STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor
Susan Bysiewicz
Lt. Governor

HEALTHCARE QUALITY AND SAFETY BRANCH

BLAST FAX 2020-16

TO: All Hospitals

FROM: Commissioner Renée D. Coleman-Mitchell, MPH

CC: Deputy Commissioner Heather Aaron, LNHA
Barbara Cass, RN., Branch Chief, Healthcare Quality and Safety Branch
Donna Ortelle, Section Chief, Facility Licensing and Investigations Section

DATE: March 19, 2020

SUBJECT: Answers to FAQs from the FDA related to tests for SARS-CoV-2

The attached information from the Food and Drug Administration (FDA) provides answers to frequently asked questions (FAQs) relating to the development and performance of diagnostic tests for SARS-CoV-2.

Connecticut Department of Public Health

Phone: (860) 509-7400• Fax: (860) 509-7543
Telecommunications Relay Service 7-1-1
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

FAQs on Diagnostic Testing for SARS-CoV-2

Coronavirus COVID-19 Diagnostic Tests Hotline

- For test developers and labs who have questions about the EUA process or spot shortages of testing supplies.
- Contact our toll-free line 24 hours a day: 1-888-INFO-FDA, choose option *

This page provides answers to frequently asked questions relating to the development and performance of diagnostic tests for SARS-CoV-2.

The page includes questions and answers regarding the new policy outlined in the *Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)*, originally introduced as *Immediately in Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff: Policy for Diagnostic Tests in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency* on February 29th, 2020 and updated on March 16, 2020. On this page, this guidance is referred to as the Policy for Diagnostic Tests for Coronavirus Disease-2019.

Note: Throughout this page and the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency), references to laboratories that are "certified to perform high complexity testing under CLIA" are referring to CLIA certified laboratories that meet the regulatory requirements to perform high-complexity testing.

Recent Updates (as of March 17, 2020):

- Q: What laboratories are offering testing under the Policy for Diagnostic Tests for Coronavirus Disease-2019?
- Q: I am developing a COVID-19 assay that is a modification of a previously EUA authorized COVID-19 assay. Do I need to start from scratch with my validation or can I validate my test with a bridging study?
- Q: I am developing a SARS-CoV-2 test kit for distribution to clinical laboratories. Can I follow the policy outlined in the Policy for Diagnostic Tests for Coronavirus Disease-2019?

On this page:

General FAQs

Q: What laboratories are offering testing under the *Policy for Diagnostic Tests for Coronavirus Disease-2019 (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)*?

A: Many commercial and healthcare system/academic laboratories have notified the FDA that they have validated their own COVID-19 test and have started patient testing as set forth in the FDA's *Policy for Diagnostic Tests for Coronavirus Disease-2019 (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)*. The below list of laboratories have agreed to be identified on the FDA's website.

- AdventHealth
- ARUP Laboratories
- Assurance Scientific
- Baylor Scott and White Medical Center - Temple

- BioReference Laboratories
- The Children's Hospital of Philadelphia
- Diatherix Eurofins
- Emory Medical Laboratory, Emory Healthcare
- Gravity Diagnostics
- Henry Ford Health System
- HMH Hackensack University Medical Center
- Hospital of the University of Pennsylvania
- Houston Methodist Hospital
- Integrity Laboratories
- Johns Hopkins Medical Microbiology Laboratory at Johns Hopkins Hospital
- Montefiore Medical Center
- New York Presbyterian Hospital -Weill Cornell Medicine (NYPH-WCM)
- Next Bio-Research Services LLC
- NYU Langone Medical Center
- Quest Diagnostics Infectious Disease, Inc.
- Stanford Health Care Clinical Laboratory
- Texas Children's Hospital Department of Pathology
- TGen North, Clinical Laboratory
- UCSF-Health
- University of Washington
- Viracor Eurofins Clinical Diagnostics

Note that many other laboratories, including public health, commercial, and healthcare system/academic laboratories, around the country are providing testing for COVID-19 using an EUA authorized test (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019).

In addition, under the *Policy for Diagnostic Tests for Coronavirus Disease-2019 (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)* issued on March 16, States may choose to authorize COVID-19 testing by laboratories within their State. Since FDA will not receive notification regarding those laboratories, they will not be listed on FDA's website.

Q: Are two or more viral targets needed to validate an RT-PCR SARS-CoV-2 assay?

A: Based on evidence that has become recently available, and with the increased spread of COVID-19, FDA believes an appropriately validated *single* viral target SARS-CoV-2 assay could provide acceptable performance. Please refer to the policy outlined in *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency), which includes recommendations regarding the minimum testing to be performed to ensure analytical and clinical validity for COVID-19 diagnostic assays, as well as the templates for EUA submissions (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) provided on FDA's website.

