December 17, 2021

Ayu Sucipto
Regulatory Affairs Specialist
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave.
Tarrytown, NY 10591
Re: Revocation of EUA201696

Dear Ayu Sucipto:

This letter is in response to a request from Siemens Healthcare Diagnostics Inc. (Siemens), received December 9, 2021, that the U.S. Food and Drug Administration (FDA) voluntarily remove the Atellica IM SARS-CoV-2 IgG (COV2G) -EUA201696 issued on July 31, 2020 and amended on September 23, 2021 from FDA's list of authorized devices. FDA understands that the authorized product is no longer being marketed.

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 Siemens has notified FDA that Siemens has decided to no longer market the authorized product and requested FDA voluntarily remove the Atellica IM SARS-CoV-2 IgG (COV2G) -EUA201696 from FDA's list of authorized devices, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201696 for the Atellica IM SARS-CoV-2 IgG (COV2G), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Atellica IM SARS-CoV-2 IgG (COV2G) 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