U.S. FOOD & DRUG ADMINISTRATION

May 9, 2020

Marlene Hanna
Director, Regulatory Affairs
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14262

Re: EUA200233/A001
Trade/Device Name: VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total
Dated: May 1, 2020
Received: May 1, 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) revise the intended use in accordance with the May 4, 2020 *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency*, (2) revise the Sensitivity section to incorporate the new data from 50 additional SARS-CoV-2 positive samples, and delete the Clinical Agreement table, (4) revise the Substances that do not Interfere table with results from the supplemental interference study required as part of the condition "S" in the April 14, 2020 Letter of Authorization, and (4) make various technical and editorial clarifying revisions, is granted. Upon review, we concur that the data and information submitted in EUA200233/A001 supports the requested updates for use with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total. In addition, you have fulfilled condition "S" in the April 14, 2020 Letter of Authorization that required a supplemental interference study. By submitting this amendment 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 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