



FAQ: COVID-19 Home Test Kits

4/29/2021

| Frequently Asked Questions | Kroger Health COVID-19 Test Home Collection Kit | Optum At-home COVID-19 Test Kit |
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| Can any employer order these home testing kits? | Yes, any employer can order as there are no restrictions on employer eligibility. | Yes, however there is a 500-kit minimum order. It should be noted that for multi-site customers this program is not available for consumers residing in NY, NJ, and RI (as of 8/12/20). |
| When will home kits arrive after an employer order has been placed? | When a test is needed, the individual test kit is delivered directly to the employees home next day via overnight delivery. | Participant must first complete the registration process online. Test kits are then delivered to the individual's home. |
| Are the return envelopes pre-paid and pre-addressed for overnight delivery to a lab for processing? | Yes. All shipping logistics are pre-paid and pre-addressed for overnight delivery back to the lab for processing. | Yes. The self-collected participant samples are returned to lab with the overnight shipper provided with each test kit. |
| Can the return envelopes be sent by USPS, or is it required to be sent by Fed-Ex or UPS? | Currently, our arrangement to ensure overnight delivery is via FedEx. <ul style="list-style-type: none"> ○ Patients will receive a link listing the nearest drop box and location options. ○ The drop box allows for zero contact delivery. | Kits are delivered to participants via USPS. The pre-paid return label / envelope is sent back to the lab via United Parcel Service (UPS). |
| Which lab/labs serve as the sample processing partner? | Gravity Diagnostics in Covington, KY is the laboratory partner. | N/A |
| 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 depending on the diligence of patients/employers in taking and returning test kits in a timely manner. | Processing takes 24-48 hours once the sample has reached the lab. Turnaround time for results is 3-5 days from order date, including overnight shipping. |



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| Have the processing labs been experiencing any delays in turnaround time? | There have not been any delays to date. Currently, 80% of samples are processed within the first 24 hours of the turnaround time frame, and laboratory capacity is being actively expanded. Future issues with turnaround time are not anticipated. | N/A |
| How are test results provided? | Overall test results are delivered to the employer via email. 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. | Results are provided online on HIPAA-compliant digital platform. For those with positive results: <ul style="list-style-type: none">○ Consult with a board-certified physician regarding next steps is provided.○ Positive results are automatically reported to the appropriate mandated local and federal reporting agencies. |
| 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 | Total cost for each test including lab work is \$119.90: <ul style="list-style-type: none">○ \$59.00 plus a \$10.90 admin fee billed upon shipment of kit○ \$50.00 lab processing fee billed when a kit is returned for processing○ |
| Are the costs of these kits covered by commercial insurers in Indiana such as Anthem and UnitedHealthcare? | Currently the tests are available via B2B contract only and are not covered by or billable to insurance. The \$119/test cost would be invoiced to the employer monthly based on test utilization. | N/A |



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| <p>What if an employer wants to order 1000 tests and just 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?</p> | <p>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.</p> | <p>N/A</p> |
| <p>Who can I contact for more information?</p> | <p>Jeremy Richardson <i>National Director of Sales</i> <i>Kroger Specialty Pharmacy</i> <i>Email:</i> jeremy.richardson@krogerhealth.com</p> | <p>Paula Conner <i>Client Executive</i> <i>Optum Health</i> <i>Email:</i> paula.conner@optum.com Phone: +1 763-797-2244</p> |

Abbott BinaxNOW COVID-19 Antigen Self Test

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| <p><u>Emergency Use Authorization</u></p> | <p>The FDA issued an EUA for on August 26th for the use of BinaxNOW COVID-19 Ag Card in the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from people suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.</p> |
| <p>What is the cost of this test?</p> | <p>The BinaxNOW Self Test is sold in 2-count packs for a manufacturer suggested retail price of \$23.99.</p> |
| <p>Where can I purchase it?</p> | <p>The BinaxNOW COVID-19 Self Test is available online and in stores, over the counter without a prescription, at CVS Pharmacy, Walgreens, and Walmart.</p> |
| <p>What are the capabilities of this test?</p> | <p>This new rapid test has shown a sensitivity of 84.6%, and a specificity of 98.5% in people seven days or less post-symptom onset at all Ct counts.^{1,2}</p> |
| <p>How is it used?</p> | <p>Only a minimally invasive nasal self-swab is needed (not the deep nasopharyngeal swab), and all materials required to perform the test (swab, test card, and reagent solution) will come in the boxed package.</p> |



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| Does this test require the sample to be sent to a lab? | No. The test card displays results in a similar manner to a home pregnancy test. <ul style="list-style-type: none">○ If the patient is negative, the display will show one band at the 'control' line.○ If the patient is positive, the display will show two bands at the 'control' and 'sample' line. |
| How long does this test take to display results? | This test provides results in 15 minutes. |
| <u>How can patients get proof of their COVID-19 test results?</u> | Abbott offers an optional free mobile app, the NAVICA app. This allows patients to display their results, obtained through a healthcare provider, to access facilities or activities that require proof of testing. <ul style="list-style-type: none">○ The NAVICA app is an optional tool that allows people to store, access, and display their results with organizations that accept the results.○ The app is supported by Apple and Android digital wallets. |
| <u>Is the NAVICA app used for contact tracing?</u> | No. The app is not used for contact tracing, and only collects the patient's first name, last name, email address, phone number, zip code, date of birth, and test results. <ul style="list-style-type: none">○ Regardless of whether patients use the app, healthcare providers in all settings will be required to report positive test results to the CDC and other public health authorities. |
| Where can I find out more about the BinaxNOW COVID-19 Ag Card? | You can read more about the procedures, result interpretation, and performance characteristics of the test from an FDA publication found here: <ul style="list-style-type: none">○ BinaxNOW COVID-19 Ag CARD. You can also view the following videos about the test: <ul style="list-style-type: none">○ Abbott video○ WGN News video |

1. Higher test **sensitivity** means fewer false negative results, which means less disease cases are missed. A higher **specificity** means the test is better able to designate an individual who does not have a disease as negative. A highly specific test means that there are few false positive results.
2. Ct counts are the number of times a PCR instrument has to cycle through in order to amplify enough genetic material of the SARS CoV-2 virus to be detectable.



[Ellume COVID-19 Home Test Kit](#)

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| <u>Emergency Use Authorization</u> | The FDA issued an EUA for on December 15 th , 2021 for the use of Ellume COVID-19 Home Test in the qualitative detection of SARS-CoV-2 nucleocapsid antigens from mid-turbinate nasal swabs from self-collected samples, or collected by an adult from an individual 2 years old or older. This is for use in those with or without symptoms. |
| What is the cost of this test? | The Ellume COVID-19 Home Test Kit test costs \$38.99. |
| <u>Where can I purchase it?</u> | This home test kit has been launched in select stores in CVS pharmacy and will increase availability online and in physical stores by the end of May. |
| <u>How is it used?</u> | Patients download and open the Ellume COVID-19 home test to follow the step-by-step instructions for 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. |
| How long does this test take to display results? | This test provides results in 15 minutes. |