CORONAVIRUS DISEASE

Rapid Point-of-Care Testing Toolkit

Table of Contents

***NOTE:** Appendices Can Be Found in the Microsoft Word and Excel Documents Accompanying This Toolkit*

CORONAVIRUS DISEASE

Introduction & Background

The purpose of this toolkit is to help inform entities that are interested in implementing rapid point-of-care (POC) testing in their communities. This toolkit is current as of December 15, 2020. It will be updated as new rapid POC test products and procedures become available. Users are advised to contact test manufacturers directly with product-specific questions. In addition to the resources below, the Maryland Department of Health maintains a web page on rapid POC testing. The page features a variety of informational materials, including official orders and guidance for the use of rapid POC tests. Please use this page as a resource and submit suggestions for content to MDH.RapidPOCtest@Maryland.gov.

About Rapid Point-of-Care Testing

There are different types of tests used for the diagnosis of COVID-19 infection. Each type of test plays an important role in mitigating the ongoing COVID-19 pandemic. Rapid POC tests are useful in detecting the virus in the early stages of infection, when an individual has enough virus in their system and is likely to be more contagious. Rapid POC tests can provide results quickly, are low cost, and can be used frequently and in a variety of settings. Proper interpretation of rapid POC test results is critical for identification and accurate clinical management of individuals with suspected COVID-19.

CORONAVIRUS DISEASE

Maryland Department of Health - COVID-19 Testing Basics

Learn more about the three most common types of COVID-19 tests available in Maryland.

PCR or Molecular Amplification Diagnostic	Rapid Point-of-Care (Antigen Diagnostic*)	Serology (Antibody)
Detects genetic material from the virus	Detects protein from the virus	Detects antibodies made by the immune system if the virus was present in the past
Shows active COVID-19 infection	Shows active COVID-19 infection but may be less sensitive than a PCR test	Shows past COVID-19 infection
Best test for highly accurate diagnosis of individual patients and only test recommended in outbreaks	Best used for rapid screening of individuals, especially symptomatic individuals, including those in congregate settings such as nursing homes or dormitories	Only test for confirming past infections (but *does not* confirm immunity to future infection)
Samples taken via nasal or throat swab (most tests) -*OR*– saliva (few tests)	Samples taken via nasal swab	Samples taken via finger stick or blood draw
Results generally available in 1-2 days. **NOTE:** Turnaround time for results may vary according to testing demand Most molecular diagnostic tests are run in a lab and take time to transport and process. However, there are also "point-of-care" (POC) molecular diagnostic tests that can provide results within 15-45 minutes	Results can be available in 15-20 minutes Results are processed onsite at the point of care. These tests are commonly called "rapid" tests **NOTE:** Antigen tests are generally not as accurate as PCR tests and produce more false-negative and false-positive results than PCR tests	Results available in 1-3 days
The most common COVID-19 test MDH reports all PCR-confirmed cases on corona-virus.maryland.gov	MDH tracks results	MDH reports aggregate serology data here

CORONAVIRUS DISEASE

NOTE: *Every patient and situation are unique. Patients are encouraged to discuss available testing options with a physician before determining which test will work best in their situation.*

*Only rapid antigen tests that have received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) -*OR*- that have been independently verified by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory may be used. As of December 15, 2020, six separate assays have been awarded an EUA through the FDA: Abbott BinaxNOW, Access Bio, Celltrion, Becton Dickinson (BD) Veritor, LumiraDx, and Quidel Sofia. More information is available in the U.S. Centers for Disease Control and Prevention's *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2*.

Training

MDH recommends that all staff involved with POC test administration learn how to use each of the Abbott BinaxNOW, BD Veritor, and Quidel Sofia POC test products. A selection of webinars, e-learning platforms, and other training resources can be found in the chart below.

