



September 8, 2021

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

Re: EUA210322/S001

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: August 5, 2021

Received: August 10, 2021

Dear Ms. Hanna:

This is to notify you that your request to update information on interference testing for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative test is granted. Upon review, we concur that the data and information submitted in EUA210322/S001 supports the requested update and the corresponding updates to the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative test Instructions for Use. 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