FAQs on Diagnostic Testing for SARS-CoV-2

Industry Hotline: Coronavirus COVID-19 Diagnostic Tests and Shortages

- For Industry Questions: COVID-19 Diagnostic Tests, and COVID-19 device shortages, including all Personal Protective Equipment for masks and respirators
- Contact our toll-free line 24 hours a day: 1-888-INFO-FDA, choose option *

Or Email:

- Shortages: deviceshortages@fda.hhs.gov (mailto:deviceshortages@fda.hhs.gov)
- Diagnostic Tests: COVID19DX@FDA.HHS.GOV (mailto:COVID19DX@FDA.HHS.GOV)

COVID-19 Resources

- FDA's Role: Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions)
- Coronavirus Disease (COVID-19) Emergency Use Authorization (EUA) Information (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)
- Coronavirus Disease (COVID-2019) updates from FDA (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov)

Reporting Problems to the FDA

The sale of fraudulent COVID-19 products is a threat to the public health. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program (/safety/report-problem-fda/reporting-unlawful-sales-medical-products-internet) or the Office of Criminal Investigations (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm). You can also email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov (mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov).

> If you think you had a problem with your diagnostic test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).
>
> Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

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.

Tests, including serology tests, being offered prior to or without an EUA under a policy outlined in the *Policy for Diagnostic Tests for (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency)Coronavirus Disease-2019* (/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency), have not been reviewed or authorized by the FDA. As stated 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), all such tests should be validated by the developer prior to being offered for clinical use.

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.

Get Updates: In Vitro Diagnostics

The FDA intends to update this page regularly. Sign up for email alerts.

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? (Updated 4/20)

A: At this time, the FDA has not authorized any COVID-19 test to be completely used and processed at home. However, on April 20, 2020, the FDA authorized the first COVID-19 test for home collection of specimens (/media/136148/download) to be sent to a laboratory for processing and test reporting. Please note that this authorization is specific only to the home collection test that has been issued the authorized EUA (LabCorp's COVID-19 RT-PCR Test). Any COVID-19 test intended for at-home testing, including self-collection of a specimen at home, with or without the use of telemedicine, requires an authorized EUA. All tests that have received an authorized EUA, including any authorizations for home collection of a specimen, can be found on our Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) page. 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 (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#offeringtests)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? (Updated 4/21)

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 (https://www.fda.gov/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. Where the Authorization Status is "FDA Authorized," the FDA reviewed and issued an EUA for the test after notification was given. Where the Authorization Status is shown as "Not FDA Authorized," the FDA has not yet reviewed the manufacturer's validation and issued an EUA for the manufacturer's test, and the test is included in this list to provide transparency regarding the notifications submitted to FDA. The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing.

Laboratories that 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:

Search:

Laboratory	Authorization Status	Settings for Use[1]
Access Genetics, dba OralDNA Labs	Not FDA Authorized	H

Laboratory	Authorization Status	Settings for Use[1]
Access Medical Laboratories	Not FDA Authorized	H
Accu Reference Medical Lab LLC	Not FDA Authorized	H
Advanced Diagnostics Laboratory, National Jewish Health	Not FDA Authorized	H
AdventHealth	Not FDA Authorized	H
Alphadera Labs, LLC	Not FDA Authorized	H
Altru Diagnostic, Inc.	Not FDA Authorized	H
ARUP Laboratories	Not FDA Authorized	H
Assurance Scientific	Not FDA Authorized	H
ASU Biodesign Clinical testing Laboratory, Center for Personalized Diagnostics	Not FDA Authorized	H
Avellino Lab USA, Inc.	FDA Authorized (/media/136450/download)	H
Bako Pathology Associates/DBA Bako Diagnostics	Not FDA Authorized	H
Baptist Hospital of Miami Clinical Lab	FDA Authorized (/media/136943/download)	H
Baylor Scott and White Medical Center – Temple	Not FDA Authorized	H
Baystate Medical Center Whitney Ave Laboratories	Not FDA Authorized	H
Bedford Research Foundation	Not FDA Authorized	H
Beth Israel Deaconess Medical Center	Not FDA Authorized	H
Biodesix, Inc.	Not FDA Authorized	H
BioReference Laboratories	Not FDA Authorized	H
Boston Children's Hospital Infectious Diseases Diagnostics Laboratory	FDA Authorized (/media/136972/download)	H
Brigham and Women's Hospital	Not FDA Authorized	H
Bryan Medical Center West	Not FDA Authorized	H
Children's National Hospital	Not FDA Authorized	H
Clarity Lab Solutions	Not FDA Authorized	H

Laboratory	Authorization Status	Settings for Use[1]
Cleveland Clinic	Not FDA Authorized	H
Clinical Laboratories of Hawaii	Not FDA Authorized	H
Clinical Laboratory University Hospital at University of Arkansas for Medical Sciences	Not FDA Authorized	H
Clinical Pathology Laboratories	Not FDA Authorized	H
Clinical Research Sequencing Platform, LLC at the Broad Institute of MIT & Harvard	Not FDA Authorized	H
Compass Laboratory Services, LLC	Not FDA Authorized	H
Consolidated Medical Bio-Analysis, Inc.	Not FDA Authorized	H
CSI Laboratories	Not FDA Authorized	H
Devansh Lab Werks Inc.	Not FDA Authorized	H
Diagnostic Solutions Laboratory LLC	Not FDA Authorized	H
Diatherix Eurofins	Not FDA Authorized	H
Dynamic DNA Laboratories, LLC	Not FDA Authorized	H
Eli Lilly Clinical Diagnostics Laboratory	Not FDA Authorized	H
Emory Medical Laboratory, Emory Healthcare	Not FDA Authorized	H
Exact Sciences Laboratories	Not FDA Authorized	H
Gene By Gene	Not FDA Authorized	H
Genesys Diagnostics Inc.	Not FDA Authorized	H
Gravity Diagnostics	Not FDA Authorized	H
Henry Ford Health System	Not FDA Authorized	H
HMH Hackensack University Medical Center	Not FDA Authorized	H
Hospital of the University of Pennsylvania	Not FDA Authorized	H
Houston Methodist Hospital	Not FDA Authorized	H
iGenomeDx	Not FDA Authorized	H
Integrity Laboratories	FDA Authorized (/media/136941/download)	H

