



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

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



GAVIN NEWSOM  
Governor

October 21, 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

**NOTICE OF INTENT TO IMPOSE SANCTIONS**

Dear Dr. Rosendorff,

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.

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.

In our letter of May 17, 2021, we notified you that your four previous submissions on March 1, March 8, March 11, and March 30, 2021, failed to remove all condition level deficiencies.

In our June 8, 2021, letter, the Department notified you that your May 24, 2021, submission failed to remove the remaining condition level deficiency. We also notified you that this was our final request for information.

We received email communications from the laboratory on June 18, 2021, and July 3, 2021. We also received another submission from your laboratory on August 20, 2021. After carefully reviewing your submission, the Department determined that you failed to remove this remaining Condition level deficiency:

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

Your August 20, 2021, submission failed to address the issues we identified in our June 8, 2021, letter.

Pursuant to Title 17 of the California Code of Regulations (17 CCR) sections 1065, 1067 and 1067.10, notice is hereby given that the California Department of Public Health (Department) intends to impose the alternative sanctions of a directed plan of correction and on-site monitoring upon the CDPH Branch Laboratory.

#### **Intent to impose a directed plan of correction**

CDPH Branch Laboratory shall address the issues we identified in our June 18, 2021, letter and provide validation data from the proposed validation plan it submitted to the Department on June 18, 2021, and July 3, 2021.

#### **Intent to impose onsite monitoring**

CDPH Branch Laboratory shall be subjected to random, unannounced, on-site monitoring by the Department for compliance with the directed plan of correction for one year, at the CDPH Branch Laboratory's expense. In addition, CDPH Branch Laboratory shall be subjected to random, unannounced, on-site inspections by the Department or its designee for the next two years.

## Response by Laboratory

The laboratory shall have **10** calendar days from the date of receipt of the Notice of Intent to Impose Sanctions to send on **November 1, 2021**, a written response and evidence or information against the imposition of the proposed sanction. Any written response or submitted evidence or information shall supplement the laboratory's previous submissions.

If you have any question regarding this letter, please contact Catherine Tolentino at [Catherine.Tolentino@cdph.ca.gov](mailto:Catherine.Tolentino@cdph.ca.gov) or contact me at [Elsa.Eleco@cdph.ca.gov](mailto:Elsa.Eleco@cdph.ca.gov).

Sincerely,



Elsa Eleco  
Section Chief, On-Site Licensing

cc: Catherine C. Tolentino  
Examiner II

Robert J. Thomas  
Branch Chief, Laboratory Field Services

LeeAnn Dennewitz  
SVP, Strategic Partnerships & Alliances, PerkinElmer