June 4, 2020

Mrudula Rakhade
CSO
Altru Diagnostics, Inc.
8562 Katy Freeway, Suite 152
Houston, TX, 77024

Re: EUA200123/A001
Trade/Device Name: Altru Dx SARS-CoV-2 Assay
Laboratory: Altru Diagnostic, Inc.

Dated: May 23, 2020
Received: May 23, 2020

Dear Ms. Rakhade:

This is to notify you that your request to update the Instructions for Use (IFU) of the Altru SARS-CoV-2 Assay to add the MagMAX Viral/Pathogen II (MVPII) Nucleic Acid Isolation kit as an extraction method to your EUA, is granted. Upon review, we concur that the data and information submitted in EUA200123/A001 supports the requested updates for use with the Altru SARS-CoV-2 Assay. FDA also made some minor changes to the EUA Summary. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the March 31, 2020 Letter Of Authorization for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (Molecular LDT COVID-19 Authorized Test), for which the Altru SARS-Co-V-2 Assay was added to Appendix A as an authorized test on April 30, 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