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

TOMÁS J. ARAGÓN, M.D., Dr.P.H
Director and State Public Health Officer

GAVIN NEWSOM
Governor

IMPORTANT NOTICE – ACTION NECESSARY

Confirmation of successful transmission by email constitutes proof of receipt of this letter.

October 8, 2021

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STATE: CPH 889339
CLIA: 05D2197416

PUBLIC HEALTH LABORATORY STATE INSPECTION – Complaint Inspection
CONDITIONS REMAIN – Request for Information

Dear Laboratory Director/Owner:

In order for a public health laboratory to perform testing under the California Health and Safety Code (HSC) subsections 101160 (a) – (b), it must comply with all federal CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and Title 42 Code of Federal Regulations part 493 (42 C.F.R. § 493). Compliance with these regulations is a condition of certification for the State Public Health Laboratory Certification program.

A complaint inspection of your laboratory was conducted by Elsa Eleco, Examiner III, and Catherine Tolentino, Examiner II, representatives of the California Department of Public Health (the Department), Laboratory Field Services. This complaint inspection concluded on April 22, 2021.

As a result of that inspection, Department examiners determined that your laboratory is **not** in compliance with the requirements specified in the Health and Safety Code (HSC) section 101160 and/or California Code of Regulations (CCR), title 17, sections 1078 and 1083.

Department examiners also determined that your laboratory is **not** in compliance with all of the Conditions required for certification in the State Public Health Laboratory Certification program.

The Department notified you in a letter dated **April 23, 2021**, of deficiencies found during the survey of your laboratory. We requested that you submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited within ten days of receipt of our notification letter. You were advised that a credible allegation of compliance is a statement or documentation that is:

1. Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2. Realistic in terms of the possibility of the corrective action being accomplished between the date of the inspection and the date of the allegation; and
3. Indicates resolution of the problems.

You were also advised that the laboratory's allegation of compliance must be substantiated by acceptable evidence of correction, including documentation showing for each deficiency:

1. What corrective actions have been taken for patients found to be affected by the deficient practice.
2. How the laboratory has identified other patients who may have been affected by the same deficient practice and what corrective actions were taken.
3. What measures have been put into place or what systemic changes have been made to ensure that the deficient practice does not recur.
4. How the corrective actions are being monitored to ensure the deficient practice does not recur.

In response to our April 23, 2021 letter, the Department received a submission from your laboratory on May 3, 2021.

After careful review of your submission, the following Condition level deficiencies remain:

D5200 – 42 CFR section 493.1230 Condition: General Laboratory Systems

D5200 (Refer to D5209)

GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 1 of 43, "The roster personnel provided on 2/8/2021 was ***an official one***, an issue being addressed through audit preparation training and exercises."

However, the laboratory stated in the Provider's Plan of Correction Page 4 of 43 under findings 4 and 5, "The roster provided on 2/8/2021 was ***not an official one***, therefore, the following numbers (personnel list) as presented in the LFS findings vary slightly."

To correct this deficiency, the laboratory must address the information specified in the following bullets:

- Correct the inaccuracy/inconsistency in the statement provided. Clarify whether the laboratory provided an "official" roster or "not an official" roster (personnel list).

In its submission, the laboratory also stated, "A review of our records found that 412/412 (100%) of employees involved in the testing process have documented training; however, a limited number of delays in capturing training documentation

were noted. These delays did ***not*** affect the Data Analysts, who are the only staff who report patient results, among whom 21/21 (100%) had no delay in training documentation."

- The laboratory failed to provide documentation to support the statement above. Testing involves preanalytical, analytical, and postanalytical processes. Data Analysts are involved in the postanalytical process as they report patient results. Accuracy of patient test results can also be affected by the training and competency of the preanalytical and analytical laboratory personnel.

- The laboratory also needs to correct the deficiency cited at D5209.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated, "An enhanced Training/Orientation (CA-PER-SOP-001) and Competency (CA-PER-SOP-002) v.4.0, was recently implemented as of 04/11/2021. The Quality Management Plan (QMP) was revised (v3, 04/11/2021) and in Section 6.2 Assessment of Competency, the statement that a separate competency in addition to the training documentation attesting that the individual is competent to perform the tasks were both removed. Personnel competence is assessed at the following times for existing, new, or changed job processes and procedures: 6 and 12 months from start of training (first year), at least annually throughout the laboratory tenure after the first 12 months on a workstation (ongoing), and when assessment reveals the need for improvement (remedial)."

