

Florida Department of Health Emergency Rule 64DER21-12 provides opportunities for public school students to reduce quarantine or isolation if they are asymptomatic and receive a negative diagnostic test for COVID-19.<sup>1</sup> If a public school student is using one of the opportunities, as described in Emergency Rule 64DER21-12, to obtain a diagnostic COVID-19 test result to shorten their isolation or quarantine period, the COVID-19 diagnostic test should have received Emergency Use Authorization (EUA) from, or full approval by, the Food and Drug Administration (FDA) and the COVID-19 test should be used in the same manner specified by FDA's authorization or approval. The table below lists current COVID-19 diagnostic tests that have received an EUA by the FDA and how they can (i.e., over the counter or at-home) and should (i.e., symptomatic and/or asymptomatic) be used.

<b>COVID-19 Tests that have received EUA from the FDA</b>				
<b>Antigen Tests<sup>2</sup></b>	<b>Symptomatic Use</b>	<b>Asymptomatic Use<sup>3</sup></b>	<b>Over the Counter Tests</b>	<b>Prescription At-Home Tests</b>
Ellume COVID-19 Home Test	X	X	X	
BinaxNOW COVID-19 Ag Card 2 Home Test	X		X	
QuickVue At-Home OTC COVID-19 Test	X		X	
BinaxNOW 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
BinaxNOW COVID-19 Ag Card Home Test	X			X
QuickVue At-Home COVID-19 Test	X			X
InteliSwab COVID-19 Rapid Test Pro	X			
BinaxNOW COVID-19 Ag Card	X			
BinaxNOW 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			

<sup>1</sup> <https://www.flgov.com/wp-content/uploads/2021/08/8.6.21-DOH-Rule.pdf>

<sup>2</sup> <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>

<sup>3</sup> These tests have been approved for "Screening" and can be used for asymptomatic testing; this is not to be confused with "Serial Screening."

ellume.lab COVID Antigen Test	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 Immunodiagnostic Products	X			
INDICAID COVID-19 Rapid Antigen Test	X			
Status COVID-10/Flu	X			
QIAreach 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			
<b>Molecular Tests<sup>4</sup></b>				
Any PCR Test given by provider or sent to a commercial laboratory <sup>5</sup>	X	X		
Lucira CHECK-IT COVID-19 Test Kit	X	X	X	
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

<sup>4</sup> <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2>

<sup>5</sup> Includes “Direct to Consumer” and “Home Collection” tests, as these tests are sent to a commercial laboratory.

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