



June 19, 2020

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

Device: LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)

Company: Hangzhou Laihe Biotech Co., Ltd.

Indication: Qualitative detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human serum and plasma (dipotassium-EDTA, lithium-heparin, or sodium-citrate). Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

Dear Ms. Zhang:

This letter is in response to your<sup>1</sup> request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,<sup>2</sup> pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.<sup>3</sup>

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<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to Hangzhou Laihe Biotech Co., Ltd.

<sup>2</sup> For ease of reference, this letter will use the term “your product” to refer to the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) for the indication identified above.

<sup>3</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and*