- Training is separate from competency assessment. A testing person or a consultant may have received training yet may not be competent to conduct any phase (preanalytical, analytical, and postanalytical) of the testing process that they are supposed to perform.

- **CFR 493.1445 (e)(12)** states 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."

- **CFR 493.1445 (e)(13)** states the laboratory director must "ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are **competent and maintain their competency** to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills."

- **CFR 493.1451 (b)(7)** states the technical supervisor is responsible for "identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed."

- **CFR 493.1451 (b)(8)** states the technical supervisor is responsible for "evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to:

    1. ***CFR 493.1451 (b)(8)(i)***
       Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;

    2. ***CFR 493.1451 (b)(8)(ii)***
       Monitoring the recording and reporting of test results;

    3. ***CFR 493.1451 (b)(8)(iii)***
       Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

    4. ***CFR 493.1451 (b)(8)(iv)***

Direct observation of performance of instrument maintenance and function checks"

5. ***CFR 493.1451 (b)(8)(v)***
   Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

6. ***CFR 493.1451 (b)(8)(vi)***
   Assessment of problem-solving skills."

- CFR 493.1451 (b)(9) states the technical supervisor is responsible for "evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, **prior to reporting patient test results, the individual's performance must be reevaluated to include the use of new test methodology or instrumentation**."

The laboratory director must ensure that *prior to handling, processing, and testing patient samples*, all personnel have the appropriate education and experience and receive the appropriate training.

- To ensure that testing personnel are following the laboratory's policies and procedures and testing accurately and proficiently, the laboratory director and technical supervisors must ensure there is a mechanism in place to ensure personnel were only allowed to handle patient specimens when trained and assessed utilizing the six elements required by CLIA.

- The laboratory's new enhanced policies and procedures did not include the six elements specified in ***493.1451 (b)(8)(i)-(vi),*** required by CLIA to ensure that testing personnel were following the laboratory's policies and procedures, and testing accurately and proficiently, *prior to handling, processing, and testing patient samples*,

- The training and competency assessment forms submitted by the laboratory for preanalytical, analytical, and postanalytical personnel did not include the six elements required by CLIA to ensure testing personnel are following the entire laboratory process, and limit errors in all phases of testing, *prior to handling, processing, and testing patient samples*.

We reviewed the attachments your laboratory submitted and noted inconsistencies.

To correct this deficiency, the laboratory must also address the inconsistencies specified in the following bullets:

- Attachment 5209_3r and 3s_Accessioning_Day_Sun-Tue indicated 35 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated only 34 out of 34 Accessioning staff during day shift, Sunday to Tuesday.

- Attachment 5209_3v and 3w_Accessioning_Night_Sun-Tue indicated 40 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated 43 out of 43 Accessioning staff during night shift, Sunday to Tuesday.

- Attachment 5209_3t and 3u_Accessioning_Day_Wed-Fri indicated 44 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated 46 out of 46 Accessioning staff during day shift, Wednesday to Friday.

  The 44 Accessioning staff was divided into:

  1. Accessioning and Batching- there were only 43 out of 44 with competency assessments. The staff with the initials "PM" was not assessed.

  2. Heat Inactivation- there were only 43 out of 44 with competency assessments. The staff with the initials "JM" was not assessed.

- Attachment 5209_3x and 3y_Accessioning_Night_Wed-Fri indicated 28 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated 37 out of 37 Accessioning staff during night shift, Wednesday to Friday

- Attachment 5209_3i and 3j_Extraction_Day_Sun-Tue indicated 35 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated total of 37 Extraction staff during day shift, Sunday to Tuesday.

  The 35 Extraction staff was divided into:

1. JanusG3 Transfer and Reformatter

2. Nucleic Acid Extraction using Chemagic 360- there were only 34 out of 35 with competency assessments. The staff with initials “LO” was not assessed.

- Attachment 5209_3k and 3l_Extraction_Night_Sun-Tue indicated 55 initial training records for laboratory staff. [but the table provided on page 4 of 43 in the Provider’s Plan of Correction indicated total of 46 Extraction staff during night shift, Sunday to Tuesday.

