U.S. FOOD & DRUG ADMINISTRATION

January 12, 2022

Morteza Minaee
Head of Quality Assurance and Regulatory Affair
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 [illegible]plicat[illegible] (Appl) with the FDA agreed upon changes to fulfill Condition of Authorization Y. of the Letter of Authorizati[illegible]su[illegible] on Octo[illegible], 2021, that included addition of a user-facing Frequently Asked Questions section, and (2) [illegible]ate the Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Hea[illegible]are Pro[illegible]rs to i[illegible]de results of the near-cutoff study completed to fulfill Condition of Authorization U[illegible] the Letter of [illegible]thoriza[illegible] issued on October 28, 2021, is granted. Upon review, we concur that the data [illegible]nd information su[illegible]mitted in EUA210534/S001 and EUA210534/S002 supports the requested upda[illegible]s for use with the [illegible]tect Covid-19 Test and fulfills Conditions of Authorization U. and Y of the October 2[illegible]2021 [illegible]ter of Authorizat[illegible]n. By submitting this EUA revision for review by the Food and Drug Administration (FD[illegible] you h[illegible] complied w[illegible] the Conditions of Authorization stated in the letter authorizing the emergency use of th[illegible]Detect C[illegible] 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

REVOKED