November 6, 2020

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

Re: EUA201304/S001
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 add an additional authorized distributor, Telepoint Medical Services, LLC, who will distribute the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test under their own brand name, and six other authorized distributors (O'Neill Medical LLC, HORIBA instrument incorporated, Lifesaving Global LLC, THE RUHOF CORPORATION, Marlan's Group Us Inc, and JEMF Pharma), who will distribute the test under the brand name BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test, is granted. 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