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.

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On this page:

What Laboratories and Manufacturers are Offering Tests for COVID-19?

Q: Are there any tests that I can purchase to test myself at home for COVID-19?

A: At this time, the FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. The FDA sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection, and we are actively working with test developers in this space. In the other FAQs on this page you can find listings of tests that have received an EUA authorization as well as labs and manufacturers that have notified FDA as set forth in the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency#_blank).

Q: What tests for COVID-19 have received Emergency Use Authorization?

A: All in vitro diagnostic tests that have received an Emergency Use Authorization (EUA) are listed on the EUA page (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd).

Q: What laboratories are offering testing under the policy outlined in Section IV.A of the Policy for Diagnostic Tests for Coronavirus Disease-2019?

A: As stated in Section IV.A of 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), for laboratories certified under CLIA to perform high-complexity testing, 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. As noted in the guidance, FDA believes 15 business days is a reasonable period of time to prepare an EUA submission for a test that has already been validated.

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 Section IV.A of 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 laboratories listed below have agreed to be identified on the FDA's website. The FDA has not yet reviewed the laboratory's validation of tests offered under this policy or issued EUAs for these laboratories' tests and is including this list here to provide transparency regarding the notifications submitted to FDA.

- AdventHealth
- Altru Diagnostic, Inc.
- ARUP Laboratories
- Assurance Scientific
- Avellino Lab USA, Inc.
- Baylor Scott and White Medical Center - Temple
- BioReference Laboratories

- Boston Children's Hospital Infectious Diseases Diagnostics Laboratory
- Brigham and Women's Hospital
- The Children's Hospital of Philadelphia
- Cleveland Clinic
- Diagnostic Solutions Laboratory LLC
- Diatherix Eurofins
- Eli Lilly Clinical Diagnostics Laboratory
- Emory Medical Laboratory, Emory Healthcare
- Genesys Diagnostics Inc.
- 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
- Medical Diagnostic Laboratories LLC
- Montefiore Medical Center
- Nebraska Medicine Clinical Laboratory
- New York Presbyterian Hospital - Weill Cornell Medicine (NYPH-WCM)
- Next Bio-Research Services LLC

- NYU Langone Medical Center
- PTC Laboratories, Inc.
- Quest Diagnostics Infectious Disease, Inc.
- Solaris Diagnostics
- Southwest Regional PCR Laboratory dba MicroGen DX
- 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.

Q: What States or territories have chosen to authorize laboratories within that State or territory to develop and perform a test for COVID-19 under the policy outlined in Section IV.B of the Policy for Diagnostic Tests for Coronavirus Disease-2019?

A: As stated in Section IV.B of 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), a State or territory choosing to authorize laboratories within that State or territory to develop and perform a test for COVID-19 would do so under authority of its own State law, and under a process that it establishes. As noted in the guidance, FDA does not intend to object to the use of such tests for specimen testing where the notification of SARS-CoV-2 test validation is not submitted to FDA and the laboratory does not submit an EUA request to FDA, and where instead the State or territory takes responsibility for COVID-19 testing by laboratories in its State/territory during the COVID-19 outbreak.

The States and territories listed below have notified FDA that they choose to use this flexibility to expedite COVID-19 testing. As stated in the guidance, the FDA will not be reviewing the process adopted by the State or territory under this policy and is including this list here to provide transparency regarding the notifications submitted to FDA.

- State of Maryland
- State of Nevada
- State of New York Department of Health Wadsworth Center
- Washington State Department of Health

Q: What commercial manufacturers are distributing test kits under the policy outlined in Section IV.C of the Policy for Diagnostic Tests for Coronavirus Disease-2019?

A: As stated in Section IV.C of 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 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. As noted in the guidance, 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. This policy does not apply to at home testing.

The commercial manufacturers listed below have notified FDA that they have validated and are distributing test kits as set forth in Section IV.C of 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 FDA has not yet reviewed the validation of the tests of these manufacturers or issued EUAs for these manufacturers' tests and is including this list here to provide transparency regarding the notifications submitted to FDA.

- BD BioGx SARS-CoV-2 Reagents for BD MAX System
- BGI Genomics Co. Ltd
- Co-Diagnostics, Inc.

