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

This table lists FDA-authorized at-home OTC COVID-19 diagnostic tests. This 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 In Vitro Diagnostics EUAs: Tables of IVD EUAs.

Manufacturer and Test Name (Links to Instructions for Use)	Test Type	Who can use this test: Symptoms	Who can use this test: Age	Other Details
Abbott Diagnostics Scarborough, Inc.: <u>BinaxNOW COVID-19 Ag</u> <u>Card Home Test</u>	Antigen	 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 	 Nasal swab Requires supervision of a telehealth proctor and a smartphone or computer Results in 15 minutes
Abbott Diagnostics Scarborough, Inc.: <u>BinaxNOW COVID-19 Antigen</u> <u>Self Test</u>	Antigen	 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 	Nasal swabSmartphone optionalResults in 15 minutes
Access Bio, Inc.: CareStart COVID-19 Antigen Home Test	Antigen	 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 	 Nasal swab Smartphone optional Alternate brand name: On/go COVID-19 Antigen Self-Test Results in 10 minutes
ACON Laboratories, Inc: Flowflex COVID-19 Antigen Home Test	Antigen	 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 	 Nasal swab Smartphone optional Alternate brand name: On/Go One COVID-19 Antigen Home Test Results in 15 minutes
Becton, Dickinson and Company (BD): <u>BD Veritor At-Home COVID- 19 Test</u>	Antigen	 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 	Nasal swabRequires a smartphoneResults in 15 minutes
Celltrion USA, Inc.: Celltrion DiaTrust COVID-19 Ag Home Test	Antigen	 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	 Mid-turbinate nasal swab Smartphone optional Results in 15 minutes
Cue Health Inc.: Cue COVID-19 Test for Home and Over The Counter (OTC) Use	Molecular	• People with or without symptoms	 Age 18 years and older Age 2 years and older when collected by an adult 	 Nasal swab Requires a Cue Cartridge Reader (sold separately) Requires a smartphone Results in 20 minutes
Detect, Inc.: Detect Covid-19 Test	Molecular	 People suspected of COVID-19 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 	 Nasal swab Requires a Detect Hub (sold separately) Requires a smartphone Results in 60 minutes
Ellume Limited: Ellume COVID-19 Home Test	Antigen	• People with or without symptoms	 Age 16 years and older Age 2 years and older when collected by an adult 	 Mid-turbinate nasal swab Requires a Smartphone Results in 15 minutes
iHealth Labs, Inc.: <u>iHealth COVID-19 Antigen</u> Rapid Test	Antigen	• People with symptoms that began within the last 7 days	• Age 15 years and older	Nasal swabSmartphone optional

Manufacturer and Test Name (Links to Instructions for Use)	Test Type	Who can use this test: Symptoms	Who can use this test: Age	Other Details
		• People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 2 years and older when collected by an adult	• Results in 15 minutes
nBios International Inc: SCoV-2 Ag Detect Rapid Self- fest	Antigen	 People with symptoms that began within the last 5 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 	Nasal swabResults in 20 minutes
Lucira Health, Inc: Lucira CHECK-IT COVID-19 Fest Kit	Molecular	• People with or without symptoms	 Age 14 years and older Age 2 years and older when collected by an adult 	Nasal swabSmartphone optionalResults in 30 minutes
Maxim Biomedical, Inc.: MaximBio ClearDetect COVID- 19 Antigen Home Test	Antigen	 People with symptoms that began within the last 5 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 	Nasal swabResults in 15 minutes
DraSure Technologies, Inc.: nteliSwab COVID-19 Rapid Fest	Antigen	 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 18 years and older Age 2 years and older when collected by an adult 	Nasal swabSmartphone optionalResults in 30 minutes
Quidel Corporation: QuickVue At-Home OTC COVID-19 Test	Antigen	 People with symptoms that began within the last 6 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 	Nasal swabResults in 10 minutes
SD Biosensor, Inc.: COVID-19 At-Home Test	Antigen	 People with symptoms that began within the last 6 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 	Nasal swabResults in 20 minutes
Siemens Healthineer: CLINITEST Rapid COVID-19 Antigen Self-Test	Antigen	 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 	Nasal swabResults in 15 minutes