  The 55 Extraction staff was divided into:

  1. JanusG3 Transfer and Reformatter- there were only 46 out of 55 with competency assessments. The staff with the following initials were not assessed:

     a. CC
     b. EF
     c. JJ
     d. MM
     e. DM
     f. UP
     g. AP
     h. RR
     i. SS

  2. Nucleic Acid Extraction using Chemagic 360- there were only 41 out of 55 with competency assessments. The staff with the following initials were not assessed:

     a. AA
     b. AA
     c. KC
     d. CD
     e. SF
     f. JH
     g. SL
     h. GL
     i. LN
     j. CO
     k. AP

l. JR
m. IS
n. SY

- Attachment 5209_3m and 3n_Extraction_Day_Wed-Fri indicated 39 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated total of 40 Extraction staff during day shift, Wednesday to Friday.

- Attachment 5209_3o and 3p_Extraction_Night_Wed-Fri indicated 51 initial training records for laboratory staff

  The 51 Extraction staff was divided into:

  1. JanusG3 Transfer and Reformatter

  2. Nucleic Acid Extraction using Chemagic 360- there were only 48 out of 51 with competency assessments. The staff with the following initials were not assessed:

     a. TH
     b. KO
     c. MR

- Attachment 5209_3e_PCR_Night_Sun-Tue indicated 15 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan of Correction indicated 14 out of 15 PCR staff during night shift, Sunday to Tuesday.

  The 15 PCR staff was divided into:

  1. SARS-CoV-2 RT-PCR AJ-there were only 14 out of 15 with competency assessments. The staff with the initials "AS" was not assessed.

  2. SARS-CoV-2 RT-PCR Janus- there were only 14 out of 15 with competency assessments. The staff with the initials "ES" was not assessed.

- Attachment 5209_3b_Data Analysts indicated 13 initial training records for laboratory staff, but the table provided on page 4 of 43 in the Provider's Plan

of Correction indicated 21 out of 21 Data Analysts staff.

- Resubmit new evidence other than the previous information emailed on 02/08/2021.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 4 of 43, "The unofficial roster is used by Managers and Supervisors as reference for staff on shifts or in areas with which they do not work directly. Inaccuracies in this roster may result in inconvenience for laboratory staff therefore there is no patient impact on patient care."

- Provide evidence to support that the claim mentioned above did not contribute to series of Quality Exception Reports (QER) and CAPA.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 4 of 43 under (3) Preventive Measures stated, "Two training sessions and mock inspection drills have been completed."

- Provide the policy and procedures for mock inspection drills.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 6 of 43, under (1) Immediate Corrective Action. "Any task for which a training form was not captured was reassessed for the individual or that individual was removed from the testing process until re-assessment was completed."

- Provide evidence of individuals that were removed from the testing process until re-assessment was completed.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 7 of 43, "The limited number of instances of missed training documentation identified are unlikely to impact patient care since the assay steps performed in extraction do NOT include data review or analysis."

Extraction of nucleic acids from patient samples is an essential step for downstream molecular testing. The size of nucleic acid fragments present in samples can influence extraction efficiency, especially observed in circulating cell-free nucleic acids.

After sample collection, the next important step in the detection of infectious agents in most patient-derived samples is the extraction of nucleic acids to remove proteins, lipids, and other cellular components, and PCR inhibitors. The variety of

instrumentation and extraction methods available contribute to the differences in extraction of nucleic acids. Extraction efficiency can affect patient care and reproducibility of testing results.

- The laboratory failed to provide any documentation to support its claim that "instances of missed training documentation identified are likely to impact patient care."

D5400 - 42 C.F.R section 493.1250 Condition: Analytic systems

D5400 (Refer to D5407, D5779, D5787, D5791)

ANALYTIC SYSTEMS CFR(s): 493.1250
Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed.

The allegation of compliance is not credible, and the evidence of correction is not acceptable (See our reviews for D5407, D5779, D5787, and D5791).

D5407

PROCEDURE MANUAL CFR(s): 493.1251(d)
Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated in the Provider's Plan of Correction Page 9 of 43, "It is also important to note that manual pipetting is a standard laboratory practice that **all** technologist is proficient in."

- There are several types of pipettes and techniques. Not all technologists are proficient in manual pipetting. It is a skill developed through experience. Manual pipetting requires accuracy to prevent contamination and failed runs.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 9 of 43, "In response to finding 1e at no point did the laboratory director or anybody else present during the virtual meeting with LFS on 04/22/2021 (10:40 a.m.) make this affirmation. This statement is inaccurate. Please refer to attachment 1."