Q: I am developing a COVID-19 assay that is a modification of a previously EUA authorized COVID-19 assay. Do I need to start from scratch with my validation or can I validate my test with a bridging study?

A: As discussed in the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency), FDA does not intend to object to the use of a test, without a new or amended EUA, where the test is validated using a bridging study to an EUA-authorized test. One way to bridge to a new component is to establish equivalent performance between parallel testing of the same specimens with the new and original components. We recommend testing 3-fold serial dilutions of SARS-CoV-2 viral materials (e.g., whole genomic viral RNA or inactivated virus, etc.) in pooled respiratory sample matrix in triplicate.

The CDC has granted a right of reference to the performance data contained in the CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Q: I am developing a SARS-CoV-2 test and would like to request genomic RNA from SARS-related coronavirus 2, Isolate USA-WA1/2020 to validate my test. How may I do that?

A: You may request genomic RNA directly from BEI Resources; we are not aware of other sources of this material but will update this page if that changes.

Go to the BEI Resources website (https://www.beiresources.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and follow the instructions on the home page for logging in and registering. You will need to request reagent

NR-52285 (https://www.beiresources.org/Catalog/BEINucleicAcids/NR-52285.aspx) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Q: What are the current recommendations regarding minimum testing for demonstrating performance of a new COVID-19 assay?

A: Please refer to *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency), where we have provided recommendations regarding the minimum testing to be performed to ensure analytical and clinical validity of these tests. We recommend consulting with us as soon as possible if you pursue a different approach to validation or to discuss any additional questions regarding performance and validation issues.

Q: I requested and received an EUA template prior to the *Policy for Diagnostic Tests for Coronavirus Disease-2019 (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)* which was accompanied by a posting on the web of the EUA template for clinical laboratories. The first version references testing 50 clinical specimens and the new version references testing 30 clinical specimens. Which is accurate?

A. Due to the limited availability of reagents for the detection of SARS-CoV-2 and the growing need for testing suspected cases of the COVID-19, the FDA revised the EUA templates (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd) for both clinical laboratories and manufacturers with regard to EUA submissions for tests intended for the detection of SARS-CoV-2. As set forth in the guidance, the FDA recommends clinical evaluation should include 30 contrived clinical specimens.

Q: I am developing a SARS-CoV-2 test kit and want to pursue an EUA. Do I need to have all of my validation and documentation completed and submitted in an EUA request to FDA before engaging with the FDA?

A: No. The FDA is interested in early interactions with test developers and will review data on a rolling basis. We encourage you to reach out to us at CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov) to begin pre-EUA discussions, even if you do not have your validation and/or documentation completed. We can work with you on the best approach for completing your validation, documentation, and submission of your EUA request. Clinical laboratories certified to perform high-complexity testing under CLIA that are planning

to test patient samples prior to completion of an EUA should refer to the Policy for Diagnostic Tests for Coronavirus Disease-2019 (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency).

What If I Do Not Have...?

Q: I am having trouble obtaining viral transport media/universal transport media (VTM/UTM) to collect and transport patient samples. Are there alternatives that I can use?

A: While VTM/UTM remains the preferred transport media, FDA believes that the following alternative transport media could be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays in a manner that will stabilize the RNA without meaningful degradation:

- Liquid Amies-based transport media.
  - Supplies:
    - E-Swab by Copan (Catalogue # 481C and 482C) with regular or flex minitip applicator
    - Opti-Swab by Puritan (Catalogue # LA-117), swab included in kit (Catalog#3317-H).
  - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

If the above are not available, FDA believes that the following could be used to collect and transport samples for molecular RT-PCR sARS-CoV-2 assays:

- Dry swab in saline
  - Supplies:
    - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 25-3319-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
    - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
  - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

Please be aware that the CDC does not recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

We are continuing to evaluate other options for specimen collection supplies, and we will update this list accordingly as this information becomes available.

Q: What happens if I do not have the extraction platform referenced in the authorization of CDC's EUA-authorized test?

A: FDA believes that the CDC's EUA-authorized test could be used with the following extraction platforms:

