August 17, 2022

Morteza Minaee
Head of Quality Assurance and Regulatory Affair
Detect Inc.
530 Old Whitfield Street
Guilford, CT 06437

Re: EUA210534/S006
Trade/Device Name: Detect Covid-19 Test
Dated: August 9, 2022
Received: August 9, 2022

Dear Morteza Minaee:

This is to notify you that your request to update the Detect Application to improve clarity and functionality of the App, is granted. Upon review, we concur that the information submitted in EUA210534/S006 supports the requested updates for use with the Detect 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 Detect Covid-19 Test re-issued on April 11, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
DHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health