



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: EUA210259/S005  
Trade/Device Name: INDICAID COVID-19 Rapid Antigen 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 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 Test Instructions for Use from "*colloidal gold particles*" to "*latex microspheres*," is granted. Upon review, we concur that the data and information submitted in EUA210259/S005 supports the requested updates for use with the INDICAID COVID-19 Rapid Antigen 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 re-issued on November 15, 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