IFU) of the Emergency Use Authorization of the aboratory'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 Cycle threshold Result Interpretation Cycle threshold Result Interpretation Cycle threshold Result Interpretation SARS-CoV-2 Not Detected Monitoring SARS-CoV-2 Not Detected SARS-CoV-2 Not Detected			See Attachment 1. In summary, the is and unsatisfactory lower than in early Evidence of the ass corrective action (6 on 09Dec2020.	nconclusive rates are much November.		
	≤ 40		SARS-CoV-2 Not Detected					
	1		e after transmit construction of the state of					
	>40 or Undetermined	One of the targets ≤ 42 Both targets Undetermined or > 42	SARS-CoV-2 Detected Invalid result, specimen needs to be re-tested from re-extraction or recollected from patient for test.			1		

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION COMPLETION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5891 Continued From page 95 D5891 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 See Attachment 9 interpretation of patient specimen results. Summary: In summary, there is scientific and clinical debate regarding the best a. A policy and procedure signed by the interpretation of high Ct values. All reports laboratory was not available on December 8, issues did match the analysis rules in place 2020. at the time of sample processing. To manage this evolving field, a full-time, on-site b. Neither an unsigned policy and procedure was available on December 8, 2020. Laboratory Director, who is directly involved in day-to-day laboratory operations and result reporting has been e. Further interviews with the laboratory director on 12/08/2020, indicated there was a possibility hired so that decisions regarding data that patient test results were reported in error as interpretation area now made in a timely a result of incorrect data analysis and manner, with consultation of CDPH interpretation. Leadership, the Testing Taskforce and other professionals as appropriate. The following day on 12/09/2020, we conducted random sampling of an additional 32 See Attachment 11: patient test records with specimens collected during the first week December until 12/08/2020. Summary: Contrary to Laboratory Director affirmation, User Specification and On December 16, 2020, we wentback Acceptance Testing forms were signed. on-site at the laboratory to retrieve the additional patient test records. We also asked the laboratory to send via e-mail, the requested Please note, the effective date 29Oct2020 is records and its policy and procedure for the date the blank form (template) was interpretation of patient specimen results. effective. h. The policy and procedure sent via e-mail on For evolution of the interpretation of Ct Dec. 16, 2020 showed the following: values, please see Attachment 9. An annotation on the top portion of document indicated, "Effective Starting 10/29/2020" the document version history: It was an Initial document, Version 1.0, with

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: COMPLETED 05D2197416 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE **CDPH BRANCH LABORATORY** VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX (EACH CORRECTIVE ACTION SHOULD BE PRETIX DATE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5891 Continued From page 96 D5891 an effective date of December 13, 2020. (iii) The Software Name was identified as LIMC, version 1.2 The Detailed User Requirements Specifications section of the document showed the following policy for interpretation of patient specimen results. See Attachment 11. User In summary, the inconclusive and Description unsatisfactory rates are much lower than Number Update analysis rule for the new SOP: in early November. Contrary to Laboratory Director affirmation, User "Not Detected" Ct cutoff changed from 37 to 42 Specification and Acceptance Testing FAM and ROX >37 and <=42 will be called as "Inconclusiv UR001 forms were signed. stead of "Not Detected" IC Failure samples (HEX=0 or >40) will be released as "Invalid". Note, the effective date 29Oct2020 is the No changes on controls and "Detected" rules date the blank form (template) was effective. 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. 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

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/OIDENTIFICATIONNUMBI	ER:	(X2) MULTIF A. BUILDING B. WING	PLE CONSTRUCTION	(X3) DATE SU COMPLET	
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D5891	patient sample result to show it validated category of "Inconclepatient test results of the 3 retrieved on December (i) Thirteen (13) pas "Not Detected" we reported as Not Detected as Inconclusive as "Inconclusive" whereported as "Invalid" we reported as "Invalid"	its, the laboratory also fits LIS to include a result usive" prior to reporting in 11/02/2020. (See D5/2 patient test records per 16, 2020 showed: patient results were reported it should have been ve" on December 10, 20 tected, but should be	orted	D5891	See Attachment 9. In summary, there is so clinical debate regarding interpretation of high C reports issues did match in place at the time of sa To manage this evolving on-site Laboratory Directive directly involved in day-operations and result rehired so that decisions reinterpretation area now manner, with consultatic Leadership, the Testing other professionals as appropriate of the professionals as appropriate the second control of the professionals as appropriate the second control of the professionals as appropriate the second control of the professionals as a professional of the professional	g the best t values. All the analysis rules ample processing. g field, a full-time, ctor, who is to-day laboratory porting has been egarding data made in a timely on of CDPH Taskforce and	

