February 14, 2022

Jin Zhang
United Source LLC
Representing: Hangzhou Laihe Biotech Co., Ltd.
2207 Concord Pike, Suite 149
Wilmington, DE 19803

Re: EUA200667/S007
Trade/Device Name: LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
Dated: September 29, 2021
Received: October 4, 2021

Dear Mr. Zhang:

This is to notify you that your request to; (1) update the authorized labeling to address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, and (2) remove QUICKKIT Novel Coronavirus (2019-nCov) IgM/IgG Antibody Combo Test Kit as an authorized brand name, is granted. Upon review, we concur that the information submitted in EUA200667/S007 and subsequent interactive review supports the requested updates for use with the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold). FDA have also updated the Fact Sheet for Recipients to reflect more recent authorizations. By submitting these revisions 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 LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) issued on June 19, 2020 and the Viral Mutation Revision Letter issued on September 23, 2021.

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