January 29, 2021

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

Re: EUA200233/S002
Trade/Device Name: VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack/VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator and VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls
Supplement Dated: August 10, 2020
Supplement Received: August 10, 2020

Dear Ms. Hanna:

This is to notify you that your request to update the Instructions for Use (IFU) of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total test to: (1) add in the interpretation of results section the terms "*negative*" and "*positive*" next to "*Non-reactive*" and "*Reactive*" respectively, and (2) change the storage and transportation temperature of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator and VITROS Immunodiagnostic Products VITROS Anti-SARS-CoV-2 Total Controls from refrigerated to frozen, is granted. Upon review, we concur that the data and information submitted in EUA200233/S002 supports the changes to the IFU. By submitting this supplement 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 Reagent Pack issued on April 14, 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