Updated: 09/20/2022

Rapid Over-the-Counter COVID-19 Self-Test Kits

Administered at home with results in 10-15 minutes

Frequently Asked Questions	Abbott BinaxNOW COVID-19 Antigen Self Test	Ellume COVID-19 Home Test Kit	QuickVue At-Home OTC COVID-19 Test	FlowFlex COVID-19 Antigen Home Test	Pixel PCR Test Home Collection Kit
Is the test FDA Approved for Emergency Use Authorization (EUA)?	Yes, it was approved on August 26, 2020. The test is approved for people suspected of COVID-19 within the first seven days of symptom onset.	Yes, it was approved on December 15, 2020. The test is approved for those with or without symptoms. Individuals must self-collect samples, or should be collected by an individual 2 years or older.	Yes, it was approved on March 31st, 2021. The test is approved for those with or without symptoms. Individuals must self-collect nasal swab specimens or samples must be collected by an adult for individuals 2 years or older.	The FDA issued an EUA for on October 4 th , 2021 for the use of FlowFlex COVID-19 Antigen Home Test in the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from people suspected of COVID-19 within the first 7 days of symptom onset.	The FDA issued an EUA for on May 11 th , 2021 for the use of Pixel by Labcorp COVID-19 Test Home Collection Kit in the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from people suspected of COVID-19 within the first 6 days of symptom onset.
How much does this test cost?	\$23.99 for 2 tests	\$38.99	\$23.99-\$29.95 per kit (2 tests/kit) or 45 kits (90 tests) for \$1122.75	\$9.99 per test	\$124.99 per test
Where can I purchase it?	CVS Pharmacy, Walgreens, Walmart, and Optum	Target, Rite Aid, Kroger, and Walmart	Walgreens, Walmart, Amazon, and Optum	CVS Pharmacy and Walgreens	CVS Pharmacy and Walgreens
How is it used?	Only a minimally invasive nasal self-swab is needed (not the deep nasopharyngeal swab),	Patients download and open the Ellume COVID-19 home test to follow the step-by- step instructions for	The test includes a instruction manual detailing how to collect the sample, administer	The user inserts a nasal swab 2.5 cm/1 in inside the nostril and rotates the swab 5 times to	Remove the nasal swab from the container and insert it into both nostrils rotating it a few times in

	and all materials required to perform the test (swab, test card, and reagent solution) will come in the boxed package.	collecting a sample and obtaining results. The kit includes a sterile nasal swab, a dropper, processing fluid, and a Bluetooth connected analyzer that automatically links up with the user's phone to display results.	the test, and interpret test results. In addition, the kit includes, a nasal swab, tubes prefilled with the reagent, a tube holder, and test strips. The test is meant to be used twice over 2-3 days with at least 24 hours and no more than 36 hours between tests.	collect a sample. The swab is then placed into the tube and is swirled for 30 seconds. Squeeze the tube and rotate it 5 times. Swirl and flick the tube. Then squeeze 4 drops onto the assay.	each nostril. Insert it into the tube. Send a tube to the collection lab.
How long does it take to display results?	15 minutes	15 minutes	10 minutes	15-30 minutes	1-2 days after shipping
How reliable is this test?	This new rapid test has shown a high sensitivity of 97.1% and specificity of 98.5% in clinical studies according to Abbott.	This rapid test has shown a high accuracy of 96% with symptoms of illness and 91% accuracy for those without symptoms. The specificity is 97% accurate with symptoms of illness.	This rapid test has shown a high sensitivity of 99.1% with symptoms of illness. The accuracy for detection of positive specimens is 83% and 99% of negative specimens.	This new rapid test has shown a high sensitivity of 93% of positive specimens and 100% of negative specimens according to the FDA.	This rapid test has shown to have an accuracy of 95%.
Where can I find more information about this test?	FDA Instructions for Use	Product Overview for Healthcare Professionals	Test Administration Video	FlowFlex at Home test instructions	Instructions on how to use Labcorps at home PCR test
Customer Service Contact	Abbott Contact Information	Ellume Contact Information	QuickVue Contact Information (located at bottom of website)	ACON Laboratories Contact Information	Labcorp contact center