Laboratory	Authorization Status	Settings for Use[1]
Ipsum Diagnostics LLC	FDA Authorized (/media/136618/download)	H
ISPM Labs, LLC DBA Capstone Healthcare	Not FDA Authorized	H
Johns Hopkins Medical Microbiology Laboratory at Johns Hopkins Hospital	Not FDA Authorized	H
Kashi Clinical Laboratories, Inc.	Not FDA Authorized	H
Korva-Labs Inc.	Not FDA Authorized	H
Lehigh Valley Genomics	Not FDA Authorized	H
Lenco Diagnostic Laboratory	Not FDA Authorized	H
Lexar Laboratories & Analysis, LLC	Not FDA Authorized	H
MAWD Pathology Group	Not FDA Authorized	H
Mayo Clinic	Not FDA Authorized	H
Medical Diagnostic Laboratories LLC	Not FDA Authorized	H
Memorial Sloan Kettering Cancer Center	Not FDA Authorized	H
Molecular Diagnostics, Christiana Care Health Systems	Not FDA Authorized	H
Montefiore Medical Center	Not FDA Authorized	H
Nanticoke Memorial Hospital Laboratory	Not FDA Authorized	H
Nebraska Medicine Clinical Laboratory	Not FDA Authorized	H
New York Presbyterian Hospital - Weill Cornell Medicine (NYPH-WCM)	Not FDA Authorized	H
Next Bio-Research Services LLC	Not FDA Authorized	H
NIPD Genetics Public Company Limited	Not FDA Authorized	H
North Central Florida Neurodiagnostic Services DBA: NCF Diagnostics & DNA Technologies	Not FDA Authorized	H
NYU Langone Medical Center	Not FDA Authorized	H
OmniPathology Solutions Medical Corporation	Not FDA Authorized	H
Opteo Laboratory, LLC	Not FDA Authorized	H

Laboratory	Authorization Status	Settings for Use[1]
Orig3n, Inc.	FDA Authorized (/media/136874/download)	H
Orlando Health	Not FDA Authorized	H
Oxy-Gen Laboratory, LLC	Not FDA Authorized	H
Paradigm Laboratories	Not FDA Authorized	H
Patriot Medical Laboratories LLC DBA CIAN Diagnostics	Not FDA Authorized	H
Poplar Healthcare	Not FDA Authorized	H
Primex Clinical Laboratories, Inc.	Not FDA Authorized	H
Proteus Molecular and Clinical Lab LLC	Not FDA Authorized	H
PTC Laboratories, Inc.	Not FDA Authorized	H
Quest Diagnostics Infectious Disease, Inc.	FDA Authorized (/media/136228/download)	H
RCA Laboratory Services LLC DBA GENETWORx	Not FDA Authorized	H
Real Diagnostics Laboratory	Not FDA Authorized	H
Saint Mary's Medical Center	Not FDA Authorized	H
Sandia National Laboratories	Not FDA Authorized	H
Sciteck Clinical Laboratory	Not FDA Authorized	H
Sharp Copley Laboratory	Not FDA Authorized	H
Solaris Diagnostics	Not FDA Authorized	H
Sonic Reference Laboratory	Not FDA Authorized	H
Southwest Regional PCR Laboratory dba MicroGen DX	Not FDA Authorized	H
Specialty Diagnostics Inc	FDA Authorized (/media/136878/download)	H
Specialty Drug Testing	Not FDA Authorized	H
Stanford Health Care Clinical Laboratory	FDA Authorized (/media/136817/download)	H
Tampa General Hospital	Not FDA Authorized	H

Laboratory	Authorization Status	Settings for Use[1]
Texas Children's Hospital Department of Pathology	Not FDA Authorized	H
TGen North, Clinical Laboratory	Not FDA Authorized	H
The Children's Hospital of Philadelphia	FDA Authorized (/media/136657/download)	H
UC Berkeley Innovative Genomic Institute	Not FDA Authorized	H
UCSF-Health	Not FDA Authorized	H
UltimateDx Laboratories	Not FDA Authorized	H
University of Minnesota Genomics Center	Not FDA Authorized	H
University of North Carolina Medical Center McLendon Clinical Laboratories	FDA Authorized (/media/136879/download)	H
University of Washington	Not FDA Authorized	H
Viracor Eurofins Clinical Diagnostics	FDA Authorized (/media/136739/download)	H
Virginia Tech Schiffert Health Center	Not FDA Authorized	H
WestPac Labs	Not FDA Authorized	H
Wisconsin Diagnostic Laboratories	Not FDA Authorized	H
Xymbio, LLC	Not FDA Authorized	H
Yale Pathology Molecular Diagnostic Laboratory	Not FDA Authorized	H

Showing 1 to 109 of 109 entries

[1] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.
- W - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests, and deemed to be CLIA waived for use in

patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance.

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 Connecticut
- State of Maryland
- State of Mississippi
- State of Nevada
- State of New Jersey
- 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? (Updated 4/20)

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 to clinical laboratories of test kits to perform assays to detect SARS-CoV-2 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). Where the status is "Not FDA Authorized," the FDA has not yet reviewed the validation of the tests of these manufacturers and issued EUAs for these manufacturers' tests and is including this list here to provide transparency regarding the notifications submitted to FDA.

Commercial Manufacturers that have notified the FDA that they have validated and are distributing test kits as set forth in Section IV.C:

Where the Authorization Status is "FDA Authorized," the FDA reviewed and issued an EUA for the test after notification was given. Where the Authorization Status is shown as "Not FDA Authorized," the FDA has not yet reviewed the laboratory's validation and issued an EUA for the laboratory's test, and the test is included in this list to provide transparency regarding the notifications submitted to FDA. The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing.

Search:

Manufacturer and Test	Authorization Status	Settings for Use[1]
BD BioGx SARS-CoV-2 Reagents for BD MAX System	FDA Authorized (/media/136650/download)	H, M
BGI Genomics Co. Ltd	FDA Authorized (/media/136473/download)	H
Biomeme, Inc. Biomeme SARS-CoV-2 test kit	Not FDA Authorized	H
Co-Diagnostics, Inc.	FDA Authorized (/media/136684/download)	H
Genomictree, Inc. AccuraDTect SARS-CoV-2-qPCR Kit	Not FDA Authorized	H
LabGenomics, Co., Ltd. LabGunTM COVID-19 Assay kit	Not FDA Authorized	H
OSANG Healthcare Co., Ltd, GeneFinder COVID-19 Plus RealAmp Kit	Not FDA Authorized	H
QIAGEN QIAstat-Dx Respiratory SARS-CoV-2 Panel Assay	FDA Authorized (/media/136569/download)	H, M
YD Diagnostics Corp. MolecuTech Real-Time COVID-19	Not FDA Authorized	H

Showing 1 to 9 of 9 entries

[1] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.
- W - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests, and deemed to be CLIA waived for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance.

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? (Updated 4/21)

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.

To help ensure the above information is provided in the test report, as described in the guidance, commercial manufacturers could include this information in their Instructions for Use (IFU) or other labeling provided to laboratories.

This policy does not apply to at home testing.

