



August 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/S006
Trade/Device Name: INDICAID COVID-19 Rapid Antigen Test
Dated: July 6, 2022
Received: July 6, 2022

Dear Jo-Ann F. Gonzales:

This is to notify you that your request to update the INDICAID COVID-19 Rapid Antigen Test to add the following four additional sterile swabs; (1) KangDaan Swab, (2) Mandelab Swab, (3) BioTeke Swab, and (4) Rongbang Swab, as alternative authorized specimen collection swabs, is granted. Upon review, we concur that the data and information submitted in EUA210259/S006 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,

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