



June 25, 2021

Shakil Ahmed  
Sr. Director, Quality Assurance  
Twist Bioscience Corporation  
681 Gateway Boulevard  
South San Francisco, CA 94080

Re: EUA202029/S001  
Trade/Device Name: SARS-CoV-2 NGS Assay  
Dated: April 26, 2021  
Received: April 26, 2021

Dear Shakil Ahmed:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 NGS Assay to; (1) include results of the additional *in silico* inclusivity analysis completed to fulfill Condition of Authorization R. of the March 23, 2021 letter of authorization, (2) include an Research Use Only (RUO) verification protocol for the Illumina NextSeq500 and NextSeq550 Sequencing Systems to fulfill Condition of Authorization P. of the March 23, 2021 letter of authorization, and (3) update some minor errors, is granted. Upon review, we concur that the data and information submitted in EUA202029/S001 supports the requested updates for use with the SARS-CoV-2 NGS Assay. In addition, we concur that the lot release protocol provided for our review as part of Condition of Authorization M. of the March 23, 2021 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 SARS-CoV-2 NGS Assay issued on March 23, 2021.

Sincerely yours,

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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