



June 29, 2022

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

Re: EUA210322/S002

Trade/Device Name: VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative
Reagent Pack used in combination with VITROS Immunodiagnostic Products
Anti-SARS-CoV-2 IgG Quantitative Calibrator

Dated: May 25, 2022

Received: May 25, 2022

Dear Ms. Hanna:

This is to notify you that your request to update the on-board and off-board storage stability claims of the reagent pack after opening from 8 weeks to 6 weeks, for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack used in combination with VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator, is granted. Upon review, we concur that the data and information submitted in EUA210322/S002 supports the requested updates to the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative test Instructions for Use. FDA has also updated the Factsheet for Healthcare Provider and Factsheet for Patients to reflect language used in more recent authorizations. 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 IgG Quantitative test issued on July 9, 2021.

Sincerely yours,

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

Enclosure¹

¹ Technical Correction on July 13, 2022, to correct the printed date on the Letter Granting EUA Revision from June 29, 2021 to June 29, 2022 to be consistent with the date of signature.