U.S. FOOD & DRUG ADMINISTRATION

May 12, 2022

Jo-Ann F. Gonzales, RAC
Director, IVD Regulatory & Quality Consulting
Precision for Medicine
Representing - PHASE Scientific International, Ltd.
10527 Garden Grove Blvd
Garden Grove, CA, 92843

Re: EUA220152/S001
Trade/Device Name: INDICAID COVID-19 Rapid Antigen At-Home Test
Dated: March 31, 2022
Received: March 31, 2022

Dear Jo-Ann F. Gonzales:

This is to notify you that your request to update the INDICAID COVID-19 Rapid Antigen At-Home Test to; (1) add the iClean Specimen Collection Swab as an alternative authorized specimen collection swab, and (2) correct the description of the anti-SARS-CoV-2 antibody conjugates in INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use from "*colloidal gold particles*" to "*latex microspheres*," is granted. Upon review, we concur that the data and information submitted in EUA220152/S001 supports the requested updates for use with the INDICAID COVID-19 Rapid Antigen At-Home Test. By submitting this EUA 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 INDICAID COVID-19 Rapid Antigen Test issued on March 16, 2022.

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