March 14, 2022

Ilknur Cetin
Quality Assurance Manager
RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (RTA Laboratuvarlari Biyolojik Urunler Ilac ve Makine San)
76 TW Alexander Drive
Research Triangle Park, NC 27709

Re: Revocation of EUA200486

Dear Ilknur Cetin,

This letter is in response to RTA Laboratories Biological Products Pharmaceutical and Machinery Industry's (RTA's) request dated February 15, 2022, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200486) for the Diagnovital SARS-CoV-2 Real-Time PCR Kit issued on June 12, 2020 and revised on September 23, 2021. In its February 15, 2022, letter, RTA requested revocation of the EUA effective February 15, 2022, as the product will no longer be distributed or used by that date. FDA understands that RTA has decided not to continue to commercially support the Diagnovital SARS-CoV-2 Real-Time PCR Kit.

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 RTA has notified FDA that the EUA for the Diagnovital SARS-CoV-2 Real-Time PCR Kit is no longer required and requested that FDA revoke the EUA for the Diagnovital SARS-CoV-2 Real-Time PCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200486 for the Diagnovital SARS-CoV-2 Real-Time PCR Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Diagnovital SARS-CoV-2 Real-Time PCR Kit 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,

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