

## COVID-19 Testing FAQ

### **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.*

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.

*\*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 two primary types of tests available: **Polymerise Chain-Reaction (PCR)**, which is a form of Molecular testing and **Serological Antibody** tests

- **PCR tests** are a form of Molecular testing administered to detect the viral particles in the patient's nose or secretions and samples are taken via nasopharyngeal swab. This test should be administered only when people are having symptoms. The PCR tests require confirmation through further chemical analysis (lab) and typically take 24-36 hours or longer for results.
- **Serological tests** measure the amounts of antibodies or proteins present in the blood when the body is responding to an infection, detecting the body's immune response to the infection rather than detecting the virus itself. An antibody (blood) test will determine if a patient *has been* infected. In the early days of an infection

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when the body's immune response is still building, antibodies may not be detected. This test utilizes immunochromatography which highlights the presence of anti-COVID-19 IgM and IgG antibodies and verifies the validity of the test with a third control band. Recent infections are characterized by detection of IgM antibodies and past infections are characterized by detection of IgG antibodies that are not accompanied by detectable IgM antibodies. Antibody tests use a presumptive testing technique and do not require a lab for further chemical analysis and generate visual results in approximately 15 minutes or less. Antibody tests may also be helpful determining asymptomatic carriers and potentially provide guidance as it relates to restarting the economy and returning to work. Serological tests should only be conducted on asymptomatic patients; either never had symptoms or at least 7 days post experiencing symptoms. It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after the infection has been cleared.

### **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 and where can I get them?**

There are limited numbers of PCR tests available in the market currently and they are typically administered in hospitals, doctors' office or health systems.

There are numerous serology tests on the market that have been submitted to the FDA and all should be properly vetted prior to consideration.

### **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.

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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. As you can imagine, PPE is difficult to procure for commercial use given current market shortage.

### **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.