The commercial manufacturers and laboratories in the two lists 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). Unless an Emergency Use Authorization (EUA) has also been submitted and reviewed, the FDA has not reviewed the validation of tests offered by these developers, who may not be pursuing EUAs. FDA is including this list here to provide transparency regarding the notifications submitted to FDA.

Laboratories that have notified FDA that they have validated and are offering serology tests as set forth in Section IV.D:

Where the Authorization Status is "FDA Authorized," the FDA reviewed and issued an EUA for the test after notification was given. Where the Authorization Status is shown as "Not FDA Authorized," the FDA has not yet reviewed the laboratory's validation and issued an EUA for the laboratory's test, and the test is included in this list to provide transparency regarding the notifications submitted to FDA. The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing.

Search:

Laboratory	Authorization Status	Settings for Use[1]
Access Medical Laboratories	Not FDA Authorized	H
Arrayit Corporation	Not FDA Authorized	H
Beaumont Health	Not FDA Authorized	H
BioDiagnostic Labs LLC	Not FDA Authorized	H
Bioreference Laboratories Inc.	Not FDA Authorized	H
Boston Heart Diagnostics	Not FDA Authorized	H
DLS Research & Ventures	Not FDA Authorized	H
EDP Biotech Corporation	Not FDA Authorized	H
Emory Medical Laboratories	Not FDA Authorized	H
HealthQuest Esoterics	Not FDA Authorized	H
IMMYLabs	Not FDA Authorized	H
Lenco Diagnostic Laboratory	Not FDA Authorized	H
Mayo Clinic	Not FDA Authorized	H
Michigan Health Clinics	Not FDA Authorized	H
Otogenetics	Not FDA Authorized	H
Roseland Community Hospital/American Medical Lab	Not FDA Authorized	H
University of Minnesota Advanced Research and Diagnostic Laboratory	Not FDA Authorized	H
US Specialty Labs	Not FDA Authorized	H
Vibrant America Clinical Labs	Not FDA Authorized	H

Showing 1 to 19 of 19 entries

[1] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high

complexity tests.

- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.
- W - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests, and deemed to be CLIA waived for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance.

Manufacturers that have notified FDA that they have validated and are offering serology tests as set forth in Section IV.D:

Where the Authorization Status is "FDA Authorized," the FDA reviewed and issued an EUA for the test after notification was given. Where the Authorization Status is shown as "Not FDA Authorized," the FDA has not yet reviewed the manufacturer's validation and issued an EUA for the manufacturer's test, and the test is included in this list to provide transparency regarding the notifications submitted to FDA. The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing.

Search:

