

COVID-19 At-Home, Point-of-Care (POC) Tests -- as of November 10, 2021

Manufacturer	Test brand name	Date of original FDA EUA	Type of test	Rx or non-Rx test	What type of sample needs to be collected	Age range for test	Link to most recent FDA EUA letter	Test indication	Can test be mailed to person's home?	Additional information
iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test	11/5/2021	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	www.fda.gov/media/153925/download	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	yes	Lateral flow test. Visually read test result. Test result available in 15 minutes. Smartphone app is required for the test (app available for iPhones or Android). Two tests per package. For more info, see www.ihealthlabs.com . Test can be purchased online.
OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test	11/1/2021	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 15	www.fda.gov/media/149908/download	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	unknown	Lateral flow test. Visual read. Can download instructions using a smartphone device with QR code reader, but smartphone is not necessary to perform the test. Test result available in 30 minutes. Comes as a package with 2 tests. For more info, go to www.inteliswab.com .
Detect, Inc.	Detect Covid-19 Test	10/28/2021	single molecular test or serial molecular testing	non-Rx	anterior nasal swab	age ≥ 2	www.fda.gov/media/153663/download	Can use in individuals suspected of having COVID-19. Can also be used for serial screening for people without symptoms or other epidemiological reason(s) to suspect COVID-19.	uncertain, but appears to be yes	Is a Reverse Transcription Loop-mediated Isothermal Amplification (LAMP) test. Test result in one hour. Test result read visually from reader device. Smartphone with free downloadable "Detect App" is required to perform test. Two tests per package. For more info, see www.detect.com . 24/7 customer support available at 855-322-3692 or support@detect.com

Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test	10/21/2021	single antigen test or serial antigen tests	non-Rx	mid nasal turbinate swab	age ≥ 14	www.fda.gov/medwatch/2021/153418dwnload	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	unknown	Lateral flow test. Visual read. Smartphone needed to download app which provides instructions. Result read after 15 minutes. For more info see www.diastrustcovid.com . Kits comes in packages of 1 test, 2 tests, 5 tests, and 25 tests.
ACON Laboratories, Inc.	Flowflex COVID-19 Antigen Home Test	10/4/2021	single antigen test	non-Rx	anterior nasal swab	age ≥ 2	www.fda.gov/medwatch/2021/152700dwnload	within 7 days of symptom onset or without symptoms or other epi reasons to suspect COVID-19	unknown	Lateral flow test. Visual read, does not require a reader device or smartphone. Result read after 15 minutes. For more info see www.aconlabs.com . Customer service = 800-838-9502.
Becton Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test	8/24/2021	serial antigen testing	non-Rx	anterior nasal swab	age ≥ 2	www.fda.gov/medwatch/2021/151771dwnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	A lateral flow test. Requires smartphone, internet connection, and app to do test. Results available in 20 minutes. More test info available at www.bdveritorathome.com . More labeling info available at www.bd.com/e-labeling .
Access Bio, Inc.	CareStart COVID-19 Antigen Home Test	8/2/2021	serial antigen testing	non-Rx	anterior nares swab	age ≥ 2	www.fda.gov/medwatch/2021/151245dwnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results must be read between 10-15 minutes after test started. According to the package labeling, a smartphone is needed; however, the FDA EUA letter states a smartphone can be used, but is not required. For more information, see https://accessbiodiagnostics.net
OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx	6/4/2021	single antigen test	Rx	anterior nares swab	age ≥ 15	www.fda.gov/medwatch/2021/149904dwnload	within first 7 days of symptom onset	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results in 30 minutes. For more info, see www.inteliswab.com .
Lucira Health Inc.	Lucira CHECK-IT COVID-19 Test Kit	4/9/2021	single molecular test	non-Rx	anterior nasal turbinate swab	age ≥ 2	www.fda.gov/medwatch/2021/147492dwnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	yes	For more information about test or to order, see www.lucirahealth.com . Smartphone or smart device not needed for test. Result available between 11 and 30 minutes.