- **Roche MagNA Pure LC**
  Kit: Roche MagNA Pure Total Nucleic Acid Kit
  Protocol: Total NA External_lysis
  Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.
- **Roche MagNA Pure Compact**
  Kit: Roche MagNA Pure Nucleic Acid Isolation Kit I
  Protocol: Total_NA_Plasma100_400
  Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.
- **Roche MagNA Pure 96**
  Kit: Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
  Protocol: Viral NA Plasma Ext Lys SV Protocol
  Recommendation(s): Add 100 µL of sample to 350 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 450 µL). Proceed with the extraction on the MagNA Pure 96. (Note: Internal Control = None). Elution volume is 100 µL.
- **QIAGEN QIAcube**
  Kit: QIAGEN QIAamp® DSP Viral RNA Mini Kit or QIAamp® Viral RNA Mini Kit
  Recommendations: Utilize 140 µL of sample and elute with 100 µL of buffer.
- **QIAGEN**
  Kit: QIAGEN QIAamp® DSP Viral RNA Mini Kit or QIAamp® Viral RNA Mini Kit
  Recommendations: Utilize 100 µL of sample and elute with 100 µL of buffer or utilize 140 µL of sample and elute with 140 µL of buffer.
- **QIAGEN EZ1 Advanced XL**
  Kit: QIAGEN EZ1 DSP Virus Kit and Buffer AVL (supplied separately) for offboard lysis
  Card: EZ1 Advanced XL DSP Virus Card
  Recommendations: Add 120 µL of sample to 280 µL of pre-aliquoted Buffer AVL (total input sample volume is 400 µL). Proceed with the extraction on the EZ1 Advanced XL. Elution volume is 120 µL.

- **QIAGEN EZ1 Advanced XL**
  Kit: QIAGEN EZ1 Virus Mini Kit v2.0 and Buffer AVL (supplied separately) for offboard lysis
  Card: EZ1 Advanced XL Virus Card v2.0
  Recommendations: Add 120 µL of sample to 280 µL of pre-aliquoted Buffer AVL (total input sample volume is 400 µL). Proceed with the extraction on the EZ1 Advanced XL. Elution volume is 120 µL.
- **bioMérieux NucliSENS easyMAG Instrument**
  Protocol: General protocol (not for blood) using "Off-board Lysis" reagent settings.
  Recommendation(s): Add 100 µL of sample to 1000 µL of pre-aliquoted easyMAG lysis buffer (total input sample volume is 1100 µL). Incubate for 10 minutes at room temperature. Elution volume is 100 µL.
- **bioMérieux EMAG Instrument**
  Protocol: Custom protocol: **CDC Flu V1** using "Off-board Lysis" reagent settings.
  Recommendation(s): Add 100 µL of samples to 2000 µL of pre-aliquoted easyMAG lysis buffer (total input sample volume is 2100 µL). Incubate for 10 minutes at room temperature. Elution volume is 100 µL. The custom protocol, **CDC Flu V1**, is programmed on the bioMérieux EMAG instrument with the assistance of a bioMérieux service representative. Installation verification is documented at the time of installation. Laboratories are recommended to retain a record of the step-by-step verification of the bioMérieux custom protocol installation procedure.

Q: What happens if I do not have the instruments referenced in the authorization of the CDC's EUA-authorized test?

A: The FDA believes that the CDC's EUA-authorized test could be performed on the following instruments designed to detect RNA viruses, and which were FDA cleared in K190302 for the CDC's RNA-based influenza panel:

- Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument with SDS software version 1.4
- Applied Biosystems™ QuantStudio™ Dx with version 1.0.3 software
- QIAGEN Rotor-Gene Q MDx with AssayManager version 1.0.4.1 and Epsilon version 1.0.1 software

Q: If I do not have assay positive control material, how can I obtain it?

A: If you do not have assay positive control material:

- Obtaining N1/N2 Positive Controls, for the CDC EUA design:

- Novel Coronavirus extracted RNA is available from BEI. To create N1/N2 positive controls from BEI's concentrated RNA, dilute the concentrated RNA into extracted nucleic acid to approximately 2 to 3 times the assay LOD per reaction.
  or
- IDT sells a plasmid control (2019-nCoV_N_Positive Control #10006625). To create N1/N2 positive controls from IDT's plasmid control, dilute the plasmid into extracted nucleic acid to approximately 2 to 3 times the assay LOD per reaction.

- Obtaining RNase P (RP) Control, for the CDC EUA design:
  - Human RNA can be extracted from human specimens or cultured human cells and used directly as the RP positive control
    or
  - IDT sells a plasmid control (Hs_RPP30 Positive Control #10006626). Dilute the plasmid into extracted nucleic acid to approximately 2 to 3 times the assay LOD per reaction.

Q: If I do not have human extraction control material, how can I obtain it?

A: Human RNA can be extracted from human specimens or cultured human cells and used directly as the HSC control which is used as an RNA extraction procedural control to demonstrate successful recovery of RNA as well as extraction reagent integrity. The HSC should yield a positive result with the RP primer and probe set and negative results with all 2019-nCoV markers.

Clinical Laboratory FAQs

Q: I am offering my own test under the new policy outlined in the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency). Do I report all my results as presumptive?

A: Under the policy outlined in the *Policy for Diagnostic Tests for Coronavirus Disease-2019 (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)*, the first five positive and first five negative results should be reported as presumptive and confirmed by an EUA authorized test. If all ten of these results are confirmed by an EUA authorized test, confirmatory testing for subsequent results is not recommended in the guidance.

Q: I am a clinical laboratory certified to perform high-complexity testing under CLIA. I have developed a SARS-CoV-2 test and want to begin accepting patient samples. What should I do?