- Refer to the 12 questions emailed to the laboratory on February 23, 2021, and 14 additional questions emailed on March 01, 2021. The questions were re-emailed again on March 12, 2021 due to lack of response.

- Again, refer to the response provided by the laboratory on March 18, 2021, specifically "question number 2" about the above-mentioned policy and procedure.

- At the time of virtual meeting on 04/22/2021, the examiner only affirmed the absence and inaccurate response provided to question number 2 (March 1, 2021). The laboratory director sent via email the responses to all 26 questions on March 18, 2021.

- At the time of virtual meeting on 04/22/202, the laboratory director asked about the missing procedure, and the examiner explained the missing procedure as indicated in the laboratory's March 18, 2021, email response.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 9 of 43, "(2) Patient Impact, as this was an acceptable deviation from the SOP tracking of the occurrences was not required; as there was **no** tracking, a look-back between 01/27/2020 and 01/27/2021 is **not** possible."

- Provide a mechanism to ensure that loss of tracking which resulted in lack of look-back can be prevented in the future.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 10 of 43 under preventive measures, "The current Laboratory Director participates in regular meetings with technical, general supervisors and wet laboratory managers to discuss improvement and regulatory initiatives."

- Provide evidence of minutes of the meetings, agenda, and attendees (with signatures).

In its submission, the laboratory stated in the Provider's Plan of Correction Page 10 of 43 under finding 2, "QER-20-031 was further investigated and was not due to low volume STO plate issue, rather a cassette of specimens that was tipped during decapping, prior to extraction, and a small portion of some of the specimen volumes spilled. This was treated as a ***minor spill***, remaining volumes in the sample tubes were determined to be adequate, and the specimens were submitted to Extraction for processing on the JanusG3."

- Provide the laboratory's definition of a minor spill.

- Provide a mechanism to ensure there was no contamination after the "minor spill."

- How does the laboratory define an adequate volume after a minor spill.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 11 of 43, "In response to finding 2e at no point did the laboratory director or anybody else present during the virtual meeting with LFS on 04/22/2021 (10:40 a.m.) make this affirmation. This statement is inaccurate. Please refer to attachment 1."

- Refer to the 12 questions emailed to the laboratory on February 23, 2021, and 14 additional questions emailed on March 01, 2021. The questions were re-emailed again on March 12, 2021, due to lack of response.

- Again, refer to the response provided by the laboratory on March 18, 2021, specifically "question number 2" about the above-mentioned policy and procedure.

- At the time of virtual meeting on 04/22/2021, the examiner only affirmed the absence and inaccurate response provided in the #8 (February 23, 2021) question. The laboratory director sent via email the responses to all 26 questions on March 18, 2021.

- At the time of the virtual meeting on 04/22/2021, the laboratory director asked about the missing procedure, and the examiner explained the missing procedure as indicated in the laboratory's March 18, 2021, email response.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 11 of 43 under (2) Patient Impact, "Only one sample, D-6415087003 tested positive and review of batch QC for this samples well as the batch heatmap did not indicate sample or batch contamination. Per Laboratory Director, there was no change in diagnosis, treatment, or recommended patient action for the 16 samples references in this citation and there would NOT be patient harm. The results were reported."

- Only one sample came out "positive." Provide evidence that lack of positive results was not due to "minor spill" which can potentially result in "inadequate" sample.

- Provide statistics of (+) and (-) results per batch of sample near the date of the incident.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 12 of 43, "In response to finding 1d at no point did the laboratory director or anybody else present during the virtual meeting with LFS on 04/22/2021 (10:40 a.m.) make this affirmation. This statement is inaccurate. Please refer to attachment 1."

- At the time of the virtual meeting on 04/22/2021, the examiner emphasized multiple times that LFS has consistently affirmed that the finding at the time of the complaint investigation was that the laboratory director accurately and clearly indicated in the 2567 form, which is a legal document, that CDPH Branch Lab recognizes that v.1.0 of the protocol for issuing amended or corrected reports was in draft mode and had not been signed by the laboratory director, who served part-time from 10/24/2020 to 01/27/2021.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 12 of 43 under (2) Patient Impact, "With respect to the health of the patient and community, the current Laboratory Director, determined that the lack of an approved procedure did not impact the health of the patient as amended reports were generated and submitted as described in the draft procedure."

