March 15, 2022

Mari Meyer
DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082-0285

Re: Revocation of EUA202004

Dear Mari Meyer:

This letter is in response to a request from DiaSorin Inc., received March 10, 2022, that the U.S. Food and Drug Administration (FDA) revoke the DiaSorin LIAISON SARS-CoV-2 IgM Assay–EUA202004 issued on September 29, 2020, and revised September 23, 2021. DiaSorin Inc. has decided to discontinue commercial distribution and support of the DiaSorin LIAISON SARS-CoV-2 IgM Assay and there is not any viable/non-expired product remaining in distribution.

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 DiaSorin Inc. has notified FDA that DiaSorin Inc. has decided to discontinue commercial distribution and support of the DiaSorin LIAISON SARS-CoV-2 IgM Assay and requested FDA revoke the EUA for the DiaSorin LIAISON SARS-CoV-2 IgM Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202004 for the DiaSorin LIAISON SARS-CoV-2 IgM Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the DiaSorin LIAISON SARS-CoV-2 IgM 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