A: Please refer to the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency).

The FDA encourages such laboratories developing tests to consider the validation recommendations in the guidance as they seek to validate their tests. If you pursue an alternate approach, we recommend discussing plans with us early, through the pre-EUA program. Please contact us at CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov).

As noted in the guidance, once your test is validated and you are ready to begin clinical testing, labs should notify the FDA at CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov) and provide the name of the lab, lab director, address, and contact person. In the guidance, we recommend that you confirm the first five positive and the first five negative samples with an EUA-authorized test and include in your test report a statement that the FDA review of the validation is pending.

As stated in the guidance, the FDA does not intend to object to the use of validated tests for specimen testing for a reasonable period of time after validation while the laboratory is preparing an EUA request. The FDA believes 15 business days is a reasonable period of time to prepare an EUA submission for a test that has already been validated.

We strongly encourage laboratories testing under this policy to contact their state public health department *as early as possible* in the process (perhaps even before receipt of any orders or samples) to help ensure they have capacity for the validation testing described in the guidance and have the information necessary to support case investigations. We also encourage laboratories to be sure they are familiar with state and local laws mandating reporting of diseases and conditions of public health significance.

Q: I am a clinical laboratory certified to perform high-complexity testing under CLIA. Do I need an EUA if I purchase a CDC-qualified lot of SARS-CoV-2 test kit reagents and follow the CDC's protocol?

A: No, you do not need your own EUA if you use reagents from a lot that has been qualified by the CDC and follow the CDC's EUA-authorized protocol. Testing using the CDC's EUA-authorized protocol and CDC-qualified lots of reagents is considered to be testing done under the CDC's EUA. Labs performing such testing under the CDC's EUA should be aware of any applicable conditions set forth in the EUA.

Currently, reagents qualified by the CDC are being sold through:

- Integrated DNA Technologies (IDT) (https://www.idtdna.com/pages/landing/coronavirus-research-reagents) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Biosearch Technologies (https://www.biosearchtech.com/products/pcr-kits-and-reagents/pathogen-detection/2019-ncov-cdc-probe-and-primer-kit-for-sars-cov-2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Q: I am a clinical laboratory certified to perform high-complexity testing under CLIA. Do I need an EUA if I purchase a CDC-qualified lot of SARS-CoV-2 test kit reagents and develop my own protocol?

A: Yes. Laboratories that wish to develop their own protocol should refer to the streamlined EUA policy outlined in the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency).

FDA encourages laboratories to discuss their plans with us early, through the pre-EUA program. Please contact us at CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov).

Q: I am a clinical laboratory certified to perform high-complexity testing under CLIA and am interested in developing a SARS-CoV-2 test. What do I need to do if I make my own primers/probes or order the individual components?

A: Please refer to the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency).

The FDA encourages such laboratories developing tests, whether using purchased components or making their own primers/probes, to consider the validation recommendations in the guidance as they seek to validate their tests. If you pursue an alternate approach, we recommend discussing plans with us early, through the pre-EUA program. Please contact us at CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov).

As noted in the guidance, once your test is validated and you are ready to begin clinical testing, labs should notify the FDA at CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov) and provide the name of the lab, lab director, address, and contact

person. In the guidance, we recommend that you confirm the first five positive and the first five negative samples with an EUA-authorized test and include in your test report a statement that the FDA review of the validation is pending.

As stated in the guidance, the FDA does not intend to object to the use of validated tests for specimen testing for a reasonable period of time after validation while the laboratory is preparing an EUA request. The FDA believes 15 business days is a reasonable period of time to prepare an EUA submission for a test that has already been validated.

Test Kit Manufacturer FAQs

Q: I am developing a SARS-CoV-2 test kit for distribution to clinical laboratories. Can I follow the policy outlined in the *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)?

A: The *Policy for Diagnostic Tests for Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency) as updated on March 16, 2020 now includes information applicable to manufacturers developing test kits for distribution. As stated in the guidance, the 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. The FDA believes 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated.

Q: I am developing a SARS-CoV-2 test kit for distribution to clinical laboratories. Should I use the "Accelerated" EUA template that was posted online with the new policy guidance?

A: The "accelerated" EUA template (/media/135658/download) is intended for laboratories certified to perform high-complexity testing under CLIA that are offering tests as set forth in the guidance. We have a separate EUA template for manufacturers (/media/135900/download),

now also posted online, to use which includes the same clinical validation information and also addresses information regarding manufacturing, distribution, and stability, which are relevant only to distributed kits.

For More Information

If you need additional information for completing the EUA template, would like to know how to submit your Pre-EUA/EUA submission to FDA, or wish to consider use an alternative specimen type, please contact the Division of Microbiology Devices at (301) 348-1778 or email CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov).