



January 12, 2022

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

Re: EUA210534/S001 & S002  
Trade/Device Name: Detect Covid-19 Test  
Dated: November 24, 2021 and December 7, 2021  
Received: November 29, 2021 and December 8, 2021

Dear Morteza Minaee:

This is to notify you that your request to (1) update the Detect Application (App) with the FDA agreed upon changes to fulfill Condition of Authorization Y. of the Letter of Authorization issued on October 28, 2021, that included addition of a user-facing Frequently Asked Questions section, and (2) update the Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers to include results of the near-cutoff study completed to fulfill Condition of Authorization U. of the Letter of Authorization issued on October 28, 2021, is granted. Upon review, we concur that the data and information submitted in EUA210534/S001 and EUA210534/S002 supports the requested updates for use with the Detect Covid-19 Test and fulfills Conditions of Authorization U. and Y of the October 28, 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 Detect Covid-19 Test issued on October 28, 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