January 31, 2022

Joe Shia
o/b/o Azure Biotech Inc.
LSI International Inc.
504 East Diamond Ave. Suite I
Gaithersburg, MD 20877

Re: EUA200487/S005 and EUA200487/S006
Trade/Device Name: Assure COVID-19 IgG/IgM Rapid Test Device
Dated: October 18, 2021 and December 15, 2021
Received: October 18, 2021 and December 16, 2021

Dear Joe Shia:

This is to notify you that your request to (1) update the Assure COVID-19 IgG/IgM Rapid Test Device authorized labelling (the Instructions for Use (IFU) and Healthcare Provider Fact Sheet) in response to Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) minor edits to the Intended Use of the test, (3) extend the reagent shelf-life up to 18 months at 2-30°C, and (4) include updated list of distributors, is granted. Upon review, we concur that the data and information provided in EUA200487/S005 and EUA200487/S006 supports the requested updates to the authorized labelling for Assure COVID-19 IgG/IgM Rapid Test Device and the additional brand names: Fastep COVID-19 IgG/IgM Rapid Test Device and Ecotest COVID-19 IgG/IgM Rapid Test Device. FDA has also updated the Factsheet for Healthcare Provider and Factsheet for Patients to reflect language used in more recent authorizations. By submitting this supplement for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Assure COVID-19 IgG/IgM Rapid Test Device re-issued on September 23, 2020 and the Viral Mutation Revision Letter issued on September 23, 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

CC: Frank Lou, Director, Azure Biotech, Inc.