



September 23, 2022

Ronald Lollar
Vice President, Clinical, Medical, Regulatory Affairs and Validation
Quidel Corporation
9975 Summers Ridge Road
San Diego, CA 92121

Re: EUA210269/S003/A001
Trade/Device Name: QuickVue At-Home OTC COVID-19 Test
Dated: June 2, 2022
Received: June 2, 2022

Dear Ronald Lollar:

This is to notify you that your request to update the QuickVue At-Home OTC COVID-19 Test to 1) extend the shelf-life expiration date to 16 months when stored at 15°C – 30°C, based on the results of your ongoing stability studies, 2) update the “QuickVue At-Home OTC COVID-19 Test Kit Healthcare Provider Instructions for Use”, the “QuickVue At-Home OTC COVID-19 Test User Instructions” multi-page format, and the “QuickVue At-Home OTC COVID-19 Test User Instructions” 2-page format with the product storage temperature range, and 3) update the labeling for the CVS Health At Home COVID-19 Test Kit (alternate brand name/trade name) with the product storage temperature range, correction to website address, and minor formatting changes, is granted. Upon review, we concur that the data and information submitted in EUA210269/S003/A001 support the requested update for the QuickVue At-Home OTC COVID-19 Test. 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 QuickVue At-Home OTC COVID-19 Test re-issued on October 21, 2021.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health