U.S. FOOD & DRUG ADMINISTRATION

September 18, 2020

Brittany Manus
Quality Coordinator
Ethos Laboratories
29 E. 6th Street
Newport, KY 41071

Re: EUA201422/S002
Trade/Device Name: Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay
Dated: August 26, 2020
Received: August 27, 2020

Dear Ms. Manus:

This is to notify you that your request to include minor updates to the Ethos Laboratories U-Collect At Home Collections -COVID-19 Viral Test Instruction and website, is granted. Upon review, we concur that the information submitted in EUA201422/S002 supports the requested updates for use with the Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay issued on August 3, 2020.

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