

January 12, 2022

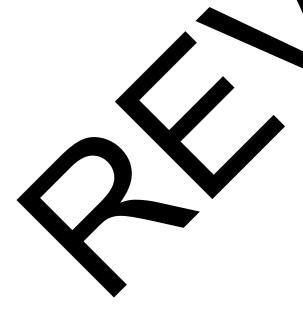
Morteza Minaee Head of Quality Assurance and Regulatory Affair Detect Inc. 530 Old Whitfield Street Guilford, CT 06437

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 Detection licat to fulfill Condition of Authorization Y. of the Letter of Authorization รน addition of a user-facing Frequently Asked Questions see and (2 Molecular Home Test Instructions for Use For Hea s to T completed to fulfill Condition of Authorization the Letter o horiz granted. Upon review, we concur that the data hd information su EUA210534/S002 supports the requested upda for use with the Authorization U. and Y of the October 2 2021 ter of Authorizat by the Food and Drug Administration (FD you h complied w letter authorizing the emergency use of th etect C

alicat an (inc) with the FDA agreed upon changes a usual on October 2007, 2021, that included (2) that the Detect Covid-19 Test Covid-19 rs to hande results of the near-cutoff study athorization issued on October 28, 2021, is a mitted in EUA210534/S001 and e attect Covid-19 Test and fulfills Conditions of attent. By submitting this EUA revision for review the Conditions of Authorization stated in the assued on October 28, 2021.



Sincerely yours,

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

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20903 www.fda.gov