- QIAGEN QIAstat-Dx Respiratory SARS-CoV-2 Panel Assay

Q: What serology tests are being offered under the policy outlined in Section IV.D of the Policy for Diagnostic Tests for Coronavirus Disease-2019?

A: As stated in Section IV.D of 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 FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

This policy does not apply to at home testing.

The commercial manufacturers and laboratories listed below have notified FDA that they have validated and are offering serology tests as set forth in Section IV.D of 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 FDA has not reviewed the validation of tests offered by these developers, who will not be pursuing EUAs, and is including this list here to provide transparency regarding the notifications submitted to FDA.

- Assure Tech (Hangzhou) Co., Ltd.'s COVID-19 IgG/IgM Rapid Test Device
- Autobio Diagnostics' Anti-SARS-CoV-2 Rapid Test
- BioMedomics, Inc. COVID-19 IgM-IgG Rapid Test
- BTNX, Inc. Rapid Response™ COVID-19 IgG/IgM Test Cassette
- Core Technology Co., Ltd. CoreTest COVID-19 IgM/IgG Ab Test
- Coronacide™ COVID-19 IgM/IgG Rapid Test
- Diazyme Laboratories, Inc. Diazyme DZ-LITE SARS-CoV-2 IgG CLIA Kit
- Diazyme Laboratories, Inc. Diazyme DZ-Lite SARS-Cov-2 IgM CLIA Kit
- Guangzhou Wondfo Biotech Co., Ltd. SARS-CoV-2 Antibody Test
- Hangzhou Clongene Biotech Co., Ltd. Clungene COVID-19 IgM/IgG Rapid Test Cassette
- Hangzhou Biotest Biotech's COVID-19 IgG/IgM Rapid Test Cassette
- Jiangsu Macro & Micro-Test Med-Tech Co., Ltd. SARS-CoV-2

IgM/IgG Rapid Assay Kit (Colloidal Gold)

- Nirmidas Biotech, Inc. COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit
- Phamatech Inc. COVID19 IgG/IgM Rapid Test
- Promedical COVID-19 Rapid Test {Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)}
- SD Biosensor STANDARD Q COVID-19 IgM/IgG Duo
- Suzhou Kangheshun Medical Technology Co., Ltd SARS-CoV-2 IgG/IgM Rapid Test Cassette
- United Biomedical, Inc. UBI® SARS-CoV-2 ELISA
- Zhejiang Orient Gene Biotech, Co., Ltd. COVID-19 IgG/IgM Rapid Test Cassette
- Zhengzhou Fortune Bioscience Co., Ltd. COVID-19 IgG Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)
- Zhengzhou Fortune Bioscience Co., Ltd. COVID-19 IgM Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)
- Zhengzhou Fortune Bioscience Co., Ltd. COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)
- Zhuhai Encode Medical Engineering Co., Ltd Novel Coronavirus (COVID-19) IgG/IgM Rapid Test Device
- Zhuhai Livzon Diagnostics, Inc. Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Colloidal Gold)

General FAQs

Q: Can I offer my test for home use and/or self-collection under the Policy for Diagnostic Tests for Coronavirus Disease-2019?

A: As noted in the guidance, the policies 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 not apply to at-home testing, including self-collection of samples to be sent to a clinical laboratory.

FDA encourages developers to discuss their validation of home use and/or self-collection tests with us early in their development process.

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: 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 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) and a flocked nasopharyngeal swab to collect and transport patient samples. Are there alternatives that I can use?

A: The alternative recommendations below are made in the context of limited quantities of testing supplies during this public health crisis, based on the best available evidence and in consultation with outside experts. We have included a list of examples of products, including catalog numbers for different distributors. The information provided is not an endorsement of any one product over another of the same type. Other companies may write to FDA at CDRH-EUA-Templates@FDA.HHS.GOV (mailto:CDRH-EUA-Templates@FDA.HHS.GOV) to request their products be included here.

If you have validated additional alternatives, FDA would like to see your validation data informally through an email to CDRH-EUA-Templates@FDA.HHS.GOV (mailto:CDRH-EUA-

Templates@FDA.HHS.GOV). If FDA's review of validation data indicates that it could be applicable more broadly, and you agree to FDA sharing that information on our website for use by other laboratories, FDA intends to update our FAQs so other laboratories can learn from this validation data.

