June 16, 2023

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

Re: EUA210259/S008
Trade/Device Name: INDICAID COVID-19 Rapid Antigen Test
Dated: April 27, 2023
Received: April 27, 2023

Dear Jo-Ann Gonzales:

This is to notify you that your request to update the INDICAID COVID-19 Rapid Antigen Test to extend the shelf-life expiration date to 15 months when stored at 2 – 30˚C based on the results of your extended stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210259/S008 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 reissued on November 15, 2021.

Sincerely yours,

_____

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health