BD Veritor	Abbott BinaxNOW	Quidel Sofia
Register for Webinars & Watch Past Webinars	COVID-19 Ag Card and VAVICA App | Getting Started	Sofia SARS Antigen FIA Training Video
Product Training Information & eLearning Registration	Card Product Insert	Product Insert
Education Available	Introduction to CLIA-Waived Testing	Healthcare Provider Fact Sheet
YouTube Videos	Specimen Collecting & Handling	Sample Collection Guidance
SARS-CoV-2 IFU PDF	Patient Fact Sheet (English)	Patient Fact Sheet (English)
Batch Testing Guide	Patient Fact Sheet (Spanish)	Patient Fact Sheet (Spanish)

CORONAVIRUS DISEASE

Things to Consider Before Implementing POC Testing

- ❑ Have an approved CLIA Certification and Maryland Laboratory License on file
  - ❑ If you already have a Maryland laboratory license and federal CLIA certification, you will need to fully complete a change form to add the COVID antigen test
  - ❑ If you do not have a Maryland laboratory license and federal CLIA certification, you will need to apply for a Maryland laboratory license by fully completing a State Compliance Application. To apply for federal CLIA certification, you will need to fully complete a CLIA Certification Application ($180 fee)
- ❑ Individual with education qualifications as per latest executive order on site to administer and to process the POC test
- ❑ Access to Maryland's Health Information Exchange (CRISP)
- ❑ Appropriate personnel to report the POC test results into CRISP
- ❑ Adequately trained staff available to provide POC test results and clinical guidance to individuals that received a POC test
- ❑ Completed POC testing training: Abbott BinaxNOW, BD Veritor, or Quidel Sofia
- ❑ A primary point of contact that MDH can communicate with as needed
- ❑ If testing minors, a signed consent form including:
  - ❑ Consent for the minor to be tested, **and**
  - ❑ Consent for the test results to be input into CRISP
- ❑ A Standard Operating Procedure (SOP) document outlining the following:
  - ❑ Current mitigation strategies in effect: What measures (if any) have been taken to mitigate the spread of COVID-19 in your institution? What measures do you intend to implement?
  - ❑ Plan/infrastructure capacity: Do you have the appropriate setting, infrastructure, and Implementation plan for POC testing (e.g., spacing for testing and isolation for COVID-19 positive individuals, sufficient PPE, storage for POC testing supplies, storage and disposal of biomedical waste, quality assurance and control procedures, etc.)?

CORONAVIRUS DISEASE

Standard Operating Procedures

The purpose of this standard operating procedure (SOP) is to establish general procedures for implementation of rapid POC testing. For specific clinical guidance regarding use of POC tests and interpretation of results, please visit the CDC and MDH web pages regularly. Guidance is updated as information becomes available. Supplemental, modifiable tracking logs are included in the appendices for your convenience.

KEY GUIDANCE

SELECTIONS FROM CDC GUIDANCE

Performing the POC Test (Adapted from: CDC, ready-set-test-booklet.pdf, p. 7)

When performing a test, some important points to remember are:

- Ensure all personnel are adequately trained on how to perform the test
  - Tip: Track staff completion of trainings through training certificates or rosters
- Follow the testing steps in the exact order as they are in the manufacturer's instructions
- Test quality control (QC) following the manufacturer's instructions
- Have the manufacturer's instructions, site specific procedure, or a quick reference guide at the testing area
- Use timers and follow the required timing intervals before reading test results
  - Reading the results too soon can cause invalid or false negative results due to incomplete reaction of the sample and reagents
  - Reading a test after the time given in the manufacturer's instructions can lead to:
    - false positive results – due to over development of color;
    - false negative results – fading of the reaction or color; or
    - invalid results – the reaction moves beyond a visible area

Performing the POC Test (Adapted from: CDC, ready-set-test-booklet.pdf, p. 12)

Ready?

- Clean work surfaces before and after testing
- Perform testing in a well-lit area
- Check and record temperatures of the testing and reagent storage areas
- Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing
- Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired
    - 🔔Tip: Use the oldest reagents/kits first to help avoid unnecessary waste
    - 🔔Tip: Some POC tests must be processed by a testing device and may have a maximum shelf life and test capacity limit (i.e., maximum number of tests the device can process). Keep track of the number of tests processed and device shelf life and check before you begin testing
- Check that all kit reagents came from the same kit lot. Do not mix reagents
- Inspect reagents for damage, discoloration, or contamination, and discard if found
- Prepare reagents according to manufacturer's instructions
- Allow time for refrigerated reagents/samples to come to room temperature prior to testing
- Inspect equipment and electrical connections to be sure they are working
- Perform calibration checks, as needed, following the manufacturer's instructions
- File the old manufacturer's instructions and replace with the new copy if there are changes
    - 🔔Tip: Keep a quick reference instruction guide on hand at POC testing sites (most manufacturers provide such cards online or with shipment of POC tests)
- Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing
- Treat and test quality control (QC) samples the same as patient samples
- Perform QC as recommended in the manufacturer's instructions

CORONAVIRUS DISEASE

Set?

