December 28, 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/S007
Trade/Device Name: INDICAID COVID-19 Rapid Antigen Test
Dated: December 7, 2022
Received: December 8, 2022

Dear Jo-Ann Gonzales:

This is to notify you that your request to update the authorized labeling of the INDICAID COVID-19 Rapid Antigen Test in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA210259/S007 supports the requested updates for use with the INDICAID COVID-19 Rapid Antigen Test. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients has been updated by FDA consistent with this revision and are included along with this letter. By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022.

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