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)

May 17, 2021

Adam Rosendorff, MD
CLIA Laboratory Director
CDPH Branch Laboratory
28454 Livingston Ave
Valencia, CA 91355

Timothy Bow
Emergency Procurement Officer, Owner Representative
California Department of Public Health
850 Marina Bay Parkway, Bldg. P
Richmond, CA 94804

STATE: CPH889339
CLIA: 05D2197416

PUBLIC HEALTH LABORATORY STATE INSPECTION – Routine Inspection
CONDITION REMAINS – Additional Information Required

Dear Laboratory Director/Owner:

In order for a public health laboratory to perform testing under the Health and Safety Code 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 42 Code of Federal Regulations, Part 493 (42 CFR 493). Compliance with these regulations is a condition of certification for the State Public Health Laboratory Certification program.

An inspection of your laboratory was conducted on December 8, 2020, and December 9, 2020, and on December 16, 2020, by Elsa Eleco, Examiner III, Elaine Flores, Examiner II, Catherine Tolentino, Examiner II, and Jinong Feng, Examiner I, representatives of the California Department of Public Health (the Department), Laboratory Field Services. This routine inspection concluded on February 17, 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 **February 19, 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 February 19, 2021, letter, the Department received four submissions from your laboratory on March 1, March 8, March 11, and March 30, 2021.

After careful review of your cumulative submissions, this Condition level deficiency remains:

D5400 - 42 CFR 493.1250 Condition: Analytic systems

We are providing you with the list of remaining deficiencies that you need to address.

D3027 - Retention Requirements

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

In its submission, the laboratory stated in the monitoring mechanism:

> "Monthly audits for FY 2021 to determine availability and compliance with all required elements are performed by the quality organization. The availability of the requisition and report was confirmed for 10 samples via a routine tracer audit performed 02/26/2021. An audit of an additional 25 samples was initiated 03/11/2021 to verify that requisitions are available and include all necessary requisition elements."

To correct this deficiency, the laboratory must

- During the on-site follow-up inspection on March 18, 2021, the laboratory was able to provide the audit performed on February 26, 2021.

- Provide the March 11, 2021, **audit of 25 additional samples** mentioned in the allegation of compliance.

D5301 – Test Request

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

In its submission, the laboratory stated in the immediate corrective action:

> "Through cooperation with Color Genomics and the CDPH Branch Laboratory, a method to present the data from the electronic order in the form of a requisition was established. The Laboratory Director and the member of the Quality

Assurance team received training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics, on demand."

To correct this deficiency, the laboratory must

- Identify the quality assurance team who received the training that allows them to effectively and efficiently access the electronic requisitions and reports stored by Color Genomics.

- Provide the training records.

D5400 Condition Analytic Systems

See D5423.

D5423 Establishment of Performance Specifications

CFR 493.1253(b)(2) states that

(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

(i) Accuracy.
(ii) Precision.
(iii) Analytical sensitivity.
(iv) Analytical specificity to include interfering substances.
(v) Reportable range of test results for the test system.
(vi) Reference intervals (normal values).
(vii) Any other performance characteristic required for test performance.

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

a. Review of the EUA and IFU for Perkin Elmer New Coronavirus Nucleic Acid Detection Kit (01/12/2021) indicated, "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."

In its submission, the laboratory stated in the immediate corrective action:

"The laboratory reviewed the current IFU (version 6) to confirm that use in asymptomatic individual is appropriate."

To correct this deficiency, the laboratory must:

- Provide the supporting documentation regarding the statement in the EUA/IFU 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."

b. Interpretation of Test Results

In its submission, the laboratory stated the following data analysis timeline for the interpretation of test results:

1. 10/28/2020 to 11/11/2020- results were reported as per the IFU
2. 11/11/2020 to 12/11/2020- a lower Ct cutoff was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU
3. 12/11/2020 to 01/25/2021- high Ct values (>37-<42 was interpreted as inconclusive
4. 01/25/2021-present- high Ct values (>37-<42 was interpreted as presumptive positive

To correct this deficiency, the laboratory must:

- The laboratory's current interpretation of results is not indicated in the IFU of the EUA. Provide documentation, i.e. current as well as historical data generated at the CDPH Branch Laboratory (Valencia Branch Laboratory) to validate the laboratory's current interpretation of results as of 01/25/2021. You may also provide any additional data demonstrating you established

performance specifications prior to adopting the current result interpretation to show compliance with this regulation.

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 has been 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 **May 27, 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,

Elsa Eleco
Section Chief, On-Site Licensing Inspections

cc: Robert J. Thomas
Branch Chief

Catherine C. Tolentino
Examiner II