



October 30, 2020

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

Re: EUA201304/S003
Device Name (Authorized): SARS-CoV-2 IgG/IgM Rapid Qualitative Test
Authorization Date: July 24, 2020
Supplement Received: October 9, 2020

Dear Ms. Natalie Huang:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 IgG/IgM Rapid Qualitative Test, to include a limitation, is granted. Upon review, for the SARS-CoV-2 IgG/IgM Rapid Qualitative Test, we concur with the additional limitation to the IFU: *“A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.”* FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting this 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 IgG/IgM Rapid Qualitative Test issued on July 24, 2020.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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