March 1, 2023

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

Re: EUA202928/S004
Trade/Device Name: VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack used in combination with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator
Dated: November 16, 2022
Received: November 16, 2022

Dear Marlene Hanna:

This is to notify you that your request to update the authorized labeling of the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack used in combination with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA202928/S004 supports the requested updates for use with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack used in combination with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients has been updated by FDA consistent with this revision and are included along with this letter. By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022.

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