Specimen Collection

FDA believes that a nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing.

If a nasopharyngeal specimen is not available, then any of the following are acceptable:

- oropharyngeal specimen collected by a healthcare professional (HCP);
- mid-turbinate specimen by onsite self-collection or HCP (using a flocked tapered swab); or
- anterior nares specimen by onsite self-collection or HCP (using a round foam swab).

Multiple specimens may be taken with a single swab. If a separate swab is used for collecting specimens from two different locations in the same patient, both swabs may be placed in the same vial in order to conserve collection and assay supplies. At this time, anterior nares and mid-turbinate specimen collection are only appropriate for symptomatic patients and both nares should be swabbed. There is currently not enough information to recommend nasal or mid-turbinate testing for asymptomatic persons.

Other swab specimens (i.e., tongue swabs) may have decreased sensitivity, so caution should be exercised when interpreting negative results.

More data are necessary on the validity of buccal swabs or saliva specimens alone.

For patients with productive cough, a sputum sample is an acceptable lower respiratory specimen.

Due to concerns with specimen stability, transport, and appropriate collection materials, self-collection at home or at sites other than designated collection sites staffed by HCPs is currently not recommended.

FDA believes that sample collection with a flocked swab, when available, is preferred. Collection should be conducted with a sterile swab. If the applicator handle requires additional trimming, the trimming should be performed with a sterile pair of scissors to prevent contamination of the sample. Swab recommendations are based on limited available evidence, and expert opinion suggests further research is needed in this area.

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.

To avoid specimens being wasted, if a lab is presented with a specimen that was collected or identified in a sub-optimal manner, e.g. with a swab for which there is less evidence of effectiveness, FDA believes that it would still be appropriate for the lab to accept the specimen for analysis and note the circumstances on the report. These specimens may have decreased sensitivity, so caution should be exercised when interpreting negative results.

Below is a list of individually wrapped swabs. All swabs are flocked unless noted:

- Puritan Nasopharyngeal swabs: 25-3317-H, 25-1406 1PF 50f, 25-800 1PD 50**, 25-3320-U, 25-3320-H EMB 80, 25-3320-U EMB 80, 25-3320-H EMB 100 and 25-3320-U EMB 100
- Copan Nasopharyngeal swabs: 503CS01, 518CS01, and 501CS01, 502CS01
- BD Nasopharyngeal swabs: 220252 and 220251
- DHI/Quidel Nasopharyngeal swabs: 503CS01.DHI
- Fisher Healthcare Nasopharyngeal swabs: 23600952, 23600956 and 23600950 Puritan Oropharyngeal swabs: 25-1506 1PF SOLID[f], 25-1506 1PF 100[f], 25-3206-H, 25-3206-U, 25-3706-H, 25-806 1PD** and 25-806 1PD BT**
- Copan Oropharyngeal swabs: 502CS01, 519CS01, 164KS01**, 167KS01**, 170KS01** and 175KS01**
- BD Oropharyngeal swabs: 220250
- Fisher Healthcare Oropharyngeal swabs: 23600950, 23600957, 1490641**, 1490640** and 1490650**
- Additional sterile flocked swabs from Puritan that may be used: 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 25-3320-U, 25-3320-H and 25-3319-H

[f] Foam swab
** Polyester swab

Additionally, swabs may be provided with transport media as identified below.

Transport Media

VTM/UTM remains the preferred transport media. Examples of universal transport media for viruses and molecular transport media are listed here. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

- Copan: 305C, 307C, 360C and 519CS01*
- Puritan: UT-367, UT-317, UT-302*, UT-366** and UT-300***
- Hardy/Healthlink: 330CHL
- BD: 220526, 220527, 220258*, 220529, 220531 DHI/Quidel: 330C.
- DHI and 503CS01.DHI
- Fisher Healthcare: 23001718, 23600952, 23600956, 23600950 and 23600957*
- PrimeStore MTM: LH-1-02 and LH-1-03***

* flocked oropharyngeal swab
** Polyester swab
*** no swab

In the absence of VTM/UTM, alternative transport media can be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays. These recommendations apply to swab-based specimen collection by healthcare providers (HCP), and to anterior nares (nasal) and mid-turbinate specimen collection onsite by self-collection. The best available evidence indicates that these transport media will stabilize the SARS-CoV-2 RNA without meaningful degradation.

