From: Geyer, Chelsie
Sent: Monday, March 30, 2020 12:07:07 PM
To: Nicholas Sanford
Subject: EUA200067 FDA Response

Dear Dr. Sanford,

Thank you for submitting your EUA, EUA200067, for the SARS-CoV-2 rRT-PCR Diagnostic Assay. I understand that your assay is a modified version of the EUA-authorized CDC assay. My understanding is that you will use either the [redacted] RNA Extraction Protocol or the [redacted], then the Roche Lightcycler 480 II with Lightcycler 480 software release 1.5.1 sp3 for rRT-PCR. It is my understanding that your assay will use the same primers/probes, positive/negative/extraction controls, and the same approach to interpretation as the CDC assay. The differences between the assays are the nucleic acid extraction methods, the thermocyclers, and the reverse transcriptase and PCR master mix.

If it is feasible, we would recommend that you perform a bridging study to demonstrate similar LoDs when the assay is run with your modifications vs. according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. There is information within the, Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergencyas to our recommendations on conducting bridging studies. If you lack the equipment to do so, 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).

If there are no other changes to your assay and you proceed according to the guidance in the template when establishing LoD, an EUA is not required for your assay at this time. You may proceed with your validation, the documentation of which would be covered under your lab's CLIA certification in this case.

We continue to refer you to the FAQs on Diagnostic Testing for SARS-CoV-2 and our current guidance, Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency in regards to notifying us when your assay has been validated and you have begun testing of patient samples. Please note that clinical testing may not be initiated until your assay has been validated. Also, FDA recommends that you obtain confirmation of the first five positive and the first five negative clinical specimens using an EUA-authorized assay and send results to CDRH-EUA-Templates@FDA.HHS.GOV. 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.

Please let me know if you have any questions regarding our assessment.

My recommendation above that an EUA is not needed was predicated on an understanding that you intend to run a modified version of the EUA-authorized CDC assay at a single testing location. If this is the case and your modified test has either been bridged to the CDC assay or demonstrated to have a comparable LoD through a well-designed study (conducted according to the recommendations described in the EUA template for CLIA High Complexity Laboratories), then as noted, an EUA for your assay is not required at this time.

Please let me know if you have any questions.

Thanks very much for your time.
Best,
Chelsie

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