November 1, 2021

Gwen Murphy
Director of Epidemiology & Clinical Studies
LetsGetChecked, Inc.
Unit 10 Calmount Avenue
Dublin D12NV97 Ireland

Re: EUA201043/S011
Trade/Device Name: LetsGetChecked Coronavirus (COVID-19) Test
Dated: September 29, 2021
Received: September 29, 2021

Dear Gwen Murphy:

This is to notify you that your request to update the Instructions for Use (IFU) of the LetsGetChecked Coronavirus (COVID-19) Test to: (1) add the Hologic Direct Load Tube (DLT) as a component of the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit is granted. Upon review, we concur that the data and information submitted in EUA201043/S011 supports the requested updates for use with the LetsGetChecked Coronavirus (COVID-19) Test. 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 LetsGetChecked Coronavirus (COVID-19) Test reissued on September 16, 2021.

Sincerely yours,

_____

For: 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov