U.S. FOOD & DRUG ADMINISTRATION

January 14, 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/S003
Trade/Device Name: INDICAID COVID-19 Rapid Antigen Test
Dated: November 15, 2021
Received: November 17, 2021

Dear Erika B. Ammirati:

This is to notify you that your request to update the INDICAID COVID-19 Rapid Antigen Test to (1) extend the shelf-life expiration date to 9 months at room temperature based on the results of your ongoing stability studies, and (2) provide the open kit stability study data completed to fulfill Condition of Authorization R. 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/S003 supports the requested updates for use with the INDICAID COVID-19 Rapid Antigen Test and fulfills Conditions of Authorization R. of the November 15, 2021 Letter of Authorization. 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