

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



Governor

July 21, 2021

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

Dear Dr. Rosendorff,

Thank you for your message. With regard to your request for an extension, please refer to our June 8, 2021, letter and our June 16, 2021, Teams Call.

Laboratory Field Services (LFS) has granted the extensions you have requested, and we have also answered your questions during the Microsoft Teams call on June 16, 2021.

The laboratory's response to our June 8, 2021, letter was due on June 18, 2021.

- On June 10, 2021, the laboratory requested a seven-week extension, until July 20, 2021. LFS granted your request on the same day, June 10, 2021.
- You also requested a conference call with LFS. LFS granted your request, and we conducted a conference call with your team on June 16, 2021.
- On July 3, 2021, the laboratory requested another extension, until September 7, 2021.
- On July 6, 2021, LFS acknowledged your request and indicated we would get back to you regarding your request for a further extension.
- On July 19, 2021, we granted your request for an extension and gave you until August 20, 2021.
- On July 19, 2021, you also requested another conference call, in addition to our previous call last June 16, 2021.

LFS will not be granting your request for another conference call. LFS is a regulatory agency. We evaluate all laboratories for compliance, including the CDPH Branch Laboratory (Valencia Branch Laboratory). We cannot cite a laboratory and act as a



Adam Rosendorff, MD July 21, 2021 Page 2

consultant to correct the deficiencies we cited. It is the laboratory director's responsibility to ensure the laboratory is in condition-level compliance with CLIA regulations at all times.

We are not granting your request for a second conference call. We will also not entertain any further requests for deadline extension.

LFS looks forward to receiving and reviewing the laboratory's response to our June 8, 2021, letter by August 20, 2021.

Sincerely,

aller & alles

Elsa Eleco Section Chief, On-Site Licensing

cc: Robert J. Thomas Branch Chief, Laboratory Field Services

> Timothy Bow Emergency Procurement Officer, California Department of Public Health

LeeAnn Dennewitz SVP, Strategic Partnerships & Alliances. PerkinElmer