June 11, 2020

Fred Turner
Chief Executive Officer
Curative Inc.
1600 Adams Drive, Suite 105
Menlo Park, CA 94025

Re: EUA200132/A001
Trade/Device Name: Curative-Korva SARS-Cov-2 Assay
Dated: April 30, 2020
Received: April 30, 2020

Dear Mr. Turner:

This is to notify you that your request to update the Instructions for Use (IFU) of the Curative-Korva SARS-Cov-2 Assay to; (1) update the specimen stability claim from 24 hours to 4 days at room temperature, and (2) update the name of the test from "Curative-Korva SARS-Cov-2 Assay" to the "Curative SARS-Cov-2 Assay", is granted. Upon review, we concur that the data and information submitted in EUA200132/A001 supports the requested updates for use with the Curative SARS-Cov-2 Assay, and we have also updated the Healthcare Provider and Patient Fact Sheets, accordingly. FDA has updated the Intended Use of the Curative SARS-Cov-2 Assay in the EUA Summary to further clarify limitations around the collection and testing of nasal swabs and oral fluid specimens. By submitting this amendment 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 Curative SARS-Cov-2 Assay (formerly Curative-Korva SARS-Cov-2 Assay) issued on April 16, 2020.



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