In Vitro Diagnostics EUAs - Molecular Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

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- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
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Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available

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without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-home tests). To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for the EUA.

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#ivd)

Molecular SARS-CoV-2 Diagnostic Tests for COVID-19 that have been granted a De Novo, 510(k) clearance or PMA

- BioFire Respiratory Panel 2.1 (RP2.1) - On March 17, 2021, FDA granted the first marketing authorization using the De Novo review pathway for the BioFire Respiratory Panel 2.1 (RP2.1) (https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf) (PDF - 630 KB). The BioFire RP2.1 is for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. Also see the FDA news release: FDA Permits Marketing of First SARS-CoV-2 Diagnostic Test Using Traditional Premarket Review Process (/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process). With granting of the De Novo for the BioFire RP2.1, the FDA revoked the EUA for this device (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations), which was initially authorized for emergency use in May 2020.

  The BioFire Respiratory Panel 2.1 (RP2.1) was reviewed under the De Novo premarket review pathway (/medical-devices/premarket-submissions/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing criteria, called special controls, that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

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Authorized Molecular Diagnostic Tests for SARS-CoV-2 are assigned the QJR product code. Authorized Home Collection Kits are assigned the QLW product code. Authorized EUAs for Multi-analyte Respiratory Panel Tests are assigned the QLT product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 10/15/2021	Gravity Diagnostics, LLC	Gravity Diagnostics SARS-CoV-2 RT-PCR Assay (/media/143932/download) 11/23/2020	Real-time RT-PCR, Home Collection, Saliva, Screening	H	HCP (/media/143933/download), Patients (/media/143934/download), EUA Summary (/media/143935/download)
+ 10/15/2021	Gravity Diagnostics, LLC	Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits (/media/145977/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/media/145978/download), Individuals (/media/145979/download), EUA Summary (/media/145980/download)
+ 10/14/2021	LMSI, LLC (dba Lighthouse Lab Services)	CovidNow SARS-CoV-2 Assay (/media/153172/download) 10/14/2021	Real-time RT-PCR, Home Collection, Screening	H	HCP (/media/153173/download), Patients (/media/153174/download), IFU (/media/153175/download), IFU (Home Collect) (/media/153176/download)
+ 10/12/2021	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit (/media/136113/download) 03/13/2020	Real-time RT-PCR, Home Collection	H	HCP (/media/136111/download), Patients (/media/136114/download), IFU (/media/136112/download)
+ 10/12/2021	Thermo Fisher Scientific Inc.	Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit (/media/147535/download) 04/09/2021	Real-time RT-PCR	H	HCP (/media/147536/download), Patients (/media/147537/download), IFU (/media/147548/download)
+ 10/08/2021	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics Collection Kit for COVID-19 (/media/152974/download) 10/08/2021	Home Collection Kit	N/A	EUA Summary (/media/152972/download), IFU (/media/152973/download)

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 10/08/2021	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR (/media/136228/download) 03/17/2020	Real-time RT-PCR, Home Collection, Pooling	H	HCP (/media/136229/download), Patients (/media/136230/download), IFU (/media/136231/download)
+ 10/08/2021	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics PF SARS-CoV-2 Assay (/media/153004/download) 07/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/media/140227/download), Patients (/media/140228/download), EUA Summary (/media/140229/download)
+ 10/08/2021	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics RC SARS-CoV-2 Assay (/media/140231/download) 07/15/2020	Real-time RT-PCR, Home Collection, Pooling	H	HCP (/media/140232/download), Patients (/media/140233/download), EUA Summary (/media/153005/download)
+ 10/08/2021	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics HA SARS-CoV-2 Assay (/media/140236/download) 07/15/2020	TMA, chemiluminescent, Home Collection	H	HCP (/media/140237/download), Patients (/media/140238/download), EUA Summary (/media/140239/download)
+ 10/06/2021	PerkinElmer, Inc.	PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 (/media/152969/download) 10/06/2021	Real-time RT-PCR, Multi-analyte	H	HCP (/media/152994/download), Patients (/media/152971/download), IFU (/media/152968/download)
+ 09/30/2021	Laboratory Corporation of America (Labcorp)	Labcorp SARS-CoV-2 & Influenza A/B Assay (/media/152743/download) 9/30/2021	Real-time RT-PCR, Multi-analyte, Home Collection	H	HCP (/media/152741/download), Patients (/media/152745/download), EUA Summary (/media/152740/download), IFU (Home Collect) (/media/152742/download)
+ 09/29/2021	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	SelfCheck cobas SARS-CoV-2 Assay (/media/152959/download) 09/29/2021	Real-time RT-PCR, Home Collection	H	HCP (/media/152957/download), Patients (/media/152960/download), EUA Summary (/media/152956/download), IFU (Home Collect) (/media/152958/download)

