September 21, 2023

Marlene Hanna
Director, Regulatory Affairs
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

Re: EUA210355/S001
Trade/Device Name: VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators
Dated: September 14, 2023
Received: September 14, 2023

Dear Marlene Hanna:

This is to notify you that your request to (1) update the name of the authorized control material "VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls" to "VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Controls" and the associated updates to the authorized labeling, and (2) various additional minor updates to the authorized labeling associated with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators device, are granted. Upon review, we concur that the information submitted in EUA210355/S001 supports the requested updates for use with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators device. 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 VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators device issued on July 22, 2021.

Sincerely yours,

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