July 21, 2022

Ronald Lollar
VP, Clinical and Regulatory Affairs – Infectious Disease
Quidel Corporation
9975 Summers Ridge Road
San Diego, CA 92121

Re: EUA210269/S004
Trade/Device Name: QuickVue At-Home OTC COVID-19 Test
Dated: June 17, 2022
Received: June 17, 2022

Dear Ronald Lollar:

This is to notify you that your request to offer the QuickVue At-Home OTC COVID-19 Test under the brand name/trade name of CVS Health At Home COVID-19 Test Kit in a 2-tests per kit configuration, is granted. Upon review, we concur that the information and CVS Health At Home COVID-19 Test Kit labeling submitted in EUA210269/S004 is consistent with and 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 QuickVue At-Home OTC COVID-19 Test re-issued on October 21, 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