HOME-BASED TESTING AVAILABILITY



Updated on December 2, 2021

As of December 2, 2021, hundreds of COVID-19 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). The FDA has granted EUAs to an increasing number of <u>home-based sample</u> <u>collection devices</u> including 89 molecular tests (4 with self-testing capabilities; 1 prescription and 3 OTC) and 14 antigen tests (all with self-testing capabilities; 3 prescription and 11 OTC).

While widespread use of all home-based tests has the potential to increase COVID-19 testing in the U.S., this document will detail the EUA-approved self-tests/at-home tests. Self-testing, which encompasses the entire testing process and not just sample collection, delivers results within a short time window (key to stopping spread) and eliminates many equity and access concerns (including the need for an internet connection and access to shipping drop-off locations). While no test works flawlessly and tests should not be a substitute for vaccination, if used frequently, at-home tests can offer an additional—if temporary—layer of protection. Self-tests/at-home tests will also become more widely available in the coming months, with the Biden administration investing \$1B+ to quadruple their availability by late 2021 and substantially reduce their costs, enabling people to more easily access these tests.

Note that the table below includes only self-tests. Consult the <u>FDA</u> for real-time information on their EUAs for other COVID-19 tests.

Brand	EUA Issued/ Updated	Diagnostic Test Name	Test Type	OTC or Prescription
Access Bio, Inc.	12/1/21	CareStart COVID-19 Antigen Home Test	Antigen	отс
Becton, Dickinson and Company (BD)	11/23/21	BD Veritor At-Home COVID-19 Test	Antigen	отс
InBios International Inc.	11/22/21	SCoV-2 Ag Detect Rapid Self-Test	Antigen	отс
Abbott Diagnostics Scarborough, Inc.	11/8/21	BinaxNOW COVID-19 Antigen Self-Test	Antigen	отс
iHealth Labs, Inc.	11/5/21	iHealth COVID-19 Antigen Rapid Test	Antigen	отс
OraSure Technologies, Inc.	11/01/21	InteliSwab COVID-19 Rapid Test	Antigen	отс
Detect, Inc.	10/28/21	Detect Covid-19 Test	Molecular Diagnostic	отс
Celltrion USA, Inc.	10/21/21	Celltrion DiaTrust COVID-19 Ag Home Test	Antigen	отс
ACON Laboratories, Inc.	10/19/21	Flowflex COVID-19 Antigen Home Test	Antigen	отс
Quidel Corporation	10/12/21	QuickVue At-Home OTC COVID-19 Test	Antigen	отс
OraSure Technologies, Inc.	6/4/21	InteliSwab COVID-19 Rapid Test Rx	Antigen	Prescription
Abbot Diagnostics Scarborough, Inc.	4/12/21	BinaxNOW COVID-19 Ag Card Home Test	Antigen	Prescription
Lucira Health, Inc.	4/9/21	Lucira CHECK-IT COVID-19 Test Kit	Molecular Diagnostic	отс
Abbot Diagnostics Scarborough, Inc.	3/31/21	BinaxNOW COVID-19 Ag Card 2 Home Test	Antigen	отс
Cue Health, Inc.	3/5/21	Cue COVID-19 Test for Home and OTC Use	Molecular Diagnostic	отс
Quidel Corporation	3/1/21	QuickVue At-Home COVID-19 Test	Antigen	Prescription
Ellume Limited	2/11/21	Ellume COVID-19 Home Test	Antigen	отс
Lucira Health, Inc.	11/18/20	Lucira COVID-19 All-In-One Test Kit	Molecular Diagnostic	Prescription

The ideas presented in this document reflect the latest public health thinking and scientific evidence as of December 2021. You are advised that the COVID-19 vaccine landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-todate information available. Partners In Health does not provide medical advice, diagnosis or treatment in the United States. Always seek the advice of a physician or other qualified health care provider with any questions regarding a medical condition. The information, including but not limited to, text, graphics, images and other material contained in this document, are intended for informational purposes only.