October 23, 2020

Natalie Huang
Registration Specialist
Xiamen Biotime Biotechnology Co., Ltd.
3F/4F, No.188, Pingcheng S. Road
Haicang District, Xiamen, Fujian
361026, P. R. China

Re: EUA201304/S002
Trade/Device Name: BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test
Dated: August 17, 2020
Received: August 17, 2020

Dear Ms. Huang:

This is to notify you that your request to 1) to revise the Test Procedure section of the Instructions for Use (IFU) for the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test to change the reading time from 10 minutes to 20 minutes and replace the time after which results should not be read from 20 minutes to 30 minutes and 2) to modify two box labels to clarify the product shelf life and temperature conditions for shipping and distribution of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test, is granted. Upon review, we concur that the data and information submitted in EUA201304/S002 supports the requested updates for use with the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test. FDA also made a minor change to the intended use of the device to reflect more recent authorizations. By submitting this supplement for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test issued on July 24, 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