Contains Nonbinding Recommendations

Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

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Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff

Document issued on the web on March 16, 2020.

This document supersedes "Policy for Diagnostics Testing in Laboratories Certified to Perform High-Complexity Testing under Clinical Laboratory Improvement Amendments (CLIA) prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency" issued February 29, 2020.

For questions about this document, contact CDRH-EUA-Templates@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

C. Commercial Manufacturer Development and Distribution of Tests Prior to EUA Submission

The policy described in this subsection applies to commercial manufacturers that seek to develop and distribute diagnostic test kits to detect the SARS-CoV-2 virus to clinical laboratories or to healthcare workers for point-of-care testing. This policy does not apply to at home testing.

In light of the increasing numbers of COVID-19 cases throughout the country and the urgent need to expand the nation's capacity for COVID-19 testing during the public health emergency, FDA does not intend to object to a commercial manufacturer's development and distribution of SARS-CoV-2 test kits for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. Transparency can help mitigate potential adverse impacts from a poorly designed test by facilitating better informed decisions by potential purchasers and users.

FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated. Soon after receiving the EUA request, FDA will perform a preliminary review to identify if there are any problems with the performance data. If a problem is identified, FDA intends to work with the manufacturer to address the problem (e.g., through labeling or bench testing). If the problem is significant and cannot be addressed in a timely manner, and the manufacturer has already distributed the device, FDA would expect the manufacturer to suspend distribution and conduct a recall of the test.

1. Validation

All clinical tests should be validated prior to use. In the context of a public health emergency, it is especially important that tests are validated as false results can have broad public health impact beyond that to the individual patient. FDA has provided recommendations regarding the minimum testing that should be performed to ensure analytical and clinical validity in section V below. FDA encourages laboratories to discuss any alternative testing with FDA that they would like to conduct.

2. FDA Notification

Following completion of assay validation, manufacturers should notify FDA (e.g., e-mail to CDRH-EUA-Templates@FDA.HHS.GOV) that their assay has been validated and they intend to begin distribution. This notification should include the name of the manufacturer, address, contact person, and a copy of the instructions for use including summary of assay performance. FDA will acknowledge receipt of this notification via auto-reply. As noted above, FDA

FDA Establishment Registration
(FDA 公司注册-美国)

Mokobio Biotechnology R&D Center, Inc

Registration Information

Facility

Registration Number
3016692399

FEI Number
3016692399

Registration Status
Active

Registration Status Reason
Registration number assigned

Initial Importer
N

Facility Name
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Owner/Operator

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Registration Status

Expiration Date
2020-12-31

PIN - PCN
50285436 - 20437069

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FDA Product Listing
(FDA 产品公示-美国)

SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay

Listing Number	D385854
Listing Status	Active
Premarket Submission Number	Enforcement

Product Code	Product Name
QKO	Reagent, coronavirus serological

Registration #	Registration Status	Registration Status Reason	Activities
3016692399	Active	Registration number assigned	Manufacturer

View Proprietary Names and Labeling

View All

Proprietary Names

Listing Number	Premarket Submission Number
D385854	

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Filter:

Proprietary Name	Confidential Flag	Device labeled for use	Device Identifier	Uploaded Labels
SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay	N			

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Acknowledgment Letter

3/4/2020

Jun Zhu, Chief Executive Officer
Mokobio Biotechnology R&D Center
1445 Research Blvd, Suite 150
Rockville, MD 20850
UNITED STATES

Dear Jun Zhu:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200023
Received: 3/3/2020
Applicant: Mokobio Biotechnology R&D Center
Device: SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
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