U.S. FOOD & DRUG ADMINISTRATION

May 3, 2022

Jacob Kurdys
Vice-President of Laboratory Operations
Cormeum Laboratory Services
160 E James Dr, Suite 200
Saint Rose, LA 70087

Re: EUA200187/S002
Trade/Device Name: Cormeum SARS-CoV-2 Assay
Dated: December 21, 2021
Received: December 22, 2021

Dear Jacob Kurdys:

This is to notify you that your request to update the Cormeum Laboratory Services Standard Operating Procedure (SOP) - COVID-19 Extraction and Plate Run for the Cormeum SARS-CoV-2 Assay to; (1) include extensive revisions to improve the overall clarity, and (2) update in response to Condition of Authorization (1) of the Viral Mutation Revision Letter dated 09-23-2021, is granted. Upon review, we concur that the information submitted in EUA200187/S002 supports the requested updates for use with the Cormeum SARS-CoV-2 Assay and the EUA Summary has been updated accordingly. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the November 15, 2021 reissued EUA for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (Molecular LDT COVID19 Authorized Test), for which the Cormeum SARS-CoV-2 Assay was added to Appendix A as an authorized test on June 12, 2020 and the and the Viral Mutation Revision Letter issued on September 23, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health