Labs can create their own viral transport media. Refer to CDC's SOP#: DSR-052-01: Preparation of Viral Transport Media (https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-

Transport-Medium.pdf). Specimens can be stored for up to 72 hours at 4°C, or frozen for longer storage.

Liquid Amies media may be used for viral transport when universal transport media is not available. Specimens can be stored in liquid Amies media for up to 72 hours at 4°C, or frozen for longer storage. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

- Copan: 481C, 482C 480C* and 480CFA*
- Puritan: LA-117, LA-116-H and LA-100***
- BD: 220246, 220532 and 220245*
- ThermoFisher: R723481, R723482 and R723480*
- Hardy/Healthlink: 481C, 482C 480C* and 480CFA*
- VWR: 89136-656, 89136-658, 89136-654* and 76181-494*
- Fisher Healthcare: 23600901, 23600902, 23600900* and 23600905*

* flocked oropharyngeal swab
*** no swab

If the above are not available, FDA recommends use of a dry swab in saline to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays. FDA believes that for saline, a sterile glass or plastic vial containing between 1mL and 3mL of phosphate buffered saline is appropriate. Specimens can be stored up to 72 hours at 4°C, or frozen for longer storage. All the products listed below do not include a swab.

- ThermoFisher: R064430, R064432, R064434, R064436 and R064438

- Hardy/Healthlink: D185, K248, R45 and R55
- Edge Biologicals: T-0625 and T-0110f

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: 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
    - Go to the BEI Resources website (https://www.beiresources.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

If you are unable to acquire genomic RNA, FDA believes the following synthetic nucleic acid material could be used to validate SARS-CoV-2 tests targeting the regions listed in the product information.

Please be aware of potential differences between the sequences these synthetic genomic materials are based on and the current circulating SARS-CoV-2 in the US. These differences could impact the clinical performance of an assay and users should take this into consideration when selecting this material for test validation. To promote RNA

stability, steps should be taken to minimize exposure to degrading conditions for instance by spiking test material into a lysis buffer prior to adding negative clinical matrix.

- SeraCare AccuPlex SARS-CoV-2 Reference Material Kit
    - Ordering information (https://digital.seracare.com/sars-cov-2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
    - Product Sheet (https://www.seracare.com/globalassets/seracare-resources/pi-0505-0126-accuplex-sars-cov-2.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Twist Bioscience
    - Follow the instructions on the product page (https://www.twistbioscience.com/coronavirus-research-tools) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for ordering. You may request SKUs 102019 and/or 102024 for the Synthetic SARS-CoV-2 RNA Controls.

Links provided to manufacturer websites are for information purposes only and not a recommendation by FDA to use that product. FDA encourages other suppliers of genetic material to email

COVID19DX@fda.hhs.gov (mailto:COVID19DX@fda.hhs.gov) to discuss whether materials they have available may also be appropriate for this use.

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.

- Obtaining Synthetic RNA Controls:
  Please be aware of potential differences between the sequences these synthetic genomic materials are based on and the current circulating SARS-CoV-2 in the US. These differences could impact the performance of an assay and users should take this into consideration when selecting this material as a positive control. To promote RNA stability, steps should be taken to minimize exposure to degrading conditions for instance by spiking test material into a lysis buffer prior to adding negative clinical matrix.
    - Twist Bioscience sells Synthetic SARS-CoV-2 RNA Controls for two strains MT007544.1 (SKU 102019) and MN908947.3 (SKU 102024). These materials provide full coverage of the full-length RNA from each respective strain. Each tube contains approximately 100 million copies of the RNA (enough for 100 samples per tube), and is BSL1 labeled for shipping and use in any laboratory
      or
    - Twist Bioscience can manufacture Synthetic SARS-CoV-2 RNA Controls for any new strains as they evolve on demand

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. 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) (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) (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?

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).