COVID-19 Testing FAQ – UPDATED 12/07/2020

On April 9, 2020, the Office of the Assistant Secretary for Health issued new guidance under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer COVID-19 tests that the U.S. Food and Drug Administration has authorized. Frequently asked questions* (FAQ) included below.

Now available: BD Veritor Antigen Covid Tests

AmerisourceBergen has been working diligently to source COVID tests for our customers that have FDA EUA approval. We also were focused on sourcing a reliable and reputable test that is in line with the standards of care that AmerisourceBergen and our customers expect. We have partnered with BD on their Veritor Antigen COVID test, which is now available in all AmerisourceBergen distribution centers.

**Note: The information below is publicly available and linked to in this document as a courtesy. We will continue to update as further guidance becomes available. Please continue to check for the latest available information.*

Q: What different type of tests can be used to test for COVID-19?

There are three primary types of tests available: **PCR Tests, Antigen Tests,** and **Antibody (Serology) Tests.**

PCR Test (also called a molecular test) - this COVID-19 test detects genetic material of the virus using a lab technique called polymerase chain reaction (PCR). A fluid sample is collected by inserting a long nasal swab (nasopharyngeal swab) into your nostril and taking fluid from the back of your nose or by using a shorter nasal swab (mid-turbinate swab) to get a sample. In some cases, a long swab is inserted into the back of your throat (oropharyngeal swab), or you may spit into a tube to produce a saliva sample. Results may be available in minutes if analyzed onsite or a few days — or longer in locations with test processing delays — if sent to an outside lab. PCR tests are very accurate when properly performed by a health care professional, but the rapid test can miss some cases. This test is also available in two versions of what is called an “at home” option. The first type of “at home” option refers to the patient collecting the sample at home and then sending off to a 3rd party lab. Due to the need for a 3rd party lab and the cost involved, AmerisourceBergen has decided not to source PCR test kits. The second type of “at home” option can be performed at home without sending to a 3rd party lab. It requires a prescription. This test is in the early stages of production and we currently anticipate availability of this product from the supplier by spring of 2021.

Antigen Test - this COVID-19 test detects certain proteins in the virus. Using a long nasal swab to get a fluid sample, antigen tests can produce results in minutes. Because these tests are faster and less expensive than PCR tests, antigen tests may be more practical to use for large numbers of people. A positive antigen test result is considered accurate when instructions are carefully followed, but there's an increased chance of false-negative results — meaning it's possible to be infected with the virus but have a negative result. Depending on the situation, the doctor may recommend a PCR test to confirm a negative antigen test result.

Antibody (Serology) Tests

Antibody tests may provide quick results but should not be used to diagnose an active infection. Antibody tests only detect antibodies the immune system develops in response to the virus, not the virus itself. It can take days to several weeks to develop enough antibodies to be detected in a test.

Q: Are all tests "approved" by the FDA through the EUA?

In March, the FDA issued a policy to allow certain serology tests available for use once they had performed specific testing and evaluation to confirm accuracy. It should be noted that the FDA has issued the following guidelines specific to the serology tests:

- All tests have not been reviewed by the FDA
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Q: What tests are available at AmerisourceBergen and how can I get them?

Currently AmerisourceBergen stocks:
BD VERITOR SARS-COV-2 RAPID TEST 30CT item #10244006.
This item requires the use of the BD Veritor Plus System Analyzer item #10187251 which is available only through drop shipment.We continue to review other tests and will communicate through the ordering platform future opportunities.

Q: Do I need a CLIA waiver to administer the test?

Yes, a CLIA Certificate of Waiver will be required to offer COVID-19 testing in a healthcare setting. The settings in which an EUA-authorized test may be used are described in the Letter of Authorization. As discussed in the Guidance for Industry and Other Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities, when the FDA authorizes point of care tests (including SARS-CoV-2 point of care test systems) under an EUA, such tests are deemed to be CLIA waived tests. Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver or Certificate of Compliance.

Additional information from the FDA available here.

Q: What do I do if I do not have a CLIA Certificate of Waiver?

You will need to apply. For most, this is a very easy process. A form will need to be completed and mailed to your state agency. Your AmerisourceBergen Business Coach can provide additional guidance.

For guidance on necessary forms to obtain a CLIA waiver, see your state agency website: CLIA State Agency contacts. Most states utilize form CMS116 which can be obtained here, Form CMS116.

Q: Who is allowed to conduct the test?

A licensed healthcare professional must administer the tests in a licensed healthcare setting.

Q: Do I need PPE?

Basic PPE is required for all laboratories, including CLIA waived labs and pharmacies. This includes gloves, eye and face protection, lab coat/gown, and respiratory protection when the job hazards warrant it. In the case of COVID-19 testing, respiratory protection (N95 masks) are warranted and considered a best practice.

CDC also updated their guidance during the COVID-19 pandemic (4/16) in general and that can be found here. NCPA also provided updated guidance for PPE use, re-use, and sanitation recommendations during COVID-19, available here.

Q: Am I able to order PPE through AmerisourceBergen?

AmerisourceBergen is working to secure PPE equipment (masks and gloves) during this time of high need. Currently masks and gloves are in stock but as you can imagine, PPE is difficult to procure for commercial use and supply may change at any time.

Q: How will I be reimbursed for testing?

Currently, reimbursement for pharmacies is primarily under a cash model. As reimbursement models evolve, community pharmacies may have opportunities to engage with local payers or employers to conduct testing for members.

Reimbursement information for Veritor can be found by utilizing the following link. You can find any/all reimbursement data here, just scroll down for the BD Veritor™:

https://www.codemap.com//BDMAX/index.cfm?page=covid

COVID-19 Serology Test Kits: An Update from AmerisourceBergen

Since the outbreak of the current crisis, AmerisourceBergen has been working diligently to source antibody (serology) COVID-19 test kits for our customers. Antibody serology tests detect the specific antibodies that could indicate if a patient has developed an immune response to COVID-19. The FDA has issued Emergency Use Authorization (EUA) for some serology tests; however, others are being marketed without EUA or other FDA approval.

Unfortunately, the quality, efficacy and accuracy of currently marketed test kits varies greatly, and the ability to source serology test kits with an EUA has proven challenging due to a multitude of factors outside of AmerisourceBergen's control. Most importantly, at the current time, AmerisourceBergen does not have confidence in the quality of serology test kits that have been offered to us.

As a result, we've made the decision not to distribute COVID-19 serology tests for our customer base at this time, and instead AmerisourceBergen's near-term efforts will focus on continuously monitoring the market for reliable test offerings, helping prepare and educate our customers and staying up-to-date on our customers' needs. We will continue to consider and prepare for market entry pending clearer FDA guidance on EUA approval and availability of reputable and reliable tests to ensure that every product sourced and distributed by AmerisourceBergen is in line with the standards of care that we and our customers expect.