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 constitute proof of receipt of this letter)

April 23, 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 - CONDITION LEVEL DEFICIENCIES – IMMEDIATE JEOPARDY

Dear Laboratory Director/Owner(s):

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 February 7, 2021, 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. In addition, the examiners determined that the deficient practices of your laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined in the California Code of Regulations (CCR) as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.) Specifically, the laboratory did not meet the following Conditions:

D5200 - 42 CFR 493.1230 Condition: General Laboratory Systems
D5400 - 42 CFR 493.1250 Condition: Analytic systems
D5800 - 42 CFR 493.1290 Condition: Postanalytic systems
D6076 - 42 CFR 493.1441 Condition: Laboratories performing high complexity testing; laboratory director

In addition, other standards were also found to be not met. Enclosed is Form 2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Because of the seriousness of these deficiencies, your laboratory no longer meets the requirements to perform testing under the Health and Safety Code. Based on the finding of immediate jeopardy, this office has contacted the Centers for Medicare & Medicaid Services (CMS), and has notified them of our determination of non-compliance.

When a laboratory's deficiencies pose immediate jeopardy, the Department requires the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance.

Failure to meet Condition-level requirements and/or failure to return the allegation of compliance and accompanying evidence within the stated time period may result in sanctions against the public health laboratory's certificate, laboratory director, and owners, suspension from the Medi-Cal and/or Medicaid program in addition to civil money penalties, and recovery of costs associated with the investigation:

1. Civil money penalties for each day of noncompliance or per violation for a condition level deficiency that poses immediate jeopardy, to the extent permitted by law.

2. Exclusion from ownership or operation (Title 17 CCR § 1065.5)

3. Revocation and/or suspension of the public health certificate (Title 17 CCR § 1065.5)

Please be advised that sanctions and/or enforcement actions can be rescinded only when compliance is verified. Please also be advised that due to the potential significant hazard to the public health and safety posed by the deficiencies identified, sanctions may become effective 21 calendar days from the date of this letter.

You have 10 CALENDAR DAYS from the date of this notice to provide this office with a credible allegation of compliance and acceptable evidence documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies in question.

You are directed to document your allegation of compliance using the enclosed State Form 2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date, and return the completed State Form 2567 documented with a credible allegation of compliance to our office, at the address shown at the end of this notice, WITHIN 10 CALENDAR DAYS from the date of this notice. Electronic submission is acceptable. You must also submit documented evidence that verifies that the corrections were made.

For your information, 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 survey and the date of the allegation; and

3. Indicates resolution of the problems.

In addition, acceptable evidence of correction must include:

1. Documentation showing what corrective action(s) the laboratory has taken for patients found to have been affected by the deficient practice;

2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) the laboratory has taken;

3. 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; and

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

If you submit a credible allegation of compliance and acceptable evidence that your laboratory has removed jeopardy and come into Condition-level compliance, postmarked by May 3, 2021, and we are able to verify compliance with all CLIA requirements through a follow-up survey, we will not impose sanctions. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

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

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

Sincerely,

ctolentino

Catherine Tolentino
Examiner II

Enclosure

cc: Robert J. Thomas
Branch Chief

Elsa Eleco
Section Chief, On-Site Licensing