December 2, 2020

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

Re: EUA200667/S002
Trade/Device Name: LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
Dated: September 1, 2020
Received: September 1, 2020

Dear Mr. Zhang:

This is to notify you that your request to revise the distribution list to add one additional authorized distributor, Unisources Group LLC. to market the Hangzhou Laihe Biotech Co., Ltd.'s EUA authorized LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) under the device name of QUICKKIT Novel Coronavirus (2019-nCov) IgM/IgG Antibody Combo Test Kit is granted. Upon review, we concur that the information submitted in EUA200667/S002 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 has also updated the intended use and the Healthcare Provider and Patient Fact Sheets for the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) 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.

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