Manufacturer and Test	Authorization Status	Settings for Use[2]
Abbott Laboratories SARS-CoV-2 IgG (for use on ARCHITECT)	Not FDA Authorized	H
Alfa Scientific Designs, Inc. Clarity COVID-19 IgG/IgM Antibody Test	Not FDA Authorized	H
Alfa Scientific Designs, Inc. Instant-view plus COVID-19 IgG/IgM Antibody Test	Not FDA Authorized	H
Anhui Deepblue Medical Technology Co., Ltd. COVID-19 (SARS-CoV-2) IgG/IgM Antibody Test Kit (Colloidal Gold)	Not FDA Authorized	H
Artron BioResearch Inc./ Artron Laboratories Inc. Artron COVID-19 IgM/IgG Antibody Test	Not FDA Authorized	H
Assure Tech (Hangzhou) Co., Ltd.'s COVID-19 IgG/IgM Rapid Test Device	Not FDA Authorized	H
Atlas Link (Beijing)Technology Co., Ltd NovaTest: One Step COVID-19 IgG/IgM rapid test	Not FDA Authorized	H
Autobio Diagnostics' Anti-SARS-CoV-2 Rapid Test	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Beijing Beier Bioengineering Co., Ltd 2019-New Coronavirus IgG/IgM Rapid Test Cassette (WB/S/P)	Not FDA Authorized	H
Beijing Decombio Biotechnology Co., Ltd. Novel Coronavirus IgM/IgG Combo Rapid Test-Cassette (Serum/Plasma/Whole blood)	Not FDA Authorized	H
Beijing Diagreat Biotechnologies Co., Ltd. 2019-nCoV IgG Antibody Determination Kit	Not FDA Authorized	H
Beijing Diagreat Biotechnologies Co., Ltd. 2019-nCoV IgG/IgM Antibody Rapid Test Kit	Not FDA Authorized	H
Beijing Diagreat Biotechnologies Co., Ltd. 2019-nCoV IgM Antibody Determination Kit	Not FDA Authorized	H
Beijing Kewei Clinical Diagnostic Reagent Inc. Genonto RapidTest10 COVID-19 IgG/IgM Antibody Rapid Test Kit	Not FDA Authorized	H
Beijing O&D BIOTECH Co., LTD. Coronavirus disease (COVID-19) Total Antibody Rapid Test (Colloidal Gold)	Not FDA Authorized	H
Beijing Wantai Biological Pharmaceutical Co., Ltd. TOTAL ANTIBODY WANTAI SARS- COV-2 Ab Rapid Test Kit	Not FDA Authorized	H
Beroni Group SARS-CoV-2 IgG/IgM Antibody Detection Kit	Not FDA Authorized	H
Biobase Biodustry (Shandong) Co., Ltd SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold)	Not FDA Authorized	H
Biocan Diagnostics Inc. Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test (Cassette Format)	Not FDA Authorized	H
Biocan Diagnostics Inc. Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test (Strip Format)	Not FDA Authorized	H
Biohit Healthcare (Hefei) Co., Ltd. SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)	Not FDA Authorized	H
Biolidics Limited 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold)	Not FDA Authorized	H
BioMedomics, Inc. COVID-19 IgM-IgG Rapid Test	Not FDA Authorized	H
BioSys Laboratories, Inc. BioSys Plus COVID-19 IgM/IgG Rapid Test	Not FDA Authorized	H
Boditech Med Inc AFIAS COVID-19 Ab serological tests	Not FDA Authorized	H
BTNX, Inc. Rapid Response™ COVID-19 IgG/IgM Test Cassette	Not FDA Authorized	H
Calbiotech, Inc. ErbaLisa® COVID-19 IgG	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Chembio Diagnostic Systems, Inc. DPP COVID-19 IgM/IgG System	FDA Authorized (/media/136965/download)	H, M
Core Technology Co., Ltd. CoreTest COVID-19 IgM/IgG Ab Test	Not FDA Authorized	H
Core Technology Co., Ltd. RapidTest COVID-19 IgM/IgG Ab Test	Not FDA Authorized	H
Coronacide™ COVID-19 IgM/IgG Rapid Test	Not FDA Authorized	H
CTK Biotech, Inc. OnSite® COVID-19 IgG/IgM Rapid Test	Not FDA Authorized	H
DIALAB(ZJG) Biotech Co., Ltd. Device Name: SARS-CoV-2 IgG/IgM Antibody Test (Fluorescence Immunoassay)	Not FDA Authorized	H
Diazyme Laboratories, Inc. Diazyme DZ-LITE SARS-CoV-2 IgG CLIA Kit	Not FDA Authorized	H
Diazyme Laboratories, Inc. Diazyme DZ-Lite SARS-Cov-2 IgM CLIA Kit	Not FDA Authorized	H
Diazyme Laboratories, Inc. Diazyme SARS-CoV-2 Antibody Rapid Test	Not FDA Authorized	H
Dynamiker Biotechnology (Tianjin) Co., Ltd. RapidCOV™ 2019-nCOV IgG/IgM Rapid Test	Not FDA Authorized	H
Eachy Biopharmaceuticals Co., Ltd. AccuRapid™ SARS-CoV-2 IgM/IgG Test Kit (Lateral Flow Immunoassay)	Not FDA Authorized	H
Eachy Biopharmaceuticals Co., Ltd. SmartScreen COVID-19 IgM/IgG Test Kit	Not FDA Authorized	H
EpiGentek SeroFlash SARS-CoV-2 IgM/IgG Antibody Detection Kit	Not FDA Authorized	H
Epitope Diagnostics, Inc. KT-1032 EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	Not FDA Authorized	H
Epitope Diagnostics, Inc. KT-1033 EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit	Not FDA Authorized	H
ET Healthcare Inc. Pylon COVID-19 IgM/IgG Assay	Not FDA Authorized	H
EUROIMMUN AG Anti-SARS-CoV-2 ELISA (IgA)	Not FDA Authorized	H
EUROIMMUN AG Anti-SARS-CoV-2 ELISA (IgG)	Not FDA Authorized	H
Fosun Pharma USA Inc. Fosun COVID-19 IgG/IgM Rapid Antibody Detection Kit	Not FDA Authorized	H
GenBody Inc. GenBody COVID-19 IgM/IgG	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Genlantis Diagnostics, Inc. CovidQuik™ Coronavirus (COVID-19) IgM/IgG Antibody Test	Not FDA Authorized	H
Genrui Biotech Inc. Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal Gold)	Not FDA Authorized	H
Getein Biotech Inc. One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	Not FDA Authorized	H
Goldsite Diagnostics Inc SARS-CoV-2 IgG/IgM ki	Not FDA Authorized	H
Guangdong Hecin Scientific, Inc. SARS-CoV-2 IgM Antibody Rapid Test Kit	Not FDA Authorized	H
Guangzhou Fenghua Bioengineering Co., Ltd. SARS-CoV-2 IgG/IgM Rapid Test	Not FDA Authorized	H
Guangzhou Wondfo Biotech Co., Ltd. SARS-CoV-2 Antibody Test	Not FDA Authorized	H
Hangzhou AllTest Biotech Co., Ltd. AllTest 2019-nCoV IgG/IgM Rapid Test Cassette	Not FDA Authorized	H
Hangzhou AllTest Biotech Co., Ltd. AllTest COVID-19 IgG/IgM Rapid Test Dipstick	Not FDA Authorized	H
Hangzhou Biotest Biotech's COVID-19 IgG/IgM Rapid Test Cassette	Not FDA Authorized	H
Hangzhou Clongene Biotech Co., Ltd. Clungene COVID-19 IgM/IgG Rapid Test Cassette	Not FDA Authorized	H
Hangzhou Clongene Biotech Co., Ltd. COMBRA COVID-19 IgM/IgG Rapid Test Cassette	Not FDA Authorized	H
Hangzhou Realy Tech Co Ltd. 2019-nCOV IgG/IgM Rapid Test	Not FDA Authorized	H
Hangzhou Testsealabs Biotecnology Co., Ltd One Step SARS-CoV2 (COVID-19) IgG/IgM Test	Not FDA Authorized	H
Healgen Scientific, LLC. COVID-19 IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	Not FDA Authorized	H
HUMASIS Co., Ltd. Humasis COVID-19 IgG/IgM Test	Not FDA Authorized	H
Hunan RunKun Pharmaceutical Co., Ltd SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)	Not FDA Authorized	H
INNOVITA (Tangshan) Biological Technology Co., Ltd. 2019-nCoV Ab Test (Colloidal Gold)	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Jiangsu Dablood Pharmaceutical Co, Ltd. AssuranceAB™ COVID-19 IgM/IgG Rapid Antibody Test	Not FDA Authorized	H
Jiangsu Dablood Pharmaceutical Co. Ltd. COVID-19 IgM/IgG Rapid Test	Not FDA Authorized	H
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd. SARS-CoV-2 IgM/IgG Rapid Assay Kit (Colloidal Gold)	Not FDA Authorized	H
Jiangsu Superbio Biomedical (Nanjing) Co., Ltd. DualTec SARS-CoV-2(COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	Not FDA Authorized	H
Jiangsu Superbio Biomedical (Nanjing) Co., Ltd. ThermoGenesis SARS-CoV-2(COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	Not FDA Authorized	H
Jiangsu Well Biotech Co., Ltd. COVID-19 IgM/IgG Rapid Test (Colloidal Gold)	Not FDA Authorized	H
Lepu Medical Technology (Beijing) Co., Ltd. Lepu SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	Not FDA Authorized	H
Lifeassay Diagnostics (Pty) Ltd Test-it COVID-19 IgM/IgG Lateral Flow Assay	Not FDA Authorized	H
Liming BioProducts Co. Ltd. SARS-CoV-2 IgM/IgG Antibody Rapid Test	Not FDA Authorized	H
LumiQuick Diagnostics, Inc., QuickProfile™ 2019-nCoV IgG/IgM Antibody Test	Not FDA Authorized	H
Maccura Biotechnology Co., Ltd. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) IgM/IgG Antibody Assay Kit by Colloidal Gold Method	Not FDA Authorized	H
Medical Systems Biotechnology Co., Ltd. Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit	Not FDA Authorized	H
Mokobio Biotechnology R&D Center SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay	Not FDA Authorized	H
Nanjing Liming Bio-products Co.,Ltd SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit	Not FDA Authorized	H
Nanjing SYNTHGENE Medical Technology Co., Ltd. SYNTHGENE COVID-19 IgM/IgG Rapid Detection Kit (Colloidal Gold Method)	Not FDA Authorized	H
NanoResearch, Inc. NanoMedicina™ SARS-COV-2 IgM/IgG Antibody Rapid Test	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Nantong Diagnos Biotechnology Co., Ltd. (2019-nCoV) New coronavirus Antibody Test (Colloidal Gold)	Not FDA Authorized	H
Nirmidas Biotech, Inc. COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	Not FDA Authorized	H
Ortho Clinical Diagnostics, Inc. VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	FDA Authorized (/media/136966/download)	H, M
Ortho-Clinical Diagnostics, Inc. VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and Calibrator	Not FDA Authorized	H
PCL Inc. COVID19 IgG/IgM Rapid Gold	Not FDA Authorized	H
Phamatech Inc. COVID19 IgG/IgM Rapid Test	Not FDA Authorized	H
Qingdao Hightop Biotech Co., Ltd. HIGHTOP 2019-nCoV IgM/IgG Rapid Test	Not FDA Authorized	H
RayBiotech, Inc. Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method)	Not FDA Authorized	H
RayBiotech, Inc. Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method)	Not FDA Authorized	H
Safecare Biotech (Hangzhou) Co., Ltd SAFECARE COVID-19 IgG/IgM Rapid Test Device	Not FDA Authorized	H
Saladax Biomedical Inc. Saladax COVID-19 IgG/IgM Rapid Antibody Test	Not FDA Authorized	H
SD Biosensor STANDARD Q COVID-19 IgM/IgG Duo	Not FDA Authorized	H
Shanghai Eugene Biotech Co., Ltd. SARS-CoV2 (COVID-19) IgG/IgM Rapid Test	Not FDA Authorized	H
Shanghai Liangrun Biomedicine Technology Co., Ltd. Liangrun COVID-19 IgM/IgG Antibody Test	Not FDA Authorized	H
Shanghai Outdo Biotech Co., Ltd. Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test	Not FDA Authorized	H
Shenzhen Landwind Medical Co., Ltd COVID-19 IgG/IgM Rapid Test Device	Not FDA Authorized	H
Shenzhen Watmind Medical Co. SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit	Not FDA Authorized	H
Sinocare, Inc. SARS-CoV-2 Antibody Test Kit (Colloidal Gold Method)	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Spring Health Care AG COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Not FDA Authorized	H
Sugentech, Inc. SGTi-flex COVID-19 IgM/IgG	Not FDA Authorized	H
Sure Bio-tech API Covid-Rapid IgM/IgG Antibody Test Kit	Not FDA Authorized	H
Suzhou Kangheshun Medical Technology Co., Ltd SARS-CoV-2 IgG/IgM Rapid Test Cassette	Not FDA Authorized	H
Telepoint Medical Services SARS-CoV-2 IgG/IgM Rapid Qualitative Test	Not FDA Authorized	H
Tianjin Beroni Biotechnology Co. Ltd SARS-CoV-2 IgG/IgM Antibody Detection Kit	Not FDA Authorized	H
Tianjin New Bay Bioresearch Co., Ltd. Quikpac II COVID-19 IgG/IgM	Not FDA Authorized	H
Türklab Tibbi Malzemeler San. ve Tic. A.Ş. INFO SARS-CoV-2 IgM/IgG Ab Test	Not FDA Authorized	H
Türklab Tibbi Malzemeler San. ve Tic. A.Ş. TOYO SARS-CoV-2 IgM/IgG Ab Test	Not FDA Authorized	H
UC Berkeley Innovative Genomic Institute	Not FDA Authorized	H
United Biomedical, Inc. UBI® SARS-CoV-2 ELISA	Not FDA Authorized	H
VITA Testing COVID-19 IgM / IgG Antibody Rapid Test Kit (Immunochromatography)	Not FDA Authorized	H
VivaChek Biotech (Hangzhou) Co., Ltd. VivaDiag COVID-19 IgM/IgG Rapid Test	Not FDA Authorized	H
W.H.P.M. Inc., COVID-19 IgM/IgG Rapid Test	Not FDA Authorized	H
W.H.P.M. Inc., COVISURE™ COVID-19 IgM/IgG Rapid Test	Not FDA Authorized	H
Wuhu 3H Biotechnology Co. Ltd. COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)	Not FDA Authorized	H
Xiamen AmonMed Biotechnology Co. Ltd Helix-19 COVID-19 IgM/IgG Test Kit (Colloidal Gold)	Not FDA Authorized	H
Zhejiang GENE SCIENCE Co., Ltd Novel Coronavirus (2019-nCoV) IgM/IgG Antibodies Detection Kit (Latex Chromatography)	Not FDA Authorized	H
Zhejiang Orient Gene Biotech, Co., Ltd. COVID-19 IgG/IgM Rapid Test Cassette	Not FDA Authorized	H

