July 21, 2020

Aditi Luthra
Genophyll Enterprises, LLC
Representing: 3B Blackbio Biotech India Ltd, a subsidiary of Kilpest India Ltd.
100 Davidson Avenue, Suite 109
Somerset, NJ 08873

Re: EUA201649/A001
Trade/Device Name: TRUPCR SARS-CoV-2 Detection Kit
Dated: July 6, 2020
Received: July 6, 2020

Dear Dr. Luthra:

This is to notify you that your request to update the authorized labeling of the TRUPCR SARS-CoV-2 Detection Kit to; (1) add two alternative workflows to the Instructions for Use (IFU) of the authorized assay to help conserve resources of the TRUPCR SARS-CoV-2 Detection Kit, and (2) include minor updates to the IFU for clarification, is granted. Upon review, we concur that the data and information submitted in EUA201649/A001 supports the requested updates for use with the TRUPCR SARS-CoV-2 Detection. We also concur with the updates made to the Healthcare Provider and Patient Fact Sheets. 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 TRUPCR SARS-CoV-2 Detection Kit issued on June 18, 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