U.S. FOOD & DRUG ADMINISTRATION

April 28, 2020

Stephanie Luong,
Project Manager
Gnomegen LLC
6440 Lusk Blvd Suite D207,
San Diego, CA 92121

Re: EUA200047/A001
Trade/Device Name: Gnomegen COVID-19 RT-Digital PCR Detection Kit
Dated: April 24, 2020
Received: April 24, 2020

Dear Ms. Luong:

This is to notify you that your request to update the Instructions for Use (IFU) labeling for the Gnomegen COVID-19 RT-Digital PCR Detection Kit to add the Gnomegen Real-Time Digital PCR Instrument, along with some additional minor edits is granted. Upon review, we concur that the data submitted in EUA200047/A001 supports the requested update for use with the Gnomegen COVID-19 RT-Digital PCR Detection Kit. 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 Gnomegen COVID-19 RT-Digital PCR Detection Kit issued on April 6, 2020.

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