



December 10, 2021

Mary Ann Fiechtner
Senior Regulatory Affairs Specialist
Becton, Dickinson and Company
BD Integrated Diagnostic Solutions – Point of Care
10865 Road to the Cure, Suite 200
San Diego, CA 92064

Re: EUA201889/S004

Trade/Device Name: BD Veritor System for Rapid Detection of SARS-CoV-2

Dated: July 12, 2021

Received: July 13, 2021

Dear Ms. Fiechtner:

This is to notify you that your request to update the shelf-life expiration date of the BD Veritor System for Rapid Detection of SARS-CoV-2 test to 10 months at 2–30°C based on the results of your real-time stability study, is granted. Upon review, we concur that the data and information submitted in EUA201889/S004 supports the requested update. 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 BD Veritor System for Rapid Detection of SARS-CoV-2 re-issued on March 31, 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