U.S. FOOD & DRUG ADMINISTRATION

May 20, 2020

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

Re: EUA200386/A001
Trade/Device Name: VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack
Dated: May 11, 2020
Received: May 11, 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 IgG Reagent Pack to; (1) update the Ortho contact email address to OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com in the Limitations of the Procedure section, (2) revise the Sensitivity section to incorporate the new data from 10 additional SARS-CoV-2 positive samples, and delete the Clinical Agreement table, and (3) add other minor updates for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200386/A001 supports the requested updates for use with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack. 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 IgG Reagent Pack issued on April 24, 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