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 09/22/2021	Southern California Permanente Medical Group	Kaiser Permanente High Throughput SARS-CoV-2 Assay (/media/147795/download) 04/19/2021	Real-Time RT-PCR, Saliva, Home Collection	H	HCP (/media/147796/download), Patients (/media/147797/download), EUA Summary (/media/147798/download), IFU (Home Collect) (/media/147799/download)
+ 09/22/2021	Life Sciences Testing Center	Life Sciences Testing Center COVID-19 Test (/media/152411/download) 09/22/2021	Real-time RT-PCR, Home Collection	H	HCP (/media/152412/download), Patients (/media/152413/download), EUA Summary (/media/152414/download), IFU (Home Collect) (/media/152415/download)
+ 09/16/2021	LetsGetChecked, Inc.	LetsGetChecked Coronavirus (COVID-19) Test (/media/138405/download) 05/28/2020	Direct to Consumer (DTC), TMA, chemiluminescent, Home Collection, Screening, Pooling	H	HCP (/media/138403/download), Individuals (/media/138404/download), EUA Summary (/media/138406/download), IFU (Home Collect) (/media/138407/download)
+ 09/15/2021	Color Health, Inc.	Color COVID-19 Self-Swab Collection Kit with Saline (/media/147609/download) 04/14/2021	Home Collection Kit, Screening	N/A	EUA Summary, (/media/147610/download) IFU (/media/147653/download)
+ 9/10/2021	Cepheid	Xpert Xpress CoV-2/Flu/RSV plus (/media/152165/download) 09/10/2021	Real-time RT-PCR, Multi-analyte	H, M, W	HCP (/media/152162/download), Patients (/media/152166/download), IFU for Labs (/media/152163/download), IFU for Point-of-Care (/media/152164/download)
+ 09/07/2021	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel DTC (/media/145981/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/media/145982/download), Individuals (/media/145983/download), EUA Summary (/media/145984/download), IFU (Home Collect) (/media/145985/download)
+ 09/3/2021	Color Health, Inc.	Color COVID-19 Self-Swab Collection Kit DTC (/media/146873/download) 03/19/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	EUA Summary (/media/146874/download), Individuals (/media/146875/download), IFU (/media/146876/download)

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 09/03/2021	Color Health, Inc.	Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC (/media/146877/download) 03/19/2021	Direct to Consumer (DTC), RT, LAMP, Home Collection, Screening	H	EUA Summary (/media/146878/download), Individuals (/media/146879/download), HCP (/media/146880/download)
+ 09/02/2021	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2 (/media/136046/download) 03/12/2020	Real-time RT-PCR, Pooling, Screening	H, M, H-Pooling	HCP (/media/136047/download), Patients (/media/136048/download), IFU (/media/136049/download)
+ 09/02/2021	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/media/138151/download) 05/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/media/138152/download), Patients (/media/138153/download), EUA Summary (/media/138154/download)
+ 09/01/2021	Thermo Fisher Scientific Inc.	TaqPath COVID-19 RNase P Combo Kit 2.0 (/media/150692/download) 07/08/2021	Real-time RT-PCR, Serial Screening, Home Collection	H	HCP (/media/150693/download), Patients (/media/150694/download), IFU (/media/150695/download)
+ 08/31/2021	Visby Medical, Inc.	Visby Medical COVID-19 (/media/142225/download) 09/16/2020	RT-PCR, Pooling	H, M	HCP (/media/142226/download), Patients (/media/142227/download), IFU (/media/142228/download)

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

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[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations:

- RT-PCR = reverse transcriptase polymerase chain reaction;
- RT = reverse transcriptase;
- LAMP = loop-mediated isothermal amplification;
- MALDI-TOF = Matrix Assisted Laser Desorption/Ionization - Time of Flight;
- TMA = Transcription Mediated Amplification;
- qSTAR = Selective Temperature Amplification Reaction;
- CRISPR = clustered regularly interspaced short palindromic repeats;

