December 9, 2022

Ahmed Bayat, MD
Director, Regulatory Affairs
Amarex Clinical Research, LLC
Representing: 1drop Inc.
20201 Century Boulevard, 4th Floor
Germantown, MD 20874

Re: EUA200078/S002/A001
Trade/Device Name: 1copy COVID-19 qPCR Multi Kit
Dated: March 10, 2022
Received: March 10, 2022

Dear Dr. Bayat:

This is to notify you that your request to update the Instructions for Use of the 1copy COVID-19 qPCR Multi Kit to; (1) update the Clinical Evaluation study data to fulfill Condition of Authorization "S." from the May 11, 2020 Letter of Authorization, (2) update the *in silico* inclusivity analysis results using more recent SARS-CoV-2 sequences, (3) add an instrument qualification procedure for the Light Cycler 480 and the Rotor-Gene Q 5Plex HRM thermocyclers, (4) add an Emergency Use Only label for application on Research Use Only instrumentation authorized for use with the test, and (5) provide minor updates to the warnings to reflect language used in more recent authorizations, is granted. Upon review, we concur that the data and information submitted in EUA200078/S002/A001 supports the requested updates for use with the 1copy COVID-19 qPCR Multi Kit. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. 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 1copy COVID-19 qPCR Multi Kit issued on May 11, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health