- A misdiagnosed communicable disease, even for a single day, can potentially affect several individuals in the community.

- How did the laboratory conclude that there was no impact to the health of the patient and community?

In its submission for D5407, the document identified as “Extraction Training Record 3” showed the date of training as “30 May 2021.” The date “30 May 2021” was entered twice in the form.

- The laboratory’s submission was received on May 3, 2021.

- The training would not have occurred on May 30, 2021. When did the training occur for the individual identified in the Extraction Record Training 3?

D5779

CORRECTIVE ACTIONS CFR(s): 493.1282(a)

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

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated in the Provider’s Plan of Correction Page 14 of 43, “The College of American Pathology (CAP) field tested 11 indicators through their Q-TRACKS program and determined a statistical median rate of 2.8 test result corrections per 10,000 billable tests. Among results released in 2020 and in 2021, CDPH Branch Lab had -0.83 and -0.24 per 10,000 test result correction which is lower than the median 2.8 reported by the CAP Q-TRACKS program, therefore, this error rate is determined to not be outside of industry standards.”

- The above response is not relevant to the cited deficiency. The laboratory was cited because it reported incorrect SARS-CoV-2 results, according to CLIA regulations as adopted by California State law, not according to CAP standards pertaining to billable tests.

The laboratory also stated on page 14, “With respect to the health of the patient and the community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially not detected results but later either detected or presumptive positive did pose a risk to the patient and to the community due to the risk of transmission to close contacts and delay in seeking medical attention. The risk would be similar to a false negative result reported by any laboratory.”

- The laboratory performs only one test, and it is SARS-CoV-2 testing. The laboratory reported incorrect test results, i.e., false negative SARS-CoV-2 results. In clinical laboratory regulations, there is no acceptable error rate for false negative results for a highly transmissible viral infection.

- Clinical laboratory regulations require corrective actions to be available and followed to ensure accurate and reliable test results.

- Reports of false negative results for a highly transmissible viral infection pose a significant risk to the patient, family members, and the community.

D5787

TEST RECORDS CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following:
(a)(1) The positive identification of the specimen.
(a)(2) The date and time of specimen receipt into the laboratory.
(a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.
(a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated in the Provider's Plan of Correction Page 17 of 43 under finding 2, "The laboratory acknowledges that a discretionary decision was made in the interest of public health to not give a patient conflicting information, but rather inform the patient an error was made and recommend re-testing. Therefore, the language in the lab record for the repeated test analysis, and the result stated on amended report are different."

The laboratory's response further affirms the cited deficiency. It also indicates the laboratory's failure to retain all records of patient testing.

The laboratory's response also failed to indicate:

- What measure the laboratory has put into place or what systemic changes the laboratory has made to ensure that the deficient practice does not recur.

- How the laboratory is monitoring corrective action(s) to ensure the deficient practice does not recur.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.
(c) The laboratory must document all analytic systems assessment activities.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

On page 21 of the May 3, 2021, allegation of compliance, the laboratory stated: “There is no regulatory requirement for a laboratory to assess any particular process with a quality indicator (42 CFR 493.1701); the selection is left to the discretion of the laboratory director.”

- As indicated in the statement of deficiencies, the laboratory was cited under 42 CFR 493.1289.

- There is no section in the current CLIA regulation identified as “42 CFR 493.1701.” Please provide the source of this information.

- The laboratory’s response failed to indicate how its quality assessment policies and procedures will address the same or similar problems described in D5407, D5779, and D5787.

In its submission, the laboratory stated in the Provider’s Plan of Correction Page 22 of 43 under finding 1c, “Patients were notified that their original result had been issued incorrectly and were advised to be retested. The result of the test was not changed due to public health concerns that changing a result could result in confusion on the part of the patient. In addition, since time had passed, it was possible that the patient’s infection status had changed and the result from the original specimen may no longer

reflect the patient's true status. Therefore, the decision was made that the amended report should only state that the original report was issued in error and recommend that the patient be re-tested."

- The laboratory's response failed to indicate the extent of the error (specifically, clinically significant results were incorrectly reported).

D5800 - 42 C.F.R section 493.1290 Condition: Postanalytic systems

D5800 (Refer to D5805, D5821)

POSTANALYTIC SYSTEMS CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.