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D5891	declaration signed by 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1 p. The Laboratory (February 12, 2021 at the laboratory falled to periodically verify sent to interfaced systems of the sent to interface of 12/08/2021 at 12/16/2020 and email 12/12/2020, 12/12/2020, 12/12/2021, review of quality control (QC) a records, it was determined to establish and procedures for an one	aboratory's annual testing the laboratory director ratory reported 00 SARS-CoV-2 test re 2/16/2020. Director affirmed at approximately 2:10 protocolor to ensure was a mechal calculated results, results and patient species. Director affirmed at approximately 2:10 protocolor to ensure was a mechal calculated results, results and patient species. Director affirmed at approximately 2:10 protocolor to ensure was a mechal calculated results, results and patient species. Director affirmed at approximately 2:10 protocolor to ensure with the laboratory 20, 12/09/2020 and 11 communication on 020, 01/06/2021 and 15 policies and procedured quality assurance (mined that the laborator of follow written policies	m) that inism Its cific	D5891			

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WING 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5891 Continued From page 99 D5891 Appendix A - The Quality Management problems identified in the postanalytic systems Plan has been revised and reorganized to specified in CFR 493.1291 (a)-(k). consolidated information about existing laboratory processes (CA-QM-SOP-001). Findings included: Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 11/01/2020)showed See Attachment 9 the laboratory failed to include an ongoing mechanism to perform or document quality Summary: In summary, there is scientific issues regarding the following: and clinical debate regarding the best interpretation of high Ct values. All b. The laboratory failed to ensure the electronic reports issues did match the analysis rules system(s) it used, accurately and reliably transmitted patient-specific data from the point of data entry to fina in place at the time of sample processing. report destination (See D5801). To manage this evolving field, a full-time, on-site Laboratory Director, who is c. The laboratory failed to ensure its test result directly involved in day-to-day laboratory provided the correct interpretation for operations and result reporting has been SARS-CoV-2 (See D5805). hired so that decisions regarding data interpretation area now made in a timely d. The laboratory failed to ensure its accurate manner, with consultation of CDPH reference intervals determined by the laboratory Leadership, the Testing Taskforce and based on LOD were available for the authorized other professionals as appropriate. 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). The laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time (See D5815). 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).

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D5891	from 12/04/2020 to 32 out of 32 results laboratory tested an results, but failed to	sampling covering the policy of the policy o	at for 2 ngoing	D5891			

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D5891	declaration signed b 12/16/2020, the laboratory approximately 430,0 from 11/02/2020 to 1: j. The Laboratory 12, 2021 at approximately 430,0 indicated, correct propostanalytic systems	boratory's annual testing the laboratory director atory reported 00 SARS-CoV-2 test respond to 2/16/2020. Director affirmed (Februately 2:10 pm) that the nonitor, assess, and whoblems identified in the second testing the second testing testing the second testing testin	suits uary e	D5891 D6076			
D6076	CFR(s): 493.1441 The laboratory must the qualification requited this subpart and provand direction in according to the subpart. This Condition is not on the severity of the was determined that Performing High Condition Director was not meritated. 1. The Laboratory Diquality of service prospection when the lab documentation of tradesessment, and contelephone, as necess personnel specific rereapportioned to technique to the supervisor, and clinical tradesessment.	have a director who mulicements of §493.1443 vides overall management ordance with §493.1445 and as evidenced by: a deficiencies cited here the condition Laborator pplexity Testing, Laborate in the postanalytic oratory failed to provide in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualic sponsibilities which calculations, generally sory in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualic sponsibilities which calculations are provided in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualications are provided in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualications are provided in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualications are provided in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualications are provided in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualications are provided in the postanalytic oratory failed to provide ining, competency insultation electronically sary; delegated to qualications are provided in the postanalytic oratory failed to provide ining.	Based ein, it ories ratory strate cic e or or by iffed n be eral				

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	performance, which analytic, and postan This Standard is not 1. Preanalytic Syste Based on interviews director on December test requisitions, and records covering the 12/08/2020, for 10 or reviewed, it was deten Director failed to ensuprovided in the preasof test requisitions for testing was not retain. Findings included: a. The Laboratory retained records of tested for SARS-Cov (See D3027). 2. Postanalytic System Based on email communication of 12/24/20, reports, and review of covering the period for 12/04/2020, for 10 or reviewed, it was deten Director failed to ensuprovided in the postation of original test reports testing were not retain.	includes the preanalytic, alytic phases of testing. I met as evidenced by: Im (Test Requisition) with staff and the laborate 8, 2020, the absence of random review of test repriod from 11/22/2020 ut of 10 patient test recordermined that the Laborate sure the quality of service malytic system when record staff and the staff and the laborate s	it ords ords it ords ords ords ords ords oratory al test ds ory ords ords	D6082	See Attachment 9 Summary: In summary, and clinical debate regard interpretation of high Ct reports issues did match in place at the time of sar To manage this evolving on-site Laboratory Direct directly involved in day-toperations and result rephired so that decisions reinterpretation area now manner, with consultation Leadership, the Testing Tother professionals as application.	ding the best values. All the analysis rules mple processing. field, a full-time, tor, who is to-day laboratory orting has been garding data made in a timely n of CDPH 'askforce and	

