January 6, 2021

Willy Hsu, PhD
Chief Operating Officer
TBG Biotechnology Corp.
13F-1, No. 237, Sec.1, XiZhi District
New Taipei City, Taiwan 221

Re: EUA201058/S001
Trade/Device Name: ExProbe SARS-CoV-2 Testing Kit
Dated: August 3, 2020
Received: August 3, 2020

Dear Dr. Hsu:

This is to notify you that your request to update the Instructions for Use (IFU) of the ExProbe SARS-CoV-2 Testing Kit to; (1) add the EZbead Viral Extraction Kit and the automated EZbead System-32 instrument as a new extraction method, (2) add the TBG Q6000 Real-Time PCR System as a new real-time PCR instrument, (3) add results of the post-authorization clinical study to fulfill Condition of Authorization V. in the June 10, 2020 Letter of Authorization, (4) update reagent stability claims, and (5) address some minor formatting and grammatical errors, is granted. Upon review, we concur that the data and information submitted in EUA201058/S001 supports the requested updates for use with the ExProbe SARS-CoV-2 Testing Kit. FDA made updates to the IFU to reflect more recent authorizations and reporting requirements for SARS-CoV-2. FDA also 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 ExProbe SARS-CoV-2 Testing Kit issued on June 10, 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