July 28, 2023

Kathy Barnecut, RAC
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks, MD 21152

Re: EUA220369/S002
Trade/Device Name: BD Respiratory Viral Panel for BD MAX System
Dated: April 21, 2023
Received: April 21, 2023

Dear Ms. Barnecut:

This is to notify you that your request to update the Instructions for Use of the BD Respiratory Viral Panel for BD MAX System to; (1) add clinical performance data provided to fulfill Condition of Authorization P. in the February 3, 2023 Letter of Authorization, (2) update the *in silico* inclusivity analysis, (3) clarify instructions for testing the external negative control, (4) clarify instructions for repeat testing of samples, and (5) provide minor clarifying edits, is granted. Upon review, we concur that the data and information submitted in EUA220369/S002 supports the requested updates for use with the BD Respiratory Viral Panel for BD MAX System and fulfills Condition of Authorization P listed in the February 3, 2023, Letter of Authorization. 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 Respiratory Viral Panel for BD MAX System issued on February 3, 2023.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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Center for Devices and Radiological Health

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