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D6082	retained records of opatients tested for S two years (See D30-3. Postanalytic Syste Assessment, Consu Duties to Qualified F Analysis) Based on email comof Informatics on 12. laboratory staff on 11 test records covering to 12/08/2020, for 60 records reviewed, the to demonstrate qual postanalytic system provide documentatic assessment, and contelephone, as necessipersonnel specific recapportioned to technological postanalysis and records reviewed, as necessipersonnel specific recapportioned to technological postanalysis and record results were taking publications and record results were taking publications. Based on interview on 12/08/2020, a lapnine data analysis lawould enable accessions.	original test reports of all ARS-CoV-2, for at least 41). em (Training, Competen Itation, and Delegation of Personnel in Remote Date of the Person on training, compete of the Person on training, compete of the Person on the Person on the Person of the Perso	ector thathe tient 2020 tilled the ed to nocy or by diffied the et time that test de of	D6082	See Attachment 10. Summary: the experient data analysis is no differ offsite, therefore, the ris with the limited analysis two qualified analysts is interpretation was that allowed this during the however, no further offsallowed.	rent onsite or k associated s done offsite by minimal. Our CMS has pandemic;	

	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMBE 05D21974	ER:	(X2) MULTIPLE A. BUILDING B. WNG	CONSTRUCTION	(X3) DATE S COMPLI	ETED
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D6082		Carrier Control		D6082			
	Director of Clinical I remote workers need able to login to LIMC are Perkin Elmer IP Laboratory Valencial 165.88.16.###. Non-Valencia IP Add 1. By EV 2165.88.255.136.165.165.88.176.91 165.88.176.64 165.88.176.64 165.88.254.202 c. Review of the Improcedures (Policy #Analysis and Report Assay, Version 1 Ef 13/2020, Version 2.16/2020, Version 3.12/16/2020, and Ve 12/16/2020, the Lademonstrate quality	2. By MN 5.88.254 65.88.254 laboratory's policies and # CA-RPT-SOP-002, Title rting of SARS-CoV-2 ffective Date 12/80 Effective Date 12/13-	e:				
	failed to provide doc competency assess electronically or by to or delegate to qualif responsibilities whice to technical supervision and clinical consultations.	cumentation on training, sment, and consultation telephone, as necessary; fied personnel specific ch can be reapportioned sor, general supervisor, ant during the time data as reporting of patient test	G.				

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPF IDENTIFICATION 05D2		R:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE S	ETED	
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D6082	results were taking of the laboratory far d. Random review period from 11/22/2 laboratory tested at SARS-CoV-2 paties laboratory personneremote reporting of Branch laboratory is documentation of trassessment, and of telephone. e. Below are 30 reach for EV and MI remotely analyzed, released remotely.	place at a location outside cility. w of test records covering to 12/08/2020, the not reported 60 out of 60 not test results, showed two led to perform data analysisutside the location of CDPI	he sand H or by	D6082				

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 02/17/2021	
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	Data Analyzed by E	v-						
	Accession Number	Date Reported	1P Ad	dress				
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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6082 D6082 Continued From page 109 The total number of results reported by MN from 12/07/2020 to 12/08/2020 was 1,974. See Attachment 10. The total number of results reported by EV from 11/22/2020 to 11/30/2020 was 13, 291. Summary: The experience of h. Based on the laboratory's annual testing performing data analysis is no declaration signed by the laboratory director on 12/16/2020, the laboratory reported different onsite or offsite. approximately 430,000 SARS-CoV-2 test results therefore, the risk associated with from 11/02/2020 to 12/16/2020. the limited analysis done offsite by i. The Laboratory Director affirmed(12/17/2020 at 12:15 two qualified analysts is minimal. p.m.) through email communication that the two data Our interpretation was that CMS analysis personnel analyzed and reported the SARS-CoV2 amplification test results which the laboratory has allowed this during the failed to provide documentation of training, competency pandemic; however, no further assessment, and consultation electronically or by offsite analysis is allowed. 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.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION DATE (X4) ID ID PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PRETIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG **DEFICIENCY** Continued From page 110 D6083 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. See attachment 1: Findings included: Summary: The use of 70% EtOH 1. The laboratory failed to ensure that meets the standard set by CDC. contamination of patient specimens, equipment, Heat inactivation is an effective instruments, reagents, materials, and supplies method to inactivate SARS-CoV-2. for the laboratory's COVID-19 Reverse Disposal of MTM sample collection Transcriptase-Polymerase Chain Reaction D6084 D6084 (RT-PCR) was minimized (See D3003). tubes that have been subjected to LABORATORY DIRECTOR RESPONSIBILITIES heat inactivation in bleach is not CFR(s): 493.1445(e)(2) necessary. Therefore, the area in which the samples were handled was The laboratory director must ensure that the physical plant and environmental conditions adequately decontaminated. provide a safe environment in which employees are protected from physical, chemical, and

