

Food and Drug Association (FDA) and Emergency Use Authorization (EUA) Approved COVID-19 Tests

COVID-19 Tests that have received EUA from the FDA

In the table below, X indicates “yes” as an approved COVID-19 test from the FDA.

Antigen Tests²	Symptomatic Use	Asymptomatic Use³	Over the Counter Tests	Prescription At-Home Tests
Ellume COVID-19 Home Test	X	X	X	
BinaxW COVID-19 Ag Card 2 Home Test	X		X	
QuickVue At-Home OTC COVID-19 Test	X		X	
BinaxW COVID-19 Antigen Self Test	X		X	
InteliSwab COVID-19 Rapid Test	X		X	
CareStart COVID-19 Antigen Home Test	X		X	
InteliSwab COVID-19 Rapid Test Rx	X			X
BinaxW COVID-19 Ag Card Home Test	X			X
QuickVue At-Home COVID-19 Test	X			X
InteliSwab COVID-19 Rapid Test Pro	X			
BinaxW COVID-19 Ag Card	X			
BinaxW COVID-19 Ag 2 Card	X			
CareStart COVID-19 Antigen	X			
BD Veritor System for Rapid Detection of SARS-CoV-2	X			
BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A&B	X			
Sampinute COVID-19 Antigen MIA	X			
LIAISON SARS-CoV-2 Ag	X			

Antigen Tests ²	Symptomatic Use	Asymptomatic Use ³	Over the Counter Tests	Prescription At-Home Tests
ellume.lab COVID	X	X	X	
GenBody COVID-19 Ag	X			
SCoV-2 Ag Detect Rapid Test	X			
CLIP COVID Rapid Antigen Test	X			
LumiraDX SARS-CoV-2 Ag Test	X			
VITROS Immudiagstic Products	X			
INDICAID COVID-19 Rapid Antigen Test	X			
Status COVID-10/Flu	X			
QIArearch SARS-CoV-2 Antigen	X			
Omnia SARS-CoV-2 Antigen Test	X			
Simoa SARS-CoV-2 N Protein Antigen Test	X			
Sofia SARS Antigen FIA	X			
Sofia 2 Flu + SARS Antigen FIA	X			
QuickVue SARS Antigen Test	X			
Sienna-Clarify COVID-19 Antigen Test Rapid Test Cassette	X			

Antigen Tests ²	Symptomatic Use	Asymptomatic Use ³	Over the Counter Tests	Prescription At-Home Tests
Molecular Tests¹				
Any PCR Test given by provider or sent to a commercial laboratory ²	X	X		
Lucira CHECK-IT COVID-19 Test Kit	X	X	X	
Molecular Tests³				
Cue COVID-19 Test for Home and Over the Counter (OTC) Use	X	X	X	
Lucira COVID-19 All-In-One Test Kit	X	X		X
Everly COVID-19 Test Home Collection Kit Direct to Consumer	X	X		X
Kroger Health COVID-19 Test Home Collection Kit	X	X		X
Color COVID-19 Self-Swab Collection Kit	X	X		X
EmpowerDX COVID-19 Home Collection Kit Direct to Consumer	X	X		X
binx health At-Home Nasal Swab Collection Kit	X	X		X
GetMyDNA COVID-19 Test Home Collection Kit	X	X		X
Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC	X	X		X
WREN Laboratories COVID-19 Saliva Test Collection Kit DTC	X	X		X

¹ <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sarscov-2>

² Includes "Direct to Consumer" and "Home Collection" tests, as these tests are sent to a commercial laboratory.

³ <https://www.flgov.com/wp-content/uploads/2021/08/8.6.21-DOH-Rule.pdf>