November 10, 2020

Long Han
Xiamen Zeesan Biotech Co., Ltd.
Building 1, 3701 Xiang'an North Road
Xiamen, China 361101

Re: EUA200684/S001
Trade/Device Name: SARS-CoV-2 Test Kit (Real-time PCR)
Dated: October 18, 2020
Received: October 19, 2020

Dear Long Han:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 Test Kit (Real-time PCR) to; (1) add the Lab-Aid Virus RNA Extraction Kit that is performed on the Lab-Aid 824s Nucleic Acid Extraction System (software v1.0.3) as a new automated extraction method, (2) add the Bio-Rad CFX96 Real-Time System with CFX Manager Software v3.1. as a new real-time PCR instrument, (3) add some minor updates and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200684/S001 supports the requested updates for use with the SARS-CoV-2 Test Kit (Real-time PCR). FDA have updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect more recent authorizations. 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 SARS-CoV-2 Test Kit (Real-time PCR) issued on July 31, 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
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Center for Devices and Radiological Health