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATIONNUMBER: A. BUILDING COMPLETED 05D2197416 B. WNG 02/17/2021 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PROVIDER'S PLAN OF CORRECTION ID (X5) COMPLETION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) D6084 Continued From page 111 D6084 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). LABORATORY DIRECTORRESPONSIBILITIES D6093 D6093 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).

	AND PLAN OF CORRECTION IDENTIFICATIONNI		RRECTION IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 02/17/2021		
	ROVIDER OR SUPPLIER RANCH LABORATO	RY	28454	ADDRESS, CITY, STATE, ZIP CODE 64 LIVINGSTON AVE ENCIA, CA 91355					
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D6093	manuals were esta followed by laborate and process. The laboratory manuals were updated by the current D5407). 4. The laboratory adopted FDA EUA to the EUA, and chapolicies and process. The laboratory labeled as required 6. The laboratory decontamination so RT-PCR were not unexpiration dates (Sc. 7. The laboratory and verified perform reporting patient test FDA EUA IFU SAR D5423). 8. The laboratory established mainter centrifuges were per (SeeD5433).	y failed to ensure procedulished, available to, and only personnel (See D54 failed to ensure the proceduling proceduling the proceduling of the pr	d 01). cedure 42 ure and See red the visions atory's as were	D6093	See Attachment 9 In summary, there is so clinical debate regarding interpretation of high Ct issues did match the ana at the time of sample promanage this evolving fiel site Laboratory Director, involved in day-to-day le operations and result rephired so that decisions reinterpretation area now manner, with consultation Leadership, the Testing Tother professionals as appointment of the professionals as appropriate the same professionals as a professional same professionals.	the best values. All reports lysis rules in place ocessing. To Id, a full-time, on- who is directly aboratory corting has been garding data made in a timely on of CDPH Taskforce and			

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING IDENTIFICATION NUMBER: COMPLETED 05D2197416 B. WNG 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 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X5) (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY COMPLETION PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D6094 Continued From page 113 D6094 The laboratory director must ensure that the See Attachment 9 quality assessment programs are established and maintained to assure the quality of laboratory In summary, there is scientific and services provided and to identify failures in quality clinical debate regarding the best as they occur. interpretation of high Ct values. All reports issues did match the analysis rules This Standard is not met as evidenced by: in place at the time of sample processing. Based on direct observation, interviews To manage this evolving field, a full-time, conducted with the laboratory staff on 12/08/2020 and 12/09/2020, and review of test on-site Laboratory Director, who is records covering the period from 11/22/2020 to directly involved in day-to-day laboratory 12/08/2020, for 60 out of 60 patient test records operations and result reporting has been reviewed, it was determined that the Laboratory hired so that decisions regarding data Director failed to ensure quality assurance interpretation area now made in a timely activities were established and maintained by the manner, with consultation of CDPH laboratory to assure the quality of services Leadership, the Testing Taskforce and provided, and to identify failures in quality as they other professionals as appropriate. 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) LABORATORY DIRECTOR RESPONSIBILITIES D6101 D6101

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10.00	CDPH BRANCH LABORATORY 28454		DDRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE CNCIA, CA 91355				
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D6101	CFR(s): 493.1445(e) The laboratory direct number of laboratory appropriate education training to provide approperly supervise a and report test result personnel responsible subpart. This Standard is not Based on direct obseconducted with the later 12/08/2020, 12/09/2 review of test record 11/22/2020 to 12/08/2020, 12	tor must employ a suffice of personnel with the son and either experience oppropriate consultation, and accurately perform the sin accordance with the sillities described in this met as evidenced by: ervation, interviews aboratory staff on 020, and 12/16/2020, as covering the period for 2020, for 60 out of 60 particles of the supervisors for high with appropriate educations of the etest performance and supervision liew with the laboratory aboratory personnel on raining documents, lack duties, it was determined under supervision of the duties of the	e or tests ne and nom atient at the ras an on, staff viding staff, c of ed e	D6101			