Manufacturer and Test	Authorization Status	Settings for Use[2]
Zhengzhou Fortune Bioscience Co., Ltd. COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)	Not FDA Authorized	H
Zhengzhou Fortune Bioscience Co., Ltd. COVID-19 IgG Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)	Not FDA Authorized	H
Zhengzhou Fortune Bioscience Co., Ltd. COVID-19 IgM Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)	Not FDA Authorized	H
Zhongshan Bio-Tech Co. Ltd SARS-CoV-2 IgM/IgG (GICA)	Not FDA Authorized	H
Zhuhai Encode Medical Engineering Co., Ltd Novel Coronavirus (COVID-19) IgG/IgM Rapid Test Device	Not FDA Authorized	H
Zhuhai Livzon Diagnostics, Inc. Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Colloidal Gold)	Not FDA Authorized	H
Zybio Inc. SARS-CoV-2 IgM/IgG Antibody Assay Kit (Colloidal Gold Method)	Not FDA Authorized	H

Showing 1 to 125 of 125 entries

[2] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.
- W - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests, and deemed to be CLIA waived for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance.1

General FAQs

Q: What is the difference between the types of tests available for SARS-CoV-2?

A: "Nucleic acid amplification tests," or "NAAT" tests are molecular tests that detect the virus's genetic material in a sample that typically comes from a patient's respiratory system. FDA-authorized NAAT tests for SARS-CoV-2 meet the EUA statutory standard, and based on the current available data, we believe are highly accurate. This means that a positive or a negative result from a NAAT test is likely to be true.

Another type of test, called a serology or antibody test, measures the amount of antibodies present in the blood when the body is responding to a specific infection, like COVID-19. This means the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19.

In response to an infection, such as COVID-19, the body develops an overall immune response to fight the infection. One component of the immune system's response is development of antibodies that attach to the virus and help eliminate it. The body's initial immune reaction produces general antibodies that attack many infections, called "IgM" antibodies. IgM antibodies indicate an active or recent infection. Because it takes time for the body to make IgM antibodies in response to SARS-CoV-2, their absence does not mean that someone is not infected. A test for IgM antibodies may give a false negative result in a patient with SARS-CoV-2, particularly early in infection. A patient may have a negative result early in infection even when they are symptomatic or asymptomatic but actively shedding the virus. Since IgM antibodies may not develop early or at all in infected patients, this type of antibody test is not used to rule out SARS-CoV-2 in an individual.