- Check patient identification and test orders
- Discuss pre-test instructions and counseling needs with the patient
- Wear appropriate personal protective equipment (PPE) such as gloves
- Collect and label a good sample for testing
- Clean hands and change gloves between patients
- Use the proper biohazard containers to dispose of waste and sharps

Test!

- Do not test samples that are improperly collected or handled
    - 🔔Tip: Document any test kit failures or issues and report to the manufacturer. Be sure to include any kit lot, specimen ID, and operator ID numbers
- Have the manufacturer's instructions or a quick reference guide at the workstation
- Follow the manufacturer's instructions in the exact order
- Follow required timing for testing. Identify and correct problems before reporting test results
- Identify and report critical values in a timely manner
- Perform or refer confirmatory or additional testing, if needed (see Appendix A for the Rapid POC Test Algorithm)
- Make sure any handwritten documents (e.g., lab requisition forms, labels for specimen collection tubes, or logs) are legible
- Make sure reports are standardized and easily distinguishable from referral laboratory test reports
- Report patient test results only to authorized persons
- Document verbal reports, followed by a written test report
    - 🔔Tip: Have fillable verification letters available upon request at your test site, for patients that may request a letter to verify that they were tested (see Appendix B)
- Report public health diseases
- Dispose of biohazardous waste safely
- Participate in proficiency testing (PT)
- Monitor, evaluate, and improve your current practice