(X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION DENTIFICATION NUMBER: COMPLETED 05D2197416 B WING 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE **VALENCIA, CA 91355** SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY D6101 Continued From page 115 D6101 indicate the name of the interviewed general supervisor, who was providing supervision to the See Attachment 15. analytic testing laboratory staff on 12/16/2020. In summary, supervision of staff was Data Analysis Supervision performed only by designated supervisors. 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. 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. 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

STATEMENT OF DEFICIENCIES (X1 AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED			
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	declaration signed b 12/16/2020, the laboratory approximately 430,0 from 11/02/2020 to 1 5. The Laboratory (12/16/2020 at 1:00	aboratory's annual testing by the laboratory director of pratory reported 00 SARS-CoV-2 test resu	lts to	D6101					

(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA A. BUILDING_ COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION 05D2197416 B WNG 02/17/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 28454 LIVINGSTON AVE CDPH BRANCH LABORATORY VALENCIA, CA 91355 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY (EACH CORRECTIVE ACTION SHOULD BE PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) D6101 D6101 Continued From page 117 for high complexity testing with appropriate training to provide supervision accordingly. LABORATORY DIRECTOR RESPONSIBILITIES D6102 D6102 CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This Standard is not met as evidenced by: Based on 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

		IDENTIFICATIONNUMB	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 02/17/2021	
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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 (EACH CORRECTIVE ACT CROSS-REFERENCED TO T DEFICIENCE	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE	
D6102	the 60 randomly rev covering the period of 12/08/2020, wherein reported 60 out of 60 results, but failed to	e the accession number	nds and test aff	D6102				

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER IDENTIFICATIONNUM 05D2197		ER:		PLE CONSTRUCTION	(X3) DATE SI COMPLE	TED		
	CDPH BRANCH LABORATORY 28454 VALE				DDRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355				
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D6102	D-6531837737 D D-6549456900 D 2. Data Analysis F CDPH Branch Lab (a. Based on review determined that the performed data analytic documentation on hareporting, direction a or by telephone whe delegated personne remote data analysis b. Review of policic CA-PER-SOP-002, Assessment) failed for remote reporting. c. Random review period from 11/22/20 laboratory tested and SARS-CoV-2 patient laboratory personne outside the location Valencia without docreporting. d. Below are 30 reeach for EV and MN	-3350939587 -5898244636 Performed Outside Remote Reporting) w of test records, it was two laboratory staff who lysis from the location of ab did not have training ow to handle remote nd consultation electron in the Laboratory Directo I were not with them duris. es and procedures (Polic Title Competency to include training for of test records covering 20 to 12/08/2020, the d reported 60 out of 60 t test results, showed two I to perform data analysi of CDPH Branch laborate cumented training for recovered	outside ically ir and ring cy #	D6102	See Attachment 10. In summary, the experiperforming data analysi on-site or off-site, there associated with the limit off-site by two qualified minimal. Our interpreta CMS has allowed this depandemic; however, no analysis is allowed.	s is no different fore, the risk ted analysis done analysts is ation was that uring the			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
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	OVIDER OR SUPPLIER ANCH LABORATOR	ťΥ		28454	RESS, CITY, STATE LIVINGSTON A ICIA, CA 91358	AVE			
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		11/24/2020	165.88.1						
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	4	11/25/2020	165.88.1	176.64					
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		11/29/2020	165.88.2	54.202					
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		11/29/2020	165.88.2						
		11/30/2020	165.88.2						
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER: 05D2197416			(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		001			B. WING			17/2021
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		12/07/2020	165.88.254	1.222				
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AND PLAN OF CORRECTION IDENTIFICATION		(X1) PROVIDER/SUPPLIER/C IDENTIFICATIONNUMB	ER:	(X2) MULTIPLE CONSTRUCTION C. BUILDING D. WING		(X3) DATE SURVEY COMPLETED		
	ROVIDER OR SUPPLIER	ay .	28454	DORESS, CITY, STATE, ZIP CODE 4 LIVINGSTON AVE ENCIA, CA 91355				
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D6102	3. Based on the la declaration signed b 12/16/2020, the labor approximately 430,0 from 11/02/2020 to 1:4. The Laboratory (12/16/2020 at 1:00 ensure the laboratory	boratory's annual testin y the laboratory director tratory reported 00 SARS-CoV-2 test res	on sults ed to	D6102				