



Information Sheet for Over-the-Counter Test Kits for SARS-COV-2 (the virus that causes COVID-19)

Over the counter COVID-19 tests (also known as self-tests) allow individuals to conveniently learn their COVID-19 status at a time and place of their choosing. Self-tests can help people discriminate between cold symptoms or allergies and COVID-19. Convenient testing with rapid results may allow infected individuals with COVID-19 to learn their status earlier, leading to earlier isolation and limiting the spread of COVID-19. Using self-tests prior to a large gathering can make gatherings safer.

Testing is one layer in a multi-layered approach to preventing the spread of COVID-19.

What are COVID-19 over-the-counter self-tests?

Over-the-counter self-tests refer to tests that are purchased without a prescription and specimens that are collected and completely processed by an individual anywhere outside of a healthcare or lab setting without the supervision of a trained professional. This is different than **home collection kits** in which specimens are collected at home, but then are sent to a laboratory for processing. Self-tests may use a nasal or a saliva specimen and can either be a molecular or an antigen-based test. Users should refer to the [CDPH Updated Testing Guidance](#) for more information about the different test types and their uses.

All individuals still need to adhere to public health measures per local and state health department recommendations, regardless of the result of one's at self-test result, as it is possible to test negative early in the infectious course. If a self-test is negative and the individual is asymptomatic, they are unlikely to be infectious only for the day they tested negative. An individual could test positive on the following day. The individual should follow manufacturer's instructions for repeat testing when applicable.

Antigen and Molecular – Over-the-Counter Self-Tests

- Antigen tests identify the nucleocapsid protein in the SARS-COV-2 virus.
- Molecular tests detect a specific genetic segment of the SARS-COV-2 virus.
- Both antigen tests and molecular tests may have a slightly lower sensitivity (might not detect all infections) but similar specificity (those who are not infected with SARS-COV-2 do reliably test negative) compared to the gold standard molecular RT-PCR tests.
- See FDA's list of [In Vitro Diagnostics Emergency Use Authorizations](#) for more information about the performance of specific authorized tests.
- Guidance on the use of COVID-19 tests is found in the [CDPH updated test guidance](#).



Performance of Approved Over the Counter COVID-19 Self-Test Kits

Company	Lucira	Cue	Ellume	Abbott	Becton, Dickinson and Company
Device	Lucira Check-It COVID-19 Test Kit	Cue COVID-19 Test for Home and OTC Use	Ellume COVID-19 Home Test	BinaxNOW COVID-19 Aq Card Self-Test	BD Veritor At-Home COVID-19 Test
Methodology	Molecular	Molecular	Antigen	Antigen	Antigen
Time for result	30 minutes	20 minutes	15 minutes	15 minutes	15 minutes
Approximate Cost	\$89	\$55	\$35	\$25 (2 tests)	\$40 (2 tests)
Specimen	Anterior nasal	Anterior nasal	mid-turbinate	Anterior nasal	Anterior nasal
Eligible Ages	2-13 years of age, when supervised by an adult, ≥14 years of age can self collect	2-17 years of age, when supervised by an adult, ≥18 years of age can self-collect	2-15 years of age, when supervised by an adult, ≥16 years of age can self-collect	2-14 years of age, when supervised by an adult, ≥15 years of age can self-collect	2-13 years of age, when supervised by an adult, ≥14 years of age can self-collect
Availability	Available	Unavailable as of 12/23/21	Recalled as of 12/23/21	Available	Available
Electronic Reporting	LUCI (lucirahealth.com)	Cue Health App	Ellume COVID-19 Home Test application	Navica App	Scanwell Health App
Intended Use per EUA	Symptomatic and asymptomatic	Symptomatic and asymptomatic	Symptomatic and asymptomatic	With or without symptoms, Serial testing test twice over two or three days with at least 24 hours and not more	Within 7 days of symptom onset, or with or without symptoms serial testing test twice over two or three days with at least 24 hours



				than 48 hours between tests	and not more than 48 hours between tests
Collection	self-collection	self-collection	self-collection	self-collection	self-collection
Positive Predictive Agreement (sensitivity)	92%	97.4%	91%	77.2% (serial testing) 84.6% (within 7 days of symptom onset)	84.6%
Negative Predictive Agreement (specificity)	98%	99.1%	96%	98.5%	99.8%
Limit of Detection	2.7*10 ³ copies per swab	20 genome copies/swab	1.0*10 ² TCID50/mL	1.4*10 ² TCID50/mL	2.8 x 10 ⁵ TCID50/mL

