U.S. FOOD & DRUG ADMINISTRATION

April 13, 2023

Joshua D. Levin, Ph.D.
Director, Quality Assurance and Regulatory Affairs
Asell, LLC
Representing: Beijing Hotgen Biotech Co., Ltd.
9th Building, No. 9 Tianfu Street
Biomedical Base, Daxing District
Beijing, 102600, P.R. China

Re: EUA210610/S001
Trade/Device Name: Hotgen COVID-19 Antigen Home Test
Dated: January 19, 2023
Received: January 19, 2023

Dear Dr. Levin:

This is to notify you that your request to update the Hotgen COVID-19 Antigen Home Test to (1) extend the shelf-life expiration date to 10 months when stored at 2°C – 30°C, based on the results of your ongoing stability studies, and (2) update the authorized labeling of the Hotgen COVID-19 Antigen Home Test to include (a) results of additional reactivity studies and (b) details of an optional web-based reporting mechanism to address Condition of Authorization R. in the November 17, 2022 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA210610/S001 support the requested updates for the Hotgen COVID-19 Antigen Home Test and fulfill Condition of Authorization R. in the November 17, 2022 Letter of Authorization. The Food and Drug Administration (FDA) has updated the Healthcare Provider Fact Sheet to reflect more recent authorizations.

By submitting this EUA revision for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Hotgen COVID-19 Antigen Home Test issued on November 17, 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