August 12, 2020

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

Re: EUA200667/S001
Trade/Device Name: LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
Dated: July 20, 2020
Received: July 20, 2020

Dear Ms. Zhang:

This is to notify you that your request to update the Instructions for Use (IFU) of the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) to: (1) revise the assay labeling to reflect the availability of external controls with separate labeling per Condition "T" of the June 19 Letter of Authorization, (2) revise the labeling to correct typographic errors, delete a duplicate statement under Limitations, update the toll-free number, remove reference to "whole blood" and remove the list of distributors, is granted. Upon review, we concur that the information submitted in EUA200667/S001 supports the requested updates for use with the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold). By submitting this supplement 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.

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