Performance of Approved Over-the-Counter COVID-19 Self-Test Kits (continued)

Company	Access Bio Carestart	Quidel	OraSure Technologies	Acon Laboratories Inc.	iHealth Labs, Inc.	Celltrion	InBios
Device	CareStart COVID-19 Antigen Home Test	QuickVue At-Home OTC COVID-19 Test	Inteliswab COVID-19 Rapid Test	Flowflex antigen Home Test	iHealth COVID-19 Antigen Rapid Test	Celltrion Diatrust COVID-19 Ag Home Test	SCoV-2 Ag Detect
Methodology	Antigen	Antigen	Antigen	Antigen	Antigen	Antigen	Antigen
Time for result	10 minutes	10 minutes	30 minutes	15 minutes	15 minutes	15 minutes	20 minutes
Approximate Cost	\$8 per test	\$24 (2 tests)	\$24 (2 tests)	<\$10	\$7 per test	Unknown	Unknown



Specimen	Anterior nasal	Anterior nasal	Anterior nasal	Anterior nasal	Anterior nasal	Anterior nasal	Anterior nasal
Eligible Ages	2-13 years of age, when supervised by an adult, ≥14 years of age can self-collect	2-13 years of age, when supervised by an adult, ≥14 years of age can self-collect	15-17 years of age, when supervised by an adult, ≥18 years of age can self-collect	2-13 years of age, when supervised by an adult, ≥14 years of age can self-collect	2-14 years of age, when supervised by an adult, ≥15 years of age can self-collect	≥14 years of age can self-collect	2-13 years of age, when supervised by an adult, ≥14 years of age can self-collect
Availability	Available	Available	Available	Not available to purchase as of 12/23/21	Available	Not available as of 12/23/21	Not available as of 12/23/21
Electronic Reporting	Not available	Not available	Not available	Not available	Not available	Not available	Not available
Intended Use per EUA	With or without symptoms, Serial testing test twice over two or three days with at least 24 hours and not more than 48 hours between tests	With or without symptoms, Serial testing test twice over two or three days with at least 24 hours and not more than 48 hours between tests	With or without symptoms, Serial testing test twice over two or three days with at least 24 hours and not more than 48 hours between tests	Symptomatic or asymptomatic individuals	Within 7 days of symptom onset, or with or without symptoms serial testing test twice over two or three days with at least 24 hours and not more than 48 hours between tests	Within 7 days of symptom onset, or with or without symptoms serial testing test twice over two or three days with at least 24 hours and not more than 48 hours between tests	Within 7 days of symptom onset, or with or without symptoms serial testing test twice over two or three days with at least 24 hours and not more than 48 hours between tests
Collection	self-collection	self-collection	self-collection	self-collection	self-collection	self-collection	self-collection
Positive Predictive	87% (within 5 days of	83.5% (within 6	84% (within 7 days of	92%	94.3%	86.1%	85.7%



Agreement (sensitivity)	symptom onset)	days of symptom onset)	symptom onset)				
Negative Predictive Agreement (specificity)	98%	99.2%	98%	100%	98.1%	99.8%	100%
Limit of Detection	2.8×10^3 TCID50/ml.	1.91×10^4 TCID50 per mL	2.5×10^2 TCID50/mL	2.5×10^3 TCID50/mL	2.0×10^4 TCID50/mL	3.2×10^1 TCID50/mL	6.3×10^3 TCID50/mL