BD Veritor™ Plus System (SARS-CoV-2 Test) Test Kits to Be Available from AmerisourceBergen

Updated October 20, 2020

Since the outbreak of the COVID-19 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.

While many test kits have been utilized by the federal and state governments to this point, **AmerisourceBergen anticipates that as of mid-November 2020 we will be able to source a limited number of the BD Veritor™ Plus System on behalf of our customers.**

As always, we will communicate any additional updates as we receive them.

Q: Will the BD Veritor test kit be available through AmerisourceBergen's ordering platform(s) (e.g. ABC Order, ABC PassPort, ASD Healthcare?)

A: The BD Veritor test kit will be available to all AmerisourceBergen Business Units, and we will be stocking the test kits based on interest in purchasing from customers.

Q: When do we estimate BD Veritor™ Plus Systems will be in stock through AmerisourceBergen?

A: We estimate that we will begin to have test materials in stock starting mid-October 2020. Exact date to come.

Q: What is the price for the BD Veritor™ Plus System?

A: The net price for tests (sold in kits of 30 tests per kit) is $948.75 and could be subject to rebates/discounts per customer contract.

Q: Can unused SARS-CoV-2 tests be returned to AmerisourceBergen?

A: No, BD Veritor™ Plus System (SARS-CoV-2 Test) Test Kits cannot be returned to AmerisourceBergen.

Q: Will the reader be provided with orders of SARS-CoV-2 test kits?

A: No, readers must be orders separately and will be drop-shipped directly from BD. Use UPC 382902560661 to find the BD Veritor reader through AmerisourceBergen. There is the opportunity to acquire a reader at no charge by purchasing the flu and strep tests (see the attached document). If you are already using a BD reader and need to update for the COVID test, this firmware update is anticipated to be delivered to most locations this month. Please use item number 10249657 to order this item.

Q: Do I need PPE?

A: 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

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hazards warrant it. In the case of COVID-19 testing, respiratory protection (N95 masks) are warranted and considered a best practice.

Q: How will providers be reimbursed for SARS-CoV-2 testing?

A: Information on reimbursement can be found here:
https://www.codemap.com//BDMAX/index.cfm?page=covid

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

A: 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.

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

A: 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: What do I do if COVID-19 positive results come back from tests issues with the BD Veritor™ Plus Systems test?

A: As mandated by the Centers for Disease Control, all COVID-19 diagnostic and screening testing sites must report COVID-19 test results.

Laboratory data elements may be reported in the following ways:

- Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with ordering provider or patient, as applicable.
- Submit laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform), where the data will then be routed to the appropriate state and local authorities and routed to CDC after removal of personally identifiable information according to applicable rules and regulations.
- Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state.

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Q: Does the BD Veritor™ Plus System expire?

A: Yes, the expiration for the BD Veritor™ Plus System is either two years, or 3,500 tests. Once the system hits 300 remaining tests, a countdown is started to let you know the system will soon hit expiration.