April 8, 2020

Navin Nauth-Misir,
Group RA QA Director
Primerdesign Ltd.
Unit 1, Watchmoor Point, Watchmoor Road,
Camberley, GU15 3AD, UK

Re: EUA200019/A001
Trade/Device Name: Primerdesign Ltd COVID-19 genesig Real-Time PCR assay
Dated: March 31, 2020
Received: March 31, 2020

Dear Navin Nauth-Misir:

This is to notify you that your request to update the Instructions for Use (IFU) of the Primerdesign Ltd COVID-19 genesig Real-Time PCR assay to add the QIAamp Viral RNA Mini kit as another extraction method, has been granted. Upon review, we concur that the data submitted in EUA200019/A001 supports the additional extraction method for use with the Primerdesign Ltd COVID-19 genesig Real-Time PCR assay. We also concur with the related changes to the Instructions for Use that reflect the requested updates and in addition FDAs request to include nasal swabs as an additional specimen type to the intended use, along with the associated update to the Healthcare Provider Fact Sheet for the Primerdesign Ltd COVID-19 genesig Real-Time PCR 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 Primerdesign Ltd COVID-19 genesig Real-Time PCR assay issued on March 20, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health