



October 30, 2020

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

Re: EUA200233/S003
Device Name (Authorized): VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack
Authorization Date: April 14, 2020
Supplement Received: September 24, 2020

Dear Ms. Marlene Hanna:

This is to notify you that your request to update the Fact Sheet for Healthcare Providers and the Instructions for Use (IFU) of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack, to include a limitation, is granted. Upon review, for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack, we concur with the additional limitation to the package insert: *"A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response."* We also concur with the additional statement to the Fact Sheet for Health Care Providers: *"Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies."* for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack. FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting this 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 Reagent Pack issued on April 14, 2020.

Sincerely yours,

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