



June 20, 2024

Jacek Gorzowski
Director, Regulatory Affairs
Abbott Laboratories Inc.
100 Abbott Park Road
Abbott Park, IL 60064

Re: EUA203119/S003
Trade/Device Name: AdviseDx SARS-CoV-2 IgG II
Dated: April 26, 2024
Received: April 26, 2024

Dear Jacek Gorzowski:

This is to notify you that your request is granted to update the AdviseDx SARS-CoV-2 IgG II to extend the shelf-life expiration date for the (1) AdviseDx SARS-CoV-2 IgG II Reagent Kit to 11 months when stored at 2 – 8°C, (2) AdviseDx SARS-CoV-2 IgG II Calibrator Kit to 12 months when stored at -20°C, and (3) AdviseDx SARS-CoV-2 IgG II Control Kit to 12 months when stored at -20°C, based on the results of your stability studies. Upon review, we concur that the data and information submitted in EUA203119/S003 supports the requested update for the AdviseDx SARS-CoV-2 IgG II. 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 AdviseDx SARS-CoV-2 IgG II issued on March 1, 2021.

Sincerely yours,

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