U.S. FOOD & DRUG ADMINISTRATION

January 26, 2022

Carlos J. Ruiz, M.D., FACP, FIDA
Lab Director
Psomagen, Inc.
1330 Piccard Drive
Rockville, MD 20850

Re: EUA200390/S002
Trade/Device Name: Psoma COVID-19 RT Test
Dated: December 6, 2021
Received: December 6, 2021

Dear Dr. Ruiz:

This is to notify you that your request to update the authorized labeling of the Psoma COVID-19 RT Test to update the reagent information from "2019-nCoV CDC qPCR Probe assay" to "SARS-CoV-2 Research Use Only qPCR Primer & Probe Kit", is granted. Upon review, we concur that the data and information submitted in EUA200390/S002 supports the requested updates for use with the Psoma COVID-19 RT Test. FDA has updated the Limitations section of the EUA Summary and the Fact Sheet for Healthcare Providers, per the Condition of Authorization of the Viral Mutation Revision Letter (September 23, 2021), as well as updated the intended use statement to reflect language used in more recent authorizations. 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 Psoma COVID-19 RT Test issued on June 30, 2020.

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