Getting you back on track

Easy to use, reliable and fast testing,
so you can operate with safety and
confidence no matter the environment

BD

Why testing matters

The global COVID-19 pandemic has disrupted our lives and daily routines unlike anything we've ever experienced. And while we can slow the spread and protect ourselves and others with facial coverings, hand washing and social distancing, if we want to get back on track it's critical to know that we are doing everything we can to minimize the threat of spread.

Used as a part of a comprehensive COVID-19 mitigation program, fast, easy to use testing for SARS-CoV-2 (the virus that causes COVID-19) allows organizations to better manage the virus and decrease the likelihood of spread. As you are well aware, an outbreak could lead to the need to shut down part or all of your facility, so safety isn't the only thing at risk.

The BD Veritor™ Plus System† provides everything your organization needs to successfully conduct testing for a variety of infections. This simple guide is designed to help you successfully activate testing in your facility.

Steps

1 **The Standing Order for Testing**

2 **CLIA-Waiver Certification**

3 **Establish a Testing Protocol**

4 **Government Reporting Requirements**

†The BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 is a chromatographic digital immunoassay intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swabs from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

- This test has not been FDA cleared or approved
- This test has been authorized by FDA under an EUA for use by authorized laboratories
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. For additional information, please refer to the HCP fact sheet.

STEP 1

The Standing Order for Testing

What and why

To make a facility a testing site, it is suggested that there be a Standing Order for COVID-19 (SARS-CoV-2) testing issued by the organization's Medical Director. The Standing Order sets out guidelines and requirements for establishing a testing site. As understanding of this virus grows, governmental and medical guidance can change quickly, so we recommend frequently visiting the websites for U.S Department of Health and Human Services (HHS), the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) for the latest guidance and requirements.

The Standing Order for Testing Checklist

- Contact your Medical Director – If your organization has an internal healthcare provider (HCP) or Medical Director, they can help with the Standing Order, as well as with selecting and training individuals in each facility. If there's no internal HCP, you could partner with a local provider or BD can connect you with resources to support your testing needs and/or provide the training required.
- Create your Standing Order

Resources

▶ **For the latest regulations:**

HHS.gov | FDA.gov | CDC.gov

STEP 2

CLIA-Waiver Certification

What and why

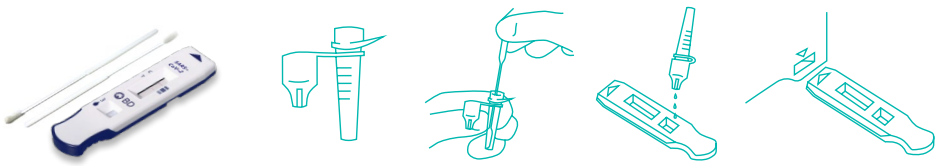
To ensure accuracy, reliability and timeliness of clinical test results, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988. In normal times, labs performing such tests would be required to obtain either a CLIA Certificate of Waiver or a Certificate of Compliance/Accreditation.

But these are not normal times.

As part of the process of issuing Emergency Use Authorizations, the US Food and Drug Administration also describes the appropriate use environment(s) for each test. The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is authorized for use in CLIA waived environments. This means that each faciity where you will do testing will be required to obtain a CLIA Waiver Certificate.

The CLIA-Waiver Certification Checklist

- Enroll in the CLIA program by completing Form CMS-116 available on the CMS CLIA website or from your local State Agency. Approval can take anywhere from 24 hours to 2 weeks, depending on the state office. If you call your state office, you may be able to expedite your application. Your state office can be found here.
- Pay the CLIA-Waived certificate fee of $200 (good for two years)
- Follow the manufacturer's instructions for the waived tests you are performing. The BD Veritor™ Plus System is fast and easy to use.



Resources

- **Download Form CMS-116 here**
- **Download the BD Veritor™ System for Rapid Detection of SARS-CoV-2 instructions for use here**
- **CMS CLIA State Office Directory**

STEP 3

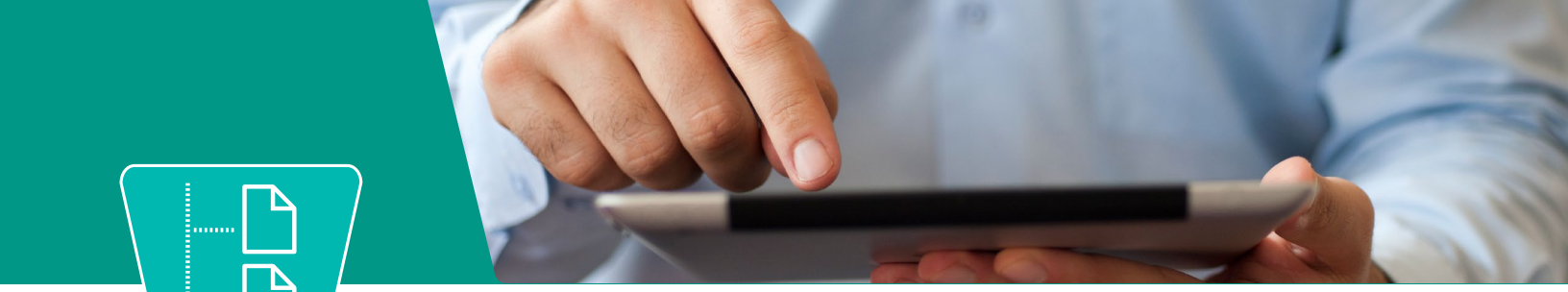
Establish a Testing Protocol

What and why

Once testing locations have been identified, you will need to assemble and train a 'Virus Squad' at each site to implement the program. A successful program will require the development of a Testing Protocol that can be customized to the specifics of each location. It will have specific steps and guidance to cover each step of the testing process.

The Testing Protocol Checklist

- Choose and train the 'Virus Squad' who will manage the program and administer the tests. BD can support you with your training needs—ask about our eLearning programs. While we recommend a healthcare provider play at least a supervisory role, it is not required to conduct testing.
- Choose and prepare the testing location within the site—as close to the facility entrance as is possible.
- Decide who should be tested and frequency of testing. Your Standing Order for COVID-19 (SARS-CoV-2) testing should provide guidance on the criteria for who is eligible for testing.
- Based on above factors, determine testing equipment supply requirements. The BD Veritor™ Kits contain everything you need to conduct testing, but do not include PPE for your 'Virus Squad' testers so be sure to add that to your supply list.



STEP 4

Government Reporting Requirements

What and why

Once the testing program is ongoing, results must be reported to the appropriate public health authority. And any positive test results must be reported in the community where the individual who tested positive lives so contact tracing can be initiated. Each state has its own reporting requirements, so your 'Virus Squad' lead will need to check with local health officials.

The Government Reporting Requirements Checklist

- Prepare for local Public Health authority reporting
- Understand how the BD Veritor™ Plus System simplifies the reporting process—with options like the BD Veritor™ System InfoScan module that can increase efficiency and help you securely get your results to HHS

Resources

- **Understand your reporting requirements and download testing data and positive test reporting forms here**
- **Download the BD Veritor™ Plus System reporting guide here**
- **Download a list of the datapoints required by the government here**

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