COVID-19 Home Test Kits

Sent to labs with results in 3-5 days

Frequently Asked Questions	Kroger Health COVID-19 Test Home Collection Kit	LetsGetChecked Corporate COVID-19 Testing for Organizations
Are there any limitations or restrictions on employer eligibility?	No, any employer can order.	No, any employer can order
When will home kits arrive after an order has been placed?	Next day via overnight delivery	Within 24 hours
Are the return envelopes prepaid and pre-addressed for overnight delivery to a lab for processing?	Yes	Yes
Can the return envelopes be sent by USPS, or is it required to be sent by Fed-Ex or UPS?	Required to be sent via FedEx	Return envelopes should be sent by UPS.
Which lab/labs serve as the sample processing partner?	Gravity Diagnostics in Covington, KY	A CLIA/CAP/BSL II certified high complexity laboratory located in the United States
What is the processing and turnaround time to receive test results?	Processing takes 24-48 hours once the specimen has reached the lab. A turnaround time of 3-4 days can be expected.	After the labs receive the samples, the results are secured and available in 24-72 hours.
Have the processing labs been experiencing delays in the turnaround time?	There have not been any delays to date.	No
How are test results provided to employers and employees?	Overall test results are delivered to the employer via email.	When the results are available, you will get an email to let you know that your results are available and can be viewed

	Individual Negative test results are provided to the employee via email. Individual Positive results are provided to the employee via phone call from a licensed clinician.	on the LetsGetChecked Dashboard.
How are these home test kits priced?	1- 10,000 tests: \$119/test 10,001 - 50,000 tests: \$109/test 50,001+ tests: \$99/test	Tests cost \$89/test which includes shipping and lab fees.
Are the costs of these kits covered by commercial insurers in Indiana such as Anthem and UnitedHealthcare?	Currently the tests are not covered by or billable to insurance The \$119/test cost will be invoiced to the employer monthly based on test utilization	Provide an invoice that can be submitted to insurers for a reimbursement
What if an employer wants to order 1000 tests and pass them out to employees, versus direct mailing to employees? Will test kits be directly sent to employers, schools, and people who want a test kit at their home to have a test just in case?	The FDA EUA encompasses the entire testing process (not just the kit) so we are not currently able to bulk ship tests to be passed out by an employer. To mitigate employer obstacles, we can assign vouchers for employers to hand out to employees so they can be sent a test immediately upon receipt of a voucher.	Tests can be ordered in bulk to be passed around to employees. They are unable to send tests directly to employees. However, employers can repost the test kits to their employees after they have received the shipment with the test kits.
How can I contact the organization or submit inquires?	To contact Kroger Health, click <u>here</u>	To submit a query, click <u>here</u>
Who can I contact for more information?	Jeremy Richardson National Director of Sales, Kroger Specialty Pharmacy Email: jeremy.richardson@krogerhealth.com	Danny Garcia Sales Representative Email: dgarcia@letsgetchecked.com Phone: 315-556-8339

The Biden Administration Provides FREE At-Home COVID-19 Tests

Details: Program now closed.

- January 14, 2022: <u>Announcement</u> of free at home COVID-19 tests
- January 19, 2022: Free at-home COVID-19 tests through COVIDTests.gov
 - 100% free and no insurance information collected
 - Test delivered by the U.S Postal Service
- September 2, 2022: Due to a shortage of congressional funding, the <u>federal program</u> to distribute free at home COVID-19 tests ended
- September 8, 2022: Biden Administration <u>Outlines Plan</u> to Get Americans an Updated COVID-19 Vaccine Shot and Manage COVID-19 this Fall