December 22, 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: EUA220152/S006 & S007
Trade/Device Name: INDICAID COVID-19 Rapid Antigen At-Home Test
Dated: October 12, 2022 and November 16, 2022
Received: October 12, 2022 and November 16, 2022

Dear Jo-Ann Gonzales:

This is to notify you that your request to update authorized labeling of the INDICAID COVID-19 Rapid Antigen At-Home Test; (1) include details of an optional web-based reporting mechanism to address Condition of Authorization S. in the March 16, 2022 Letter of Authorization, and (2) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A of the letter, and 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 data and information submitted in EUA220152/S006 & S007 supports the requested updates for use with the INDICAID COVID-19 Rapid Antigen At-Home Test and fulfills Condition of Authorization S. from the March 16, 2022, letter and Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Professionals has been updated by FDA consistent with this revision and is included along with this letter.

By submitting these supplemental requests 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, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the INDICAID COVID-19 Rapid Antigen At-Home Test reissued on March 16, 2022.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health