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and,

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when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/media/152406/download)

Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2

On April 20, 2021, the FDA issued an amendment allowing certain authorized molecular diagnostic SARS-CoV-2 tests to be distributed and used to pool anterior nasal respiratory specimens from asymptomatic individuals as part of a serial testing program after developers submit a complete notification, including meeting required validation data, as set forth in the letter. Use of tests for these indications is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, except that tests authorized for use in specific named or designated high complexity laboratories can only be used in such laboratories.

This means that tests with EUAs that are amended by this authorization may be used with pooled anterior nasal specimens from individuals without known or suspected COVID-19 when such individuals are tested as part of a testing program that includes testing at regular intervals, at least once per week. The indications in each appendix (A-H) differ in the number of specimens that can be pooled (up to 3, up to 5, or up to 10) and the type of pooling that can be done (media pooling or swab pooling).

Prior to a test being distributed or used for any new indication, the developer must submit a notification to the FDA with the information required by the amendment, including self-certifying that the applicable validation has been completed. Tests will be added to Exhibit 1 once FDA confirms that the required documentation has been submitted. Please note that being added to Exhibit 1 does not necessarily mean that the FDA has reviewed the underlying validation data submitted or confirmed that the test is appropriately validated.

- Amendment Letter (/media/147737/download)
- Appendix J - Sample Updated Fact Sheet for Health Care Providers (/media/147735/download)
- Appendix K - Sample Updated Fact Sheet for Patients (/media/147736/download)

Exhibit 1 of the Pooling and Serial Testing Amendment

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The table below includes information for the authorized RT-PCR molecular diagnostic tests for SARS-CoV-2 amended by this Pooling and Serial Testing Amendment. For authorization documents for each test, see Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 above.

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Date Added to Exhibit 1	EUA Holder	Test Name	Indication(s)*
06/24/2021	Clinical Enterprise, Inc.	Clinical Enterprise SARS-SoV-2-RT-PCR Assay	Swab: Up to 10 (Appendix C)
06/23/2021	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay	Swab: Up to 10 (Appendix C)
06/22/2021	Biomeme, Inc.	Biomeme SARS-CoV-2 Real-Time RT-PCR Test	Swab: Up to 10 (Appendix C) Media: Up to 5 (Appendix G)
06/15/2021	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3)	Swab: Up to 10 (Appendix C)

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* The indications in each appendix (A-H) differ in the number of specimens that can be pooled (up to 3, up to 5, or up to 10) and the type of pooling that can be done (media or swab pooling).

Tests authorized for Swab Pooling are authorized for:

- Qualitative detection of RNA from SARS-CoV-2 in pooled samples containing up to [3, 5, or 10, depending on the applicable appendix] individual human anterior nasal swabs placed in a single vial containing transport media after being collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week as part of a serial testing program.

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This indication is authorized for use in laboratories certified under CLIA to perform high complexity tests except tests authorized for use in specific named or designated laboratories can only be used in such laboratories.

Tests authorized for Media Pooling are authorized for:

- Qualitative detection of RNA from SARS-CoV-2 in pooled samples containing aliquots of transport media from up to [3, 5, or 10, depending on the applicable appendix] individual human anterior nasal swab specimens that were collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from any individual and placed in individual vials containing transport media, including individuals without symptoms or other reasons to suspect COVID-19, when tested as part of a serial testing program including testing at least once per week.

  This indication is authorized for use in laboratories certified under CLIA to perform high complexity tests except tests authorized for use in specific named or designated laboratories can only be used in such laboratories.

Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

On March 31, 2020, the FDA issued an umbrella EUA for molecular laboratory developed tests (LDTs) for detection of SARS-CoV-2 that meet certain criteria for eligibility described in the EUA. Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests. A manufacturer may request the addition of an eligible molecular-based LDT to Appendix A by submitting a request to CDRH-EUA-Templates@FDA.HHS.GOV (mailto:CDRH-EUA-Templates@FDA.HHS.GOV).

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/media/136598/download)
- Fact Sheet for Healthcare Providers (/media/136599/download)
- Fact Sheet for Patients (/media/136600/download)
- See Appendix A table below for a current list of included laboratories and their LTDs

The table below includes information for the high complexity molecular-based laboratory developed SARS-CoV-2 assays authorized by this Umbrella EUA (/media/136598/download) during the COVID-19 public health emergency.

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Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

To see additional authorization documents, such as letters granting EUA amendments or revisions, for a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

All authorized devices in the table below are assigned the QJR product code.

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Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 04/06/2021	Biocerna	SARS-CoV-2 Test (/media/137451/download) 04/28/2020	EUA Summary (/media/137450/download)
+ 02/03/2021	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/media/138933/download) 06/12/2020	EUA Summary (/media/138934/download)
+ 01/29/2021	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/media/138529/download) 06/01/2020	EUA Summary (/media/138528/download)
+ 01/28/2021	AIT Laboratories	SARS-CoV-2 Assay (/media/137373/download) 04/24/2020	EUA Summary (/media/137374/download)
+ 12/28/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/media/137424/download) 04/27/2020	EUA Summary (/media/137423/download)
+ 12/28/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/media/137654/download) 05/03/2020	EUA Summary (/media/137656/download)
+ 12/28/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/media/137896/download) 05/07/2020	EUA Summary (/media/137897/download)
+ 09/22/2020	Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test (/media/137256/download) 04/22/2020	EUA Summary (/media/137255/download)

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Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 09/21/2020	Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	COVID-19 RT-PCR Test (/media/136943/download) 04/13/2020	EUA Summary (/media/136944/download)
+ 09/21/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay (/media/136972/download) 04/14/2020	EUA Summary (/media/136971/download)
+ 09/21/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test (/media/137037/download) 04/15/2020	EUA Summary (/media/137036/download)
+ 09/21/2020	CirrusDx Laboratories	CirrusDx SARS-CoV-2 Assay (/media/137035/download) 04/15/2020	EUA Summary (/media/137034/download)
+ 09/14/2020	Columbia University Laboratory of Personalized Genomic Medicine	TRIPLEX CII-SARS-CoV-2 rRT-PCR TEST (/media/137982/download) 05/12/2020	EUA Summary (/media/137983/download)
+ 06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/media/138791/download) 06/10/2020	EUA Summary (/media/138790/download)
+ 06/04/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/media/137545/download) 04/30/2020	EUA Summary (/media/137546/download)
+ 06/04/2020	Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test (/media/136601/download) 03/31/2020	EUA Summary (/media/136602/download)
+ 06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/media/138624/download) 06/04/2020	EUA Summary (/media/138625/download)
+ 06/01/2020	Aspirus Reference Laboratory	Aspirus SARS-CoV rRT Assay (/media/138527/download) 06/01/2020	EUA Summary (/media/138526/download)
+ 05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/media/138331/download) 05/22/2020	EUA Summary (/media/138332/download)

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Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/media/138062/download) 05/13/2020	EUA Summary (/media/138063/download)
+ 05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	SARS-CoV-2-Assay (/media/138064/download) 05/13/2020	EUA Summary (/media/138065/download)
+ 04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/media/137371/download) 04/24/2020	EUA Summary (/media/137372/download)
+ 04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key (/media/137369/download) 04/23/2020	EUA Summary (/media/137370/download)
+ 04/13/2020	Integrity Laboratories	SARS-CoV-2 Assay (/media/136941/download) 04/13/2020	EUA Summary (/media/136942/download)
+ 04/10/2020	Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test (/media/136874/download) 04/10/2020	EUA Summary (/media/136873/download)
+ 04/10/2020	Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay (/media/136878/download) 04/10/2020	EUA Summary (/media/136877/download)
+ 04/03/2020	Massachusetts General Hospital	MGH COVID-19 qPCR assay (/media/136700/download) 04/03/2020	EUA Summary (/media/136699/download)
+ 04/02/2020	Diagnostic Molecular Laboratory - Northwestern Medicine	SARS-Cov-2 Assay (/media/136658/download) 04/02/2020	EUA Summary (/media/136669/download)
+ 04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test (/media/136657/download) 04/02/2020	EUA Summary (/media/136656/download)

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[1] The tests listed in this table are all molecular-based tests for COVID-19 and the authorized setting is for use in the identified laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

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