Over time, the body develops a second type of antibody in response to the infection that is more specific to the virus, called "IgG" antibodies. Most antibody tests detect IgG antibodies. On average, IgG antibodies take about 4 weeks to develop, but the time to development may vary substantially, and there is still a lot we do not know about SARS-COV-2. Since IgG antibodies generally do not develop until several weeks after infection, this type of antibody test, even though it is more specific to SARS-CoV-2, is not used to rule-out SARS-CoV-2 infection in an individual.

We also do not know how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after the infection has been cleared.

More information on serology tests for SARS-CoV-2 can be found in the Serology QA section of this FAQ page.

Q: When FDA authorizes under an EUA a SARS-CoV-2 test for use at the point of care, does that mean it is CLIA waived?

A: Yes. The settings in which an EUA-authorized test may be used are described in the Letter of Authorization. As discussed in the *Guidance for Industry and Other Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities* (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities), when the FDA authorizes point of care tests (including SARS-CoV-2 point of care test systems) under an EUA, such tests are deemed to be CLIA waived tests. Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver or Certificate of Compliance.

We note that the term point of care in the EUAs may include settings such as hospitals, physician offices, urgent care, outreach clinics, and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver or Certificate of Compliance. These terms generally do not apply to home specimen collection or at home testing unless otherwise specified.

Q: When tests are offered prior to or without an EUA under the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019, what is their CLIA categorization?

A: Tests being offered prior to or without an EUA under the policies outlined 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) that have not yet been reviewed by the FDA, are not FDA authorized, and have not received a CLIA categorization. While FDA has indicated that such tests may be appropriate for use in clinical laboratories and by healthcare workers at the point of care, the policies 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 provide a CLIA categorization and do not override any CLIA requirements. Therefore, in accordance with CLIA, tests offered under these policies are considered high complexity by default until or unless they are authorized and deemed to be appropriate, through an EUA authorization or general FDA review processes, to be performed as moderate or waived complexity tests.

Laboratories using tests being marketed under the FDA's EUA policy should be mindful of CLIA requirements which are enforced by CMS and certain State authorities, and CMS guidance for laboratories during the COVID-19 public health emergency. Under CMS guidance, if a facility has the appropriate CLIA certificates and follows applicable CLIA

regulations, state regulations and guidelines, the laboratory's CLIA certificate can be extended to cover testing in areas outside of the designated primary site or home base such as contiguous buildings, or any other designated temporary overflow location in its facility or temporary remote location, such as a parking lot.
https://www.cms.gov/files/document/qso-20-21-clia.pdf-0
(https://www.cms.gov/files/document/qso-20-21-clia.pdf-0)

Q: Can I offer my test for home use, including self-collection of a specimen, under the Policy for Diagnostic Tests for Coronavirus Disease-2019? (Updated 4/20)

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 a specimen at home. Any COVID-19 test for at-home testing, including self-collection of a specimen at home, with or without the use of telemedicine, requires an authorized EUA.

The FDA is supportive of at-home testing for COVID-19, provided there is data and science to support consumer safety and test accuracy. This includes demonstrating the ability of a lay user to collect their specimen, run the test, and interpret their results accurately. We also consider the safety of the consumer, including safety from any exposure to toxic chemicals that may be used in the reaction. FDA encourages developers to discuss their validation of home use tests with us early in their development process.

COVID-19 tests for home use (including home collection of a specimen) are not eligible to be added to the umbrella EUA for laboratory developed tests (LDTs). Instead, FDA would authorize individual EUAs for such tests when the criteria for authorization are met and would include any necessary conditions of authorization to address different risks presented by specimen collection at home versus collection in a health care setting, as well as testing and interpreting results by a lay consumer rather than a professional.

FDA encourages developers to discuss their validation of tests intended for at-home testing, including use and/or self-collection of a specimen at home, with us early in their development process.

Q: Can I offer my test for self-collection of a specimen at home and shipping to a laboratory for testing under the policies outlined in the Policy for Diagnostic Tests for Coronavirus Disease-2019? (Updated 4/20)

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, which includes self-collection of a specimen at home, with or without the use of telemedicine, that is then sent to a clinical laboratory. Any COVID-19 test for at-home self-collection of a specimen, with or without the use of telemedicine, requires an authorized EUA.

The FDA is supportive of at-home self-collection, provided there is data and science to support consumer safety and test accuracy. Home collection raises several issues of importance, including whether the lay user can safely and properly collect the specimen, whether the components of the specimen transport media are safe for use in the home environment (since some may be toxic), proper shipment, and adequate stability of the specimen given the time lapse between collection and testing and the potential impact of shipping conditions (such as, if the specimen sits in a hot truck). A physician watching the collection by way of telemedicine may address the issue of proper specimen collection (if the self-collection method does not raise safety concerns) but it does not address the other issues, and specimen stability and shipping conditions are still of concern. FDA encourages developers to discuss their validation of tests intended for self-collection of a specimen at home with us early in their development process.

COVID-19 tests for self-collection of a specimen at home are not eligible for authorization under the umbrella EUA for laboratory developed tests (LDTs). Instead, FDA would authorize individual EUAs for such tests when the criteria for authorization are met and would include any necessary conditions of authorization to address different risks presented by specimen collection at home versus collection in a health care setting.

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.

As noted in the guidance, in these cases, while FDA does not intend to object where no EUA request is submitted, 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 to modifications of other tests with an authorized EUA, and the laboratory agrees to FDA sharing that information on our website for use by other laboratories, FDA intends to update our FAQs so other laboratories can refer to the validation for their testing, without conducting their own bridging study for the same modification.

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. Laboratories bridging to another EUA-authorized assay must obtain a right of reference to leverage the performance data for that EUA-authorized assay.

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? (Updated 4/21)

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 absence of a specific product from

this list does not imply unacceptability of that product if it is of the correct 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.

The information provided is not an endorsement of any one product over another of the same type. We note that the information below is not intended to alter any already issued EUA for a COVID-19 diagnostic test nor is it intended to speak to any specific FDA regulatory requirement. Rather, as stated above, the information is being provided to help address availability concerns regarding certain critical components of COVID-19 diagnostic tests during this pandemic.

If you have validation data that you feel would be helpful for the community, 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 bridging a testing platform to a different anatomic sample collection site that has been validated and indicated as acceptable in this FAQ, like anterior nares, a lab may choose not to conduct a new clinical study. It is important that the swab be appropriate for the anatomic site on which it is used, and that the swab type (e.g. polyester vs rayon) is compatible with that platform. 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 or spun polyester swab).

Multiple specimens from the same patient 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.

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, saliva specimens, or other specimen types.

