June 30, 2020

James P. Canner Ph.D.
VP, Regulatory, Clinical, and Research Programs
Gravity Diagnostics, LLC
632 Russell Street
Covington, KY 41011

Re: EUA200031/A001
Trade/Device Name: Gravity Diagnostics COVID-19 Assay
Dated: June 23, 2020
Received: June 23, 2020

Dear Dr. Canner:

This is to notify you that your request to update the authorized labeling of the Gravity Diagnostics COVID-19 Assay to include use of nasal swab specimens that are self-collected by individuals using the Kroger Health COVID-19 Test Home Collection Kit, as an authorized home collection kit, is granted. Upon review, we concur that the data and information submitted in EUA200031/A001 supports use of the Kroger Health COVID-19 Test Home Collection Kit with the Gravity Diagnostics COVID-19 Assay. 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 Gravity Diagnostics COVID-19 Assay issued on June 1, 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