CORONAVIRUS DISEASE

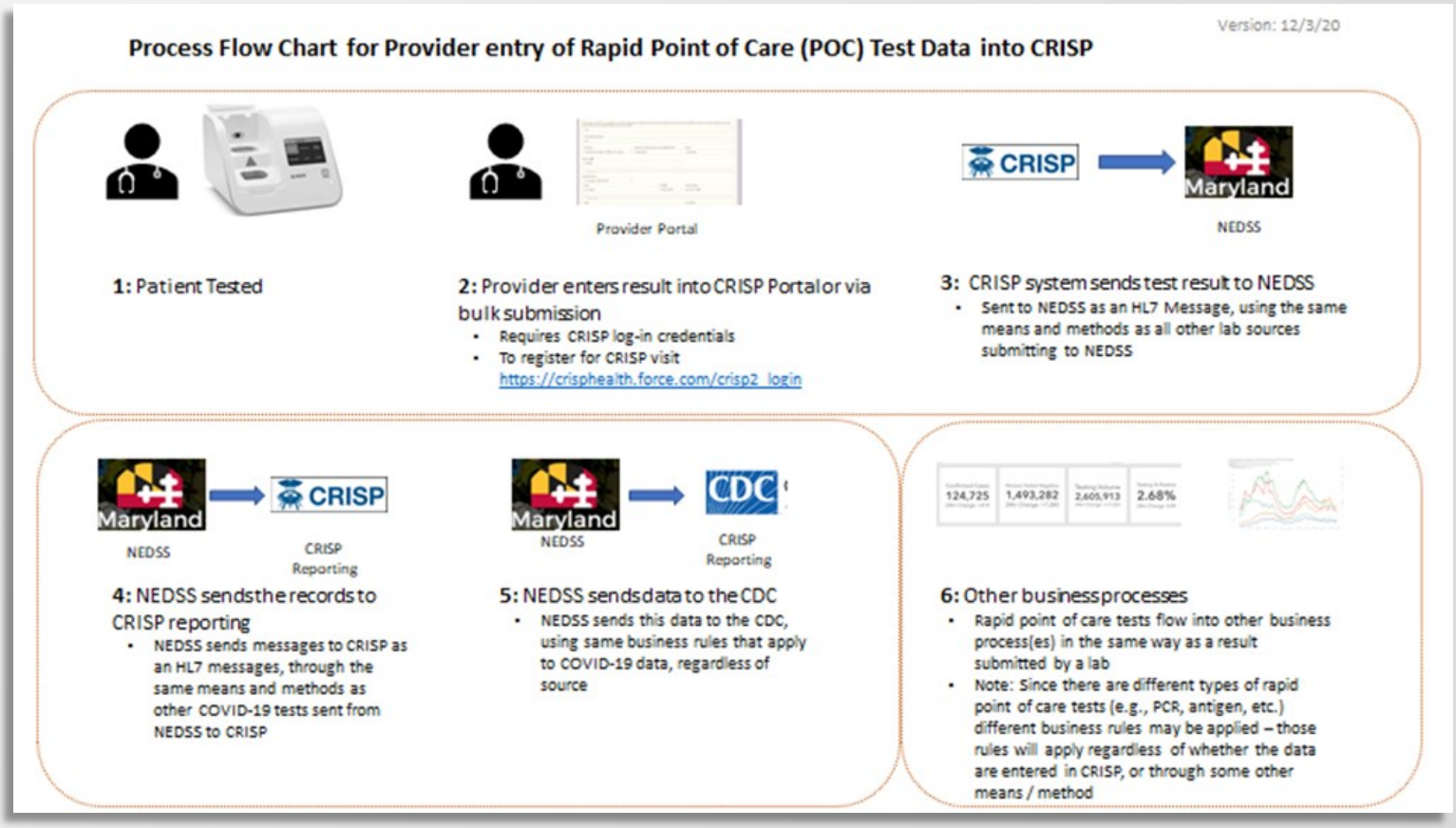
Reporting Results

Organizations that are performing COVID-19 POC testing are required to report results to MDH (see below process flow diagram). Since POC tests do not all have the capacity to deliver results electronically, providers must provide an ongoing means to report results for any tests that are not automatically configured to report. At this time, this may be accomplished by one of three methods:

1. Providers who incorporate the results into a laboratory information management system (LIMS) or electronic health record system that can generate an HL7-formatted message or formatted CSV file may submit via established electronic laboratory reporting processes (contact mdh.didsurveillancee@maryland.gov for more details)
2. Providers can also manually enter the results into the portal established by CRISP (for additional details, see https://crisphealth.org/guidance/providers/)
3. A bulk submission process (recommended for entities that are conducting at least 20 POC tests a day; see Appendix E for additional details)

First-time and existing CRISP users are encouraged to review the following resources:

1. Training video: https://youtu.be/Eo64_nyoGGk
2. Information on reporting COVID-19 test results: https://crisphealth.org/guidance/providers/



Managing Stock

Reordering

Please refer to the table below for manufacturer, Emergency Use Authorization (EUA) approval, and contact information for reordering or updates on supply availability. Nursing home administrators should contact Medline, McKesson, or their normal medical supply vendor first to reorder BD or Quidel rapid POC testing supplies (see the Rapid Point-of-Care (POC) Testing Bulletin No. 2 for more information). At this time, there is no way to reorder supplies from Abbott directly. Eligible entities interested in procuring POC testing supplies through the state may complete the Maryland Department of Health's POC Testing Supplies Interest Form so that an estimate of demand and determination of the need for additional orders can be made. Completion of this form does not constitute order fulfillment. For any additional questions, please email MDH.RapidPOCtest@Maryland.gov. are included in the table below.

BD (EUA July 2020) **1-844-823-5433** **veritorcares@bd.com**	**Abbott (EUA August 2020)** **1-800-257-9525** **M-F 8AM to 8PM (EST)**	**Quidel (EUA May 2020)** **1-800-874-1517** **customerservice@quidel.com**
Product #256082 BD Veritor™ System For Rapid Detection of SARS-CoV-2 (Includes: tests, sample collection swabs, extraction reagent, tube tray, and positive and negative control swabs)	**Product #195-000** BinaxNOW™ COVID-19 Ag Card (40 Tests)	**Product #20374** Test Kit (nasal swabs)
	Product #195-080 BinaxNOW™ COVID-19 Ag Control Swab Kit (10 positive swabs)	**Product #20383** Test Kit (nasopharyngeal swabs)