



November 16, 2021

Marlene Hanna  
Ortho Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626

Re: EUA202928/S003

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: June 14, 2021

Received: June 15, 2021

Dear Ms. Hanna:

This is to notify you that your request to update the formulation of the calibrator and control reagents and also update Instructions for Use (IFU) of the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack used in combination with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator to improve clarity, is granted. Upon review, we concur that the data and information submitted in EUA202928/S003 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. By submitting this EUA 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 SARS-CoV-2 Antigen Reagent Pack used in combination with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator reissued on March 16, 2021.

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