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 only permitted with tests authorized explicitly for use in these settings under the conditions of that authorization. All authorized tests can be found on the EUA page (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) and authorizations for self-collection at home are noted in the test's Letter of Authorization.

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 (see https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html)).

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. Some swabs may be acceptable for specimen collection at multiple locations and are therefore listed under each location.

Nasopharyngeal:

- Puritan: 25-3316-H, 25-3316-U, 25-3317-H, 25-3317-U, 25-3318-H, 25-3318-U, 25-3319-H, 25-3319-U, 25-3320-H, 25-3320-U, 25-3320-H EMB 80, 25-3320-U EMB 80, 25-3320-H EMB 100, 25-3320-U EMB 100, 25-1406 1PF 50f, 25-800 1PD 50, and 25-800 1PD ALUM 50
- Copan: 503CS01, 553C§, 518CS01, 518C§ ,501CS01, 551C§, 162C§, 160C^§, 168C^§, and 170KS01^

- BD: 220252 and 220251
- DHI/Quidel: 503CS01.DHI
- Fisher Healthcare: 23600952, 23600956, 2300961, 23500959^{t}, 2300963^{t}, 23600950, 1490623§, 1490622^§, 1490625^§, and 1490640^§
- Hardy/Healthlink: 518CS01, 501CS01,162Ct**, and 160CC^§

Oropharyngeal:

- Puritan: 25-1506 1PF SOLIDf, 25-1506 1PF 100f, 25-3206-H, 25-3206-U, 25-3706-H, 25-806 1PD and 25-806 1PD BT
- Copan: 502CS01, 552C§, 519CS01, 519C§, 164KS01, 175KS01, 159C§, 155C^§, 167KS01^, and 1U054S01, and 1C055S01
- BD: 220250 and 220115^§
- Fisher Healthcare: 23600957, 23600951, 23600960§, and 2300964§, 1490641, 1490650, and 1490619§
- Hardy/Healthlink: 519CS01, 502CS01, and 164KS01

Mid-Turbinate:

- Copan: 56380CS01, 56750CS01, 56780CS01
- Fisher Healthcare: 23600966

Anterior Nares:

Puritan: 25-3206-H, 25-3206-U, 25-3706-H, 25-1506 1PF 100 , 25-1506 1PF solid, 25-1506 1PF BT, 25-1506 1PF TT MC, 25-1506 2PF BT, 25-1406 1PF BT

- Copan: 502CS01, 552C^{t}, 519CS01, 519C^{t}, 164KS01, 175KS01, 159C§, 155C^§, 167KS01^, 1U054S01, and 1C055S01
- BD: 220144, 220145, 220250, and 220115^§
- DHI/Quidel: 20103
- Fisher Healthcare: 23600957, 23600951, 23600960§, and 2300964§, 1490641, 1490650, and 1490619§
- Hardy/Healthlink: 519CS01, 502CS01, and 164KS01
- US Cotton: Spun Polyester Swab

^ Spun rayon swab

§ Dry Tube Container

Rayon swabs may not be compatible with all molecular testing platforms. As noted above, analytical testing should be performed to confirm compatibility with individual platforms.

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 and R99
- BD: 220526, 220527, 220528*, 220529, 220531
- DHI/Quidel: 330C***
- Fisher Healthcare: 23001718, 23600952, 23600956, 23600950 and 23600957*
- PrimeStore MTM: LH-1-02 and LH-1-03***
    - This transport media **contains guanidine thiocyanate which produces a dangerous chemical reaction releasing cyanide gas when exposed to bleach** (sodium hypochlorite). For a full list of reagents in the PrimeStore MTM, see the FDA decision summary, DEN170029 (https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170029.pdf) . This media may not be compatible with in vitro diagnostic products which do not utilize guanidine thiocyanate during sample processing.
        - **WARNING: Do not use PrimeStore MTM** with the **Hologic Panther or Panther Fusion Systems** due to a disinfecting step involving bleach that is specific to the platform. When the bleach interacts with the guanidine thiocyanate in the transport media, it produces dangerous **cyanide gas**.

* flocked oropharyngeal 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.

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. 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

Other solutions may also be used for viral transport when universal transport media is not available. FDA recommends use of phosphate buffered saline (PBS), including molecular grade PBS when available, and other similar formulations including Delbecco's PBS, to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays. If PBS is not available, normal saline may be used. FDA believes that a sterile glass or plastic vial containing between 1mL and 3mL of PBS or normal saline is appropriate. Specimens can be stored up to 72 hours at 4°C. All the products listed below are examples of 1-3 mL of normal saline distributed in a vial without a swab.

- ThermoFisher: R064430, R064432, R064434, R064436 and R064438
- Hardy/Healthlink: D185, K248, R45 and R55
- Edge Biologicals: T-0625 and T-0110f

There is limited data available on test performance with specimens which have been frozen in any transport media; therefore, specimen stability should be investigated if freezing is necessary.

Q: What happens if I do not have the extraction platform referenced in the authorization of CDC's EUA-authorized test? (Updated 4/17)

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.
- **KingFisher Flex Nucleic Acid Extraction System**
  Kit: Omega Bio-Tek Mag-Bind Viral DNA/RNA 96 Kit
  Protocol: Please contact product_support@omegabiotek.com (mailto:product_support@omegabiotek.com) for instructions to upload the script and protocols for viral RNA extraction.
  Recommendation(s): Add 200 µL of patient sample and elute with 60 µL. Use 5 µL of eluant in a 20 µL final amplification reaction volume.
- **Applied Biosciences MagMAX™ Express-96 Magnetic Particle Processor**
  Kit: Applied Biosciences MagMAX™ Viral/Pathogen Ultra Nucleic Acid Isolation Kit
  Protocol: MVP_Ultra_MMe96
  Recommendation(s): Add 400 µL of sample and 50 µL of enzyme in a 96-well plate. Proceed with the extraction on the MagMAX Express-96 instrument. Elute with 100 µL TE buffer.

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

We believe the CDC's EUA-authorized test could also be performed on the following additional instruments based on independent validation studies that were conducted to demonstrate appropriate performance on these instruments:

- Applied Biosystems™ 7500 Fast Real-Time PCR Instrument with SDS software version 1.4
- Applied Biosystems™ QuantStudio™ 6 Flex Real-Time PCR System with version 1.1 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) 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).

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)
- 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)

- 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) 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)
- 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?

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.

Serology/Antibody Test FAQs

Q: Are antibody, or serology, tests used to diagnose SARS-CoV-2 infection? (Updated 4/17)

A: FDA is not aware of an antibody test that has been validated for diagnosis of COVID-19 infection. While FDA remains open to submissions of these tests for such uses, based on the underlying scientific principles of antibody tests, we do not expect that an antibody test can be shown to definitively diagnose or exclude COVID-19 infection.