The allegation of compliance is not credible, and the evidence of correction is not acceptable. (Refer to D5805, D5821)

D5805

TEST REPORT CFR(s): 493.1291(c)

The test report must indicate the following:
(c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
(c)(2) The name and address of the laboratory location where the test was performed.
(c)(3) The test report date.
(c)(4) The test performed.
(c)(5) Specimen sources, 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.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated in the Provider's Plan of Correction Page 24 of 43 under immediate corrective action, "Request was made to Color Genomics by the Laboratory Director on 04/30/2021 to change the language of the report to say, 'test could not be completed due to lab error.' It is expected that the change will be in effect no later than 06/01/2021."

- What is the laboratory's quality assurance mechanism for immediate corrective action? June 01, 2021 is a month-long wait for an immediate correction.

- Was there any patient monitoring or statistics of patients who came back for re-testing?

- Correct information about specimen disposition will provide the patient proper guidance and inform the patient that the error was due to laboratory error, and their newly re-collected samples are more likely to give a satisfactory result.

In its submission, the laboratory stated in the Provider's Plan of Correction Page 25 of 43 under (3) Preventive Measure, "The Accessioning Supervisor reviews all selected 'UNSAT' codes prior to release to ensure the correct code has been selected."

- Provide evidence of review mentioned in the above statement.

D5821

TEST REPORT CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following:

(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.
(k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.
(k)(3) Maintain duplicates of the original report, as well as the corrected report.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated in the Provider's Plan of Correction Page 31 of 43, "The laboratory must perform the activities promptly but does not specifically define the number of days. Upon review of the QERs, it was determined that the laboratory took action to provide corrected reports within the timeframes below.

a. QER-20-010: 3 days from incident to identification of issue, 4 days to perform the investigation, and verification to Color.

b. QER-20-012: 1 day from incident to identification of the issue, 4 days to perform the investigation, and notification to Color Health which included rerunning the sample in question to confirm the result.

c. QER-20-013: 6 days from incident to identification of the issue, same day to perform the investigation and notification to Color Health."

- Identify potential patient impacts secondary to >2 days delay of issuing amended reports, or without a defined timeframe, in the context of highly communicable disease.

- What measure the laboratory has put into place or what systemic changes the laboratory has made to ensure that the deficient practice does not recur.

- How the laboratory is monitoring corrective action(s) to ensure the deficient practice does not recur.

D5891 (Refer to D5805 and D5821)

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address D5805 and D5821 quality assurance issues.

D6076 – 42 CFR 493.1441 Laboratories performing high complexity testing; Laboratory Director

D6076 (Refer to D6094, D6102)

LABORATORY DIRECTOR CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address D6094 and D6102 quality assurance issues.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

The allegation of compliance is not credible, and the evidence of correction is not acceptable.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

In its submission, the laboratory stated in the Provider's Plan of Correction Page 37of 43, "There is weekly documented review of all QERs and CAPAs to monitor progress, detect trends and initiate process improvements, as appropriate."

- Provide all the QERs and CAPAs as of 04/23/2021

- Provide evidence that it was completed within 15 days.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

To correct this deficiency, the laboratory must address the information specified in the following bullets:

- Provide all the missing competency assessments indicated in the deficient practice.

We are giving you another opportunity to provide the remaining information identified in our review.

You have 10 CALENDAR DAYS from the date of this notice to provide this office (at the address shown at the end of this notice), with a credible allegation of compliance and acceptable evidence documenting action you have taken to correct all of the Condition level deficiencies in question.

If you submit the requested evidence of correction showing your laboratory has come into Condition-level compliance, postmarked by **October 18, 2021**, and we are able to verify compliance with all CLIA requirements through an on-site follow-up inspection, sanctions will not be imposed. Electronic submission is acceptable.

Please send all correspondence to the following address:

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

After we have reviewed your response and have determined your compliance, we will conduct an on-site follow-up inspection to verify your laboratory’s corrective actions.

If you have any questions regarding this letter, you may contact Catherine Tolentino at 213-422-5703 or via email at Catherine.Tolentino@cdph.ca.gov.

Sincerely,

ctolentino

Catherine C. Tolentino
Examiner II

Elsa Eleco
Section Chief

cc: Robert J. Thomas
Branch Chief