From: Barcus, Mary <Mary.Barcus@fda.hhs.gov>
Sent: Friday, April 10, 2020 1:37 PM
To: Kristen Harding <KHarding@makomedical.com>
Cc: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; EUA200193@docs.fda.gov <EUA200193@docs.fda.gov>
Subject: EUA200193

Dear Kristen,

Thank you for submitting your EUA, EUA200193, for the SARS-CoV-2 assay you have set up in your lab. I'm the lead reviewer that was assigned to your submission.

It appears that your assay is a modified version of the EUA-authorized TaqPath COVID-19 Combo Kit by ThermoFisher Scientific.

My understanding from the email string associated with your submission is that the changes you have introduced are the following:

1. Use of a Quantstudio 12k Flex, not the QuantStudio 12k Flex Dx (Diagnostic) instrument.
2. Adjustment to extraction volume, noted to have been implemented to prevent cross contamination on the Kingfisher (reduced total volume of bead mixture by 100 ul). **FDA comment: Please provide additional information on this comment. Did you experience apparent cross-contamination when doing your original validation in alignment with the TaqPath COVID-19 Combo Kit IFU?**
3. Change in the qPCR reaction volume from 25 ul to 20 ul, noted to be due to the EUA protocol being performed on a 96 well plate that can handle the 25 ul volume whereas your instrument is using 384 well plates and the maximum volume is 20 ul. You indicate that all reaction components were adjusted proportionally. **FDA comment: Please check reaction volumes within your SOP as it is not clear that all reaction components were proportionately adjusted.**

Other than the change in volumes and the non-Dx instrument, you have indicated there are no differences in the chemistry involved.

When feasible, we recommend that labs perform a bridging study to demonstrate similar LoDs when the assay is run with your modifications vs. according to the TaqPath COVID-19 Combo Kit. There is information within the updated *Policy for Diagnostic Tests for Coronavirus Disease-2019* as to our recommendations on conducting bridging studies. When not possible, however, an acceptable alternative approach is to conduct a well-designed LoD study (according to the recommendations described in the EUA template for CLIA High Complexity Laboratories).

Provided that your LoD study was conducted according to the FDA guidelines within the template and you have demonstrated comparable LoD to the original assay, our assessment is that an EUA is not required for your assay at this time. These modifications to the EUA-authorized test should be covered under your lab's CLIA certification in this case.

Note that FDA recommends that you obtain confirmation of the first five positive and the first five negative clinical specimens using an EUA-authorized assay. If any of these results cannot be confirmed, you should notify FDA at CDRH-EUA-Templates@FDA.HHS.GOV, and take other appropriate actions such as terminating testing patient specimens, and issuing a corrected test report that indicates the prior test result may not be valid.

Once you have had a chance to review this, if you are in agreement, we'd ask that you email a request to withdraw the EUA to CDRH-EUA-Templates@FDA.HHS.GOV.

Please let me know if you have any questions. I would appreciate any feedback you can provide on the one comment you had made regarding cross-contamination as well.

Best regards,
Mary

Mary Barcus, MD
Physician

Viral Respiratory and HPV Branch
Division of Microbiology Devices | OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | U.S. Food and Drug Administration
White Oak, Bldg. 66, Rm. 3264 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-4110
mary.barcus@fda.hhs.gov