As stated 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), validated antibody tests offered under the policy in that guidance should, among other things, include in test reports information that negative results do not rule out COVID-19 infection and that follow-up testing with a molecular diagnostic should be considered to rule out infection, and should be ordered only by clinicians who are familiar with the use and limitations of the test.

Q: If antibody tests are not used for diagnosis or exclusion of COVID-19 infection, what is their purpose? (Updated 4/17)

A: Serology tests that detect antibodies may detect different types of antibodies. The most common are IgM and IgG. A positive result from an appropriately validated serology test that detects IgM is likely to indicate that someone currently has or has recently had the virus. But a serology can yield a negative test result even in infected patients (e.g., if antibody has not yet developed in response to the virus) or may be falsely positive (e.g., if antibody to a coronavirus type other than the current pandemic novel strain is present). Thus, antibody tests by themselves are of limited value in the immediate diagnosis of a patient where COVID-19 infection is suspected. Using this type of test on many patients may help the medical community better understand how the immune response against the SARS-CoV-2 virus develops in patients over time and how many people may have been infected. While there is a lot of uncertainty with this new virus, it is also possible that, over time, broad use of antibody tests and clinical follow-up will provide the medical community with more information on whether or not and how long a person who has recovered from the virus is at lower risk of infection if they are exposed to the virus again.

Serology tests are of limited value in the immediate diagnosis or screening of a patient where COVID-19 infection is suspected because they cannot rule out presence of the virus. But positive results from appropriately validated serology tests that are designed to be very

specific to the SARS-CoV-2 virus can confirm either that a patient has (for IgM antibodies), or more likely has recovered from (for IgG antibodies) a COVID-19 infection. In addition, although not everyone who is infected will develop an antibody response, appropriately validated serology tests, when used broadly, can be useful in understanding how many people have been infected or exposed and how far the pandemic has progressed.

Serology tests can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who have been exposed to SARS-CoV-2 virus and have developed an immune response. In the future, this may potentially be used to help determine, together with other clinical data, whether these individuals may be less susceptible to infection. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

Q: Can I offer my SARS-CoV-2 antibody test kit in the United States without an EUA? (Updated 4/17)

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), during the COVID-19 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.

To help to ensure the above information is provided in the test report, as described in the guidance, commercial manufacturers could include this information in their Instructions for Use (IFU) or other labeling provided to laboratories.

As noted in the guidance, this policy does not apply to at home testing.

The commercial manufacturers and laboratories that 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) are listed on this FAQ page under What serology tests are being offered under the policy outlined in Section IV.D of the Policy for Diagnostic Tests for Coronavirus Disease-2019?.

In reviewing tests that are imported into the United States, the FDA will consider whether they have an EUA, as well as whether they fall within the recommendations 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)*.

Q: I am developing a SARS-CoV-2 antibody 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? (Updated 4/17)

A: If you are interested in pursuing an EUA, 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.

As noted above, if you intend to submit a notification and begin offering your validated test before FDA issues an EUA, please refer to Section IV.D of the Policy for Diagnostic Tests for Coronavirus Disease-2019.

Q: I am developing a SARS-CoV-2 antibody test kit and want to pursue an EUA. If my validation is complete, can I notify FDA and beginoffering my test for patient testing while I prepare and submit an EUA? (Updated 4/17)

A: Commercial manufacturers that develop a test kit and laboratories that are planning to test patient samples with validated tests for clinical use 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), which recommends, among other things, including information along the lines of the following statements in 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.

Q: I am developing a SARS-CoV-2 antibody test kit and want to pursue an EUA. Is there an EUA template for COVID-19 antibody tests? (Updated 4/17)

A. There is currently no template for COVID-19 antibody tests. However, if you choose to pursue an EUA for an antibody test, please see the currently available template for molecular assays (/media/135658/download) as a starting point for basic information (e.g., measurand, identifying information, Intended Use, etc.). As you will see, the template includes a table of contents, reports for the validation studies of your test (to support any claims made), and proposed instructions for use or laboratory SOP. 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.

Q: What are the current recommendations regarding minimum testing for demonstrating performance of a new SARS-CoV-2 antibody assay (Updated 4/17)?

A: Please refer to Section V.C. of the FDA guidance *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 SARS-CoV-2 antibody assays. As noted in the guidance, we encourage you to consult 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. As stated in the guidance, FDA recommends the following studies be performed for serology tests: cross-reactivity, class specificity, and clinical agreement. Depending on the characteristics of your test, such as what specimen types you are claiming, additional validation studies may be recommended in the guidance, e.g., matrix equivalency.

Q: I am offering a serology test for SARS-CoV-2 under the policy outlined in Section IV.D of the Policy for Diagnostic Tests for Coronavirus Disease-2019. Is there an opportunity to have my serology test independently validated by the FDA? (Updated 4/17)

A: All clinical tests should be validated prior to use, and our policy does not change that. Tests, including serology tests, being offered prior to or without an EUA under a policy outlined in the Policy for Diagnostic Tests for Coronavirus Disease-2019, have not been reviewed or authorized by the FDA. As stated in the guidance, all such tests should be validated by the developer prior to being offered for clinical use. The FDA has provided regulatory flexibility regarding the independent check by FDA for antibody tests that are limited in their clinical applications, but still expects all developers to validate their tests prior to offering them for limited clinical uses.

The FDA is working with the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Biomedical Advanced Research and Development Authority (BARDA) to assess the performance of serological tests offered under a policy outlined in the March 16th guidance. This project is intended to complement and inform FDA review as needed. As part of this project, the FDA, working with partnering agencies, has designed a performance assessment protocol that offers a mechanism for evaluation of lateral flow SARS-CoV-2 serological tests rapidly in a laboratory environment. Under this protocol, each test submitted to NIH will be evaluated with positive and negative plasma and serum samples. The approach represents a balanced attempt to provide a reasonable understanding of the potential performance of a significant number of the tests within a short time period. Performance results can be included by the test developer in an EUA submission.

If you are interested in participating in this validation project, please send an email to CDRH-OIR-POPS@fda.hhs.gov (mailto:CDRH-OIR-POPS@fda.hhs.gov). Include the following information in your email:

- Manufacturer and test name as provided in your notification to FDA,
- Volume of tests currently available to distribute in the United States,
- Weekly production volume available to distribute in the United States,
- Test technology,
- Sample type, and
- Pre-EUA (PEUA) or EUA number if you have been assigned one.

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).

Virtual Town Hall Meeting Materials

- March 25-April 29, 2020 - Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-04292020)
- March 6, 2020 - Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency - Immediately in Effect Guidance (/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing)
- March 2, 2020 - Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (/medical-devices/workshops-conferences-medical-devices/webinar-policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia)