December 8, 2021

Ilka Warshawsky, M.D., Ph.D.
Director, Molecular Diagnostics Laboratory
Akron Children's Hospital
One Perkins Square
Akron, OH 44308
Re: Revocation of EUA202545

Dear Dr. Warshawsky:

This letter is in response to Akron Children's Hospital's request received December 3, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA202545) for the Akron Children's Hospital SARS-CoV-2 Assay issued on September 29, 2020 and amended on September 23, 2021. Akron Children's Hospital confirmed that it stopped performing the Akron Children's Hospital SARS-CoV-2 Assay, having implemented a number of additional SARS-CoV-2 molecular assays which have received EUA.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Akron Children's Hospital has notified FDA that it stopped performing the Akron Children's Hospital SARS-CoV-2 Assay and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202545 for the Akron Children's Hospital SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Akron Children's Hospital SARS-CoV-2 Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration