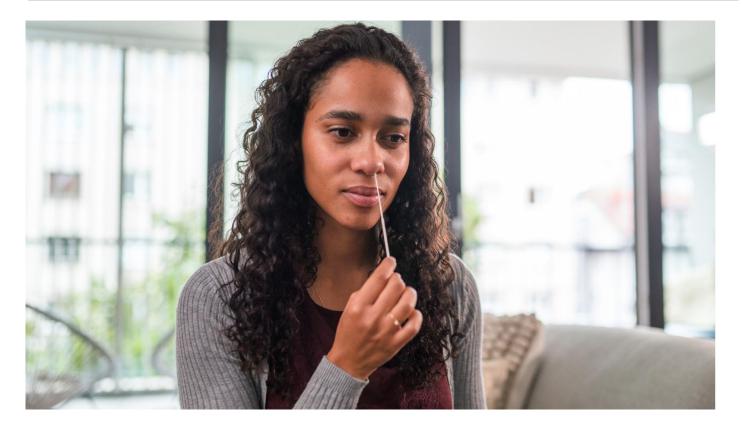
At-Home OTC COVID-19 Diagnostic Tests

Español (/medical-devices/coronavirus-covid-19-and-medical-devices/pruebas-de-covid-19-sin-receta-medica-o-de-venta-libre-para-diagnostico-en-el-hogar)



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- General Information About At-Home OTC COVID-19 Diagnostic Tests
- <u>List of Authorized At-Home OTC COVID-19 Diagnostic Tests</u>
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General Information About At-Home OTC COVID-19 Diagnostic Tests

This page has information about at-home over-the-counter (OTC) COVID-19 diagnostic tests. Diagnostic tests can show if you have an active COVID-19 infection.

These at-home OTC COVID-19 diagnostic tests are <u>FDA authorized (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)</u> for self-testing at home (or in other locations). This means you collect your own sample, perform the test, and read the result yourself without the need to send a sample to a laboratory.

There are two types of COVID-19 diagnostic tests, molecular and antigen, which detect different parts of the virus. Most authorized at-home OTC COVID-19 tests are antigen tests, and there are also a small number of authorized at-home OTC COVID-19 molecular tests.

When using a COVID-19 antigen diagnostic test, you should repeat testing following a negative result, whether you have symptoms or not, to reduce your risk of a false negative test result. For more information about this, read our <u>FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication)</u>.

For additional information on reading and understanding your test results, see <u>Understanding At-Home OTC</u> <u>COVID-19 Antigen Diagnostic Test Results</u> (/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results).

Authorized at-home OTC tests are available without a prescription and are typically available online or at local stores. Testing and other protective steps like wearing a mask and COVID-19 vaccination are important to stop the spread of COVID-19 infection.

For more information, including answers to frequently asked general questions about at-home COVID-19 diagnostic tests, visit <u>At-Home COVID-19 Diagnostic Tests</u>: <u>Frequently Asked Questions (/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions)</u>.

List of Authorized At-Home OTC COVID-19 Diagnostic Tests

The table below lists FDA-authorized at-home OTC COVID-19 diagnostic tests, and includes information on expiration dates, who can use the test, and other details that may help you decide what test is right for you. To see complete information on smaller screens, select the blue plus (+) button beside the test name.

The table includes links to home use instructions for each test. For more information about each test, including the Letter of Authorization and authorized labeling, see <u>In Vitro Diagnostics EUAs: Tables of IVD EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)</u>.

To see if the expiration date for your at-home OTC COVID-19 test has been extended, first find the row in the below table that matches the manufacturer and test name shown on the box label of your test.

- If the Expiration Date column says that the shelf-life is "extended," there is a link to "updated expiration dates" where you can find a list of the original expiration dates and the new expiration dates. Find the original expiration date on the box label of your test and then look for the new expiration date in the "updated expiration dates" table for your test.
- If the Expiration Date column **does not** say the shelf-life is extended, that means the expiration date on the box label of your test is still correct. The table will say "See box label" instead of having a link to updated expiration dates.

The FDA will update this table as additional shelf-life extensions are authorized.

To see complete information on smaller screens, select the blue plus (+) button beside the test name.

Search:	
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✓ entries Show 50

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age 🜲	Other Details 💠	Expiration Date
Abbott Diagnostics Scarborough, Inc.: BinaxNOW COVID-19 Ag Card Home Test (/media/144575/download) Abbott	 People with symptoms that began within the last 7 days People without symptoms. The test is to be performed two times over three days (serial testing) 	 Age 15 years and older Age 2 years and older when collected by an adult 	 Antigen test Nasal swab Requires supervision of a telehealth proctor and a smartphone or computer Results in 15 minutes 	 Shelf Life: 15 months (extended) Expiration Date: See link for list of updated expiration dates (/media/158002/download)
Abbott Diagnostics Scarborough, Inc.: BinaxNOW COVID-19 Antigen Self Test (/media/147255/download) (/media/160094/download)	 People with symptoms that began within the last 7 days People without symptoms. 	 Age 15 years and older Age 2 years and older when 	 Antigen test Nasal swab Smartphone optional Results in 15 minutes 	 Shelf Life: 22 months (extended) Expiration Date: See link for list of updated expiration dates (/media/158003/download)

- symptoms. The test is to be performed two times over three days (serial testing)
- when collected by an adult

Who can use Who can **Manufacturer and Test Name (Links to** use this this test: Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** Access Bio, Inc.: • People • Age 14 · Antigen test · Shelf Life: 15 months CareStart COVID-19 Antigen Home Test with years (extended) Nasal swab symptoms (/media/152188/download) and • Expiration Date: See link for · Smartphone that began older list of updated expiration optional COVID-19 within the Age 2 <u>dates</u> last 7 days Alternate years (/media/158734/download) brand name: (/media/160095/download) People and On/qo Alternate brand name: without older COVID-19 symptoms. when Antigen Self-The test is collected Test to be by an performed adult Results in 10 two times minutes over three (/media/160097/download) days (serial testing) ACON Laboratories, Inc: · Shelf Life: 21 months People • Age 14 · Antigen test Flowflex COVID-19 Antigen Home Test with years (extended) Nasal swab (/media/152699/download) symptoms and • Expiration Date: See link for Smartphone that began older **Flow**flex list of updated expiration optional within the Age 2 <u>dates</u> last 7 days Alternate years (/media/158005/download) ("/media/160099/download") brand name: People and Alternate brand name: On/Go One without older COVID-19 symptoms. when Antigen The test is collected on/go 🥽 Home Test to be by an performed adult · Results in 15 two times minutes over three (/media/160098/download) days (serial

testing)

Who can use Who can Manufacturer and Test Name (Links to this test: use this Instructions for Use) **Symptoms** test: Age **Other Details Expiration Date** Advin Biotech Inc.: Advin COVID-19 Antigen Test • Age 14 • Shelf Life: 12 months • People · Antigen test years @Home (/media/164171/download) with Nasal swab • Expiration Date: See box symptoms and label ADMN Home Use [1] Test · Results in 15that began older Advin COVID-19 Antigen Test @Home 30 minutes within the • Age 2 last 7 years days. The and test is to older be when performed collected two times by an over three adult days (serial testing). People without symptoms. The test is to be performed three times over five days

(serial testing).

Who can Who can use Manufacturer and Test Name (Links to this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** ANP Technologies, Inc.: • People • Age 14 · Antigen test • Shelf Life: 11 months NIDS COVID-19 Antigen Home Test with years Nasal swab · Expiration Date: See box (/media/163321/download) symptoms and label Results in 15that began older 30 minutes within the Age 2 last 7 years days. The and (/media/163324/download) test is to older be when performed collected two times by an over three adult days (serial testing). People without symptoms. The test is to be performed three times over five days (serial testing). • Shelf Life: 12 Months Aptitude Medical Systems Inc.: Metrix COVID-19 · People Age 14 Molecular Test with or years test · Expiration Date: See box (https://www.fda.gov/media/162404/download) without and Nasal swab label symptoms older Saliva Age 2 Requires a Metrix COVID-19 Test years Metrix and Reader (sold older separately) (/media/162438/download) when

collected

by an

adult

Smartphone

Results in 30 minutes

optional

Who can

Who can use

Manufacturer and Test Name (Links to this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** Azure Biotech Inc.: Fastep COVID-19 Antigen • People • Age 14 · Antigen test · Shelf Life: 24 months Home Test (/media/163448/download) with years Nasal swab · Expiration Date: See box symptoms and O FoStep (Fitter) label Results in 15that began older 30 minutes within the Age 2 COVID-19 Forsper below last 5 **Antigen Home Test** years days. The and (E) Communications (S) (as test is to older (/media/163451/download) when performed collected two times by an over three adult days (serial testing). · People without symptoms. The test is to be performed three times over five days (serial testing). Becton, Dickinson and Company (BD): · Shelf Life: 6 months · People Age 14 · Antigen test BD Veritor At-Home COVID-19 Test with years Nasal swab · Expiration Date: See box (/media/151763/download) and symptoms label Requires a that began older smartphone within the /ID-19 Test Age 2 last 7 days Results in 15 years (/media/160100/download) minutes People and without older symptoms. when The test is collected to be by an performed adult two times over three days (serial testing)

Manufacturer and Test Name (Links to Instructions for Use)

Who can use this test:
Symptoms

Who can use this test: Age

• Age 14

years

and

older

years

and

older

when

by an

adult

collected

Age 2

Other Details

Expiration Date

Beijing Hotgen Biotech Co., Ltd.: <u>Hotgen COVID-19 Antigen Home Test</u> <u>(/media/163439/download)</u>



(/media/163364/download)

• People with symptoms that began within the last 7 days. The test is to be performed two times over three days

(serial testing).

 People without symptoms. The test is to be performed three times over five days (serial testing).

- · Antigen test
- Nasal swab
- Results in 15-30 minutes
- · Shelf Life: 6 months
- Expiration Date: See box label

Celltrion USA, Inc.:

<u>Celltrion DiaTrust COVID-19 Ag Home Test</u> (/media/153421/download)



(/media/160101/download)

- People with symptoms that began within the last 7 days
- People
 without
 symptoms.
 The test is
 to be
 performed
 two times
 over three
 days
 (serial
 testing)
- Age 14 years and older
 - ge 14 Antigen test
 ears Mid-turbinate
 nasal swab
 - Smartphone optional
 - Results in 15 minutes
- Shelf Life: 18 months (extended)
- Expiration Date: <u>See link for updated expiration dates</u>
 (/media/159236/download)

Who can Who can use Manufacturer and Test Name (Links to this test: use this Instructions for Use) **Symptoms** test: Age **Other Details Expiration Date** CorDX, Inc.: CorDx COVID-19 Ag Test • Shelf Life: 15 months • People • Age 14 · Antigen test years (https://www.fda.gov/media/164118/download) with Nasal swab • Expiration Date: See box symptoms and label CorDx · Results in 10that began older COVID-19 te lest 30 minutes within the • Age 2 last 7 years days. The and test is to older be when performed collected (/media/163450/download) two times by an over three adult days (serial testing). People without symptoms. The test is to be performed three times over five days (serial

testing).

Who can Who can use Manufacturer and Test Name (Links to this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** CTK Biotech, Inc.: • People • Age 14 · Antigen test · Shelf Life: 12 months with ImmuView COVID-19 Antigen Home Test years Nasal swab · Expiration Date: See box (/media/164140/download) symptoms and label Results in 15that began older 30 minutes within the • Age 2 COVID-19 Home Test last 5 years days. The and test is to older be when performed collected two times by an over three adult days (serial testing). People without symptoms. The test is to be performed three times over five days (serial testing). Cue Health Inc.: · Shelf Life: 4 months · People Age 18 Molecular with or years test · Expiration Date: See box Counter (OTC) Use (/media/146471/download) without and Nasal swab label symptoms older Requires a

Cue COVID-19 Test for Home and Over The



(/media/160102/download)

- Age 2 years and older when collected by an adult
- Cue Cartridge Reader (sold separately)
- Requires a smartphone
- · Results in 20 minutes

Who can Who can use **Manufacturer and Test Name (Links to** this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** · Shelf-Life: 8 months Detect, Inc.: • People • Age 14 Molecular **Detect Covid-19 Test** suspected years test (extended) of COVID-(/media/153746/download) and Nasal swab • Expiration Date: See link for 19 older list of updated expiration Requires a · People • Age 2 <u>dates</u> Detect Hub without years (/media/158004/download) (sold symptoms. and separately) The test is older Smartphone to be when (/media/160103/download) optional performed collected two times by an Results in 60 over three adult minutes days (serial testing) Ellume Limited: People • Age 16 · Antigen test · Shelf Life: 12 months Ellume COVID-19 Home Test with years Mid-turbinate Expiration Date: See box (/media/144593/download) symptoms and nasal swab label that began older ellume Requires a within the Age 2 COVID-19 Smartphone last 7 days years Results in 15 People and minutes older without symptoms. when (/media/160104/download) The test is collected to be by an performed adult two times over three days (serial testing)

Who can Who can use **Manufacturer and Test Name (Links to** this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** Genabio Diagnostics Inc.: • People • Age 14 · Antigen test · Shelf Life: 18 months Genabio COVID-19 Rapid Self-Test Kit with years Nasal swab **Expiration Date: See box** (/media/159834/download) symptoms and label Results in 15that began older 30 minutes within the • Age 2 last 7 years (/media/160105/download) days. and People older without when symptoms. collected The test is by an to be adult performed two times over three days (serial testing) iHealth Labs, Inc.: People Age 15 · Antigen test · Shelf Life: 15 months (extended) iHealth COVID-19 Antigen Rapid Test with years · Nasal swab (/media/153924/download) symptoms and • Expiration Date: See link for • Smartphone that began older list of updated expiration optional within the Age 2 dates last 7 days Results in 15 years (/media/164551/download) (/media/160107/download) minutes People and Alternate brand name: without older Alternate symptoms. when brand name: COVID-19 The test is collected GoodToKnow to be by an COVID-19 (/media/160106/download) performed adult Antigen two times Rapid Test over three Alternate days brand name: (serial GoToKnow testing) COVID-19

Antigen Rapid Test

Who can use Who can Manufacturer and Test Name (Links to use this this test: Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** InBios International Inc: • People • Age 14 · Antigen test · Shelf Life: 13 months SCoV-2 Ag Detect Rapid Self-Test with years (extended) Nasal swab (/media/154337/download) symptoms and · Expiration Date: See link for Results in 20 that began older list of updated expiration minutes within the Age 2 <u>dates</u> last 5 days (/media/158008/download) years People and without older symptoms. when (/media/160108/download) The test is collected to be by an performed adult two times over three days (serial testing) Lucira Health, Inc: Molecular · Shelf Life: 18 months People Age 14 Lucira CHECK-IT COVID-19 Test Kit with or years test (extended) (/media/147495/download) without and Nasal swab • Expiration Date: See link for symptoms older list of updated expiration Smartphone LUCIRA CHECKET Age 2 <u>dates</u> 0-6-0 optional years (/media/161056/download) (/media/160109/download) Results in 30 and minutes older when collected by an adult Maxim Biomedical, Inc.: People Age 14 · Antigen test · Shelf Life: 12 months MaximBio ClearDetect COVID-19 Antigen Home with years (extended) Nasal swab Test (/media/155635/download) symptoms and Expiration Date: See link for Results in 15 that began older list of updated expiration minutes within the Age 2 dates COVID-19 last 5 days years (/media/160581/download) (/media/160110/download) People and without older when symptoms. The test is collected to be by an performed adult two times over three days (serial testing)

Who can Who can use **Manufacturer and Test Name (Links to** this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** Oceanit Foundry LLC: ASSURE-100 Rapid COVID-• People • Age 14 · Antigen test · Shelf Life: 12 months 19 (/media/164167/download) with years Nasal swab **Expiration Date: See box** symptoms and label that began older ASSURE-100 within the Age 2 last 7 years days. The and Results in 20test is to older 30 minutes when performed collected two times by an over three adult days (serial testing). · People without symptoms. The test is to be performed three times over five days (serial testing). OraSure Technologies, Inc.: • Shelf Life: 12 months · People Age 18 · Antigen test InteliSwab COVID-19 Rapid Test with years (extended) Nasal swab (/media/149912/download) symptoms and • Expiration Date: See link for Smartphone that began older list of updated expiration optional within the Age 2 dates last 7 days Results in 30 years (/media/161057/download) minutes People and without older symptoms. when (/media/160111/download) The test is collected to be by an performed adult

two times over three days (serial testing)

Who can use Who can **Manufacturer and Test Name (Links to** this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date** OSANG LLC: • People • Age 14 · Antigen test · Shelf Life: 12 months OHC COVID-19 Antigen Self Test with years (extended) Nasal swab (/media/157549/download) symptoms and • Expiration Date: See link for Alternate that began older OHC list of updated expiration brand name: within the Age 2 <u>dates</u> QuickFinder last 7 (/media/161358/download) years COVID-19 days. The and Antigen Self test is to older Test when (/media/161361/download) performed Results in 15 collected Alternate brand name: two times minutes by an OHC over three adult days (serial testing). People (/media/161362/download) without symptoms. The test is to be performed two times over three days (serial testing). • Shelf Life: 12 months PHASE Scientific International, Ltd.: · People Age 14 · Antigen test INDICAID COVID-19 Rapid Antigen At-Home Test with years Nasal swab · Expiration Date: See box (/media/156955/download) and symptoms label Results in 20 that began older INDICAID minutes within the Age 2 (/media/160113/download) last 6 days years People and without older symptoms. when The test is collected to be by an adult performed two times over three days (serial testing)

Who can use Who can **Manufacturer and Test Name (Links to** this test: use this Instructions for Use) **Symptoms** test: Age Other Details **Expiration Date Quidel Corporation:** • People • Age 14 · Antigen test · Shelf Life: 16 months QuickVue At-Home OTC COVID-19 Test with years Nasal swab (/media/147250/download) symptoms and Alternative that began older **Brand** within the Age 2 Names: CVS last 6 days years Health At (/media/162058/download) People and Home COVID-Alternative Brand Names: without older 19 Test Kit symptoms. when and The test is collected COVID-19 Walgreens to be by an At-Home performed adult COVID-19 two times Test Ket over three Results in 10 days minutes (serial testing) SD Biosensor, Inc.: · Antigen test · People • Age 14 Pilot COVID-19 At-Home Test with years Nasal swab $(/media/155126/download)^{1}$ symptoms and



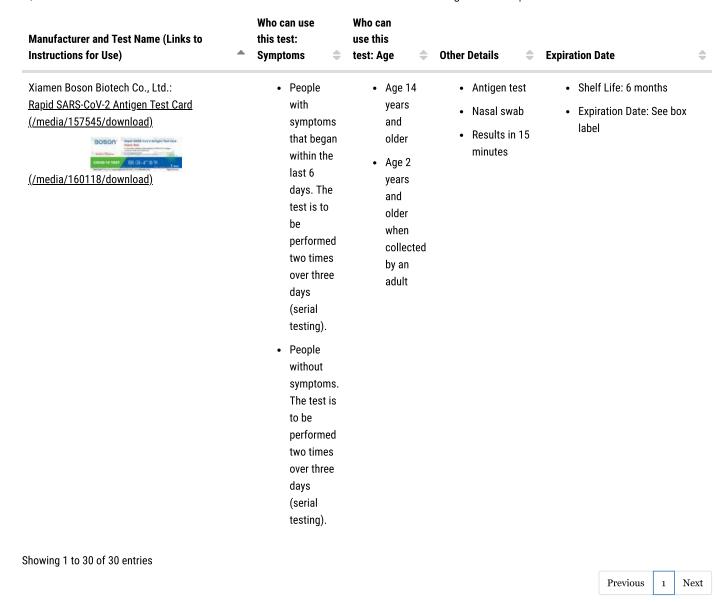
(/media/160115/download)

- that began within the last 6 days
- People without symptoms. The test is to be performed two times over three days (serial testing)
- older Age 2
 - years and older when collected by an adult
- Results in 20 minutes
- Telehealth Proctor Supervised (optional)

- (extended)
- · Expiration Date: See link for updated expiration date (/media/162056/download)

- · Shelf Life: 12 months (extended)
- Expiration Date: See link for updated expiration date (/media/159640/download)

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details 💠	Expiration Date \$
Siemens Healthineers: CLINITEST Rapid COVID-19 Antigen Self-Test (/media/155176/download) (/media/160116/download)	 People with symptoms that began within the last 7 days People without symptoms. The test is to be performed two times over three days (serial testing) 	 Age 14 years and older Age 2 years and older when collected by an adult 	 Antigen test Nasal swab Results in 15 minutes 	 Shelf Life: 24 months (extended) Expiration Date: See link for updated expiration date (/media/162503/download)
Watmind USA: Speedy Swab Rapid COVID-19 Antigen Self-Test (/media/159828/download). (/media/160117/download).	People with symptoms that began within the last 6 days. The test is to be performed two times over three days (serial testing) People without symptoms. The test is to be performed two times over three days (serial testing)	 Age 14 years and older Age 2 years and older when collected by an adult 	 Antigen test Nasal swab Results in 15 minutes 	Shelf Life: 6 months Expiration Date: See box label



Related Information:

- <u>Understanding At-Home OTC COVID-19 Antigen Diagnostic Test Results (/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results)</u>
- <u>At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions (/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions)</u>
- <u>COVID-19 Test Basics: (/consumers/consumer-updates/covid-19-test-basics)</u> Includes details on COVID-19 tests, types of samples, and other information.
- At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative: FDA Safety Communication (/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety)
- <u>Counterfeit At-Home OTC COVID-19 Diagnostic Tests (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/counterfeit-home-otc-covid-19-diagnostic-tests)</u>
- Find COVID-19 Tests at COVID.gov/tests (https://www.covid.gov/tests)
- Video: <u>How to Interpret Self-Test Results | CDC (https://www.youtube.com/watch?v=yoZL1BVP9Bs)</u> (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- <u>COVID-19 Testing: What You Need to Know | CDC (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html)</u>
- <u>COVID-19 Self-Testing At-Home or Anywhere | CDC (https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html)</u>
- What to Do If You Were Exposed to COVID-19 | CDC (https://www.cdc.gov/coronavirus/2019-ncov/your-health/if-you-were-exposed.html)
- <u>Isolation and Precautions for People with COVID-19 | CDC (https://www.cdc.gov/coronavirus/2019-ncov/yourhealth/isolation.html)</u>
- Video: What Is an EUA? (https://www.youtube.com/watch?app=desktop&v=iGkwaESsGBQ&feature=youtu.be)

 [A (http://www.fda.gov/about-fda/website-policies/website-disclaimer)]

 [A can issue an emergency use authorization (EUA) to provide more timely access to diagnostic tests that may help during the public health emergency when there is no adequate, approved, and available alternative.

^{1.} The Pilot COVID-19 At-Home Test, distributed by Roche Diagnostics, is previously known as the COVID-19 At-Home Test. As the manufacturer, SD Biosensor, transitions to this new brand, customers may receive a product with the previously authorized COVID-19 At-Home Test labeling.