U.S. FOOD & DRUG ADMINISTRATION

February 22, 2022

Erika B. Ammirati RAC, MT(ASCP)
Ammirati Regulatory Consulting
Representing - PHASE Scientific International, Ltd.
10527 Garden Grove Blvd
Garden Grove, CA, 92843

Re: EUA210259/S004
Trade/Device Name: INDICAID COVID-19 Rapid Antigen Test
Dated: January 19, 2022
Received: January 19, 2022

Dear Erika B. Ammirati:

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 12 months at room temperature based on the results of your completed stability studies to fulfill Condition of Authorization S. of the Letter of Authorization re-issued on November 15, 2021, is granted. Upon review, we concur that the data and information submitted in EUA210259/S004 supports the requested updates for use with the INDICAID COVID-19 Rapid Antigen Test and fulfills the Condition of Authorization S. of the November 15, 2021 letter. 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