U.S. FOOD & DRUG ADMINISTRATION

May 11, 2020

Steve Back,
Vice President, Global Quality Assurance and Regulatory Affairs
Luminex Corporation
12212 Technology Blvd.,
Austin, TX 78727

Re: EUA200127/A001
Trade/Device Name: ARIES SARS-CoV-2 Assay
Dated: May 1, 2020
Received: May 1, 2020

Dear Mr. Back:

This is to notify you that your request to update the Instructions for Use (IFU) of the ARIES SARS-CoV-2 Assay to; (1) provide new performance data for the Limit of Detection and Clinical Contrived studies, using the BEI Resources gamma irradiated cell lysate infected with SARS-CoV-2 isolate (BEI Cat No. NR-522-287), as opposed to the SARS-CoV-2 genomic RNA, (2) include additional data for Cross-reactivity and Microbial interference wet-testing studies, and (3) include new more general language on use of external controls with the assay, is granted. Upon review, we concur that the data and information submitted in EUA200127/A001 supports the requested updates for use with the ARIES SARS-CoV-2 Assay. By submitting this amendment 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 ARIES SARS-CoV-2 Assay issued on April 3, 2020.

Sincerely yours,

_____

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