Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

October 12, 2020

Dear Colleagues:

The Maryland Department of Health (MDH) is providing this clinical update and guidance on point of care (POC) rapid antigen testing for SARS-CoV-2 infection as part of its ongoing communications related to the mitigation and management of coronavirus disease 2019 (COVID-19). Additional information, all of the supplemental materials referred to in this letter, and guidance is forthcoming, and can also be found on the Department's website for POC testing, at https://health.maryland.gov/rapid-poc-test.

Regulatory Status of Point of Care Testing
POC testing for COVID-19 is specifically governed by the Secretary's 10/1/2020 Amended Directive and Order Regarding Various Health Care Matters (MDH No. 2020-10-01-01), which identifies the POC devices that may be used in Maryland; requirements for CLIA certification, State licensure, and certificates of waiver; and reporting requirements.

Type of Tests
Emergency User Authorizations (EUAs) for POC antigen tests issued to date by the FDA include the Becton-Dickinson Veritor, Quidel Sofia, LumiraDx, and Abbott BinaxNOW. All four currently have been authorized for CLIA-certified laboratories, CLIA-certified settings for tests of moderate complexity, and patient care settings operating under a CLIA Certificate of Waiver.

Other POC tests, such as the Cepheid Xpert® Xpress SARS-CoV-2 test and the Abbott Id Now tests are RT-PCR tests.

POC antigen tests detect antigen, rather than nucleic acid, and have been approved for use for symptomatic patients. POC antigen tests require less time to process a specimen than RT-PCR, and are cheaper to operate. The current data available for their sensitivity and specificity are pertinent for symptomatic patients only. While the CDC considers them highly specific (like RT-PCR), they are considered by the CDC to have only moderate sensitivity, unlike RT-PCR, which has high sensitivity and specificity. CDC notes that they perform best when viral load is highest, early in symptomatic infections. When disease prevalence is low, false positives may be a concern.

Rationale and Indications for Use of Point of Care Tests

POC antigen tests are currently being implemented in two principal settings: (1) in clinical settings where a rapid diagnostic procedure is useful to confirm a suspected case of COVID-19 in symptomatic individuals in order to effect prompt decision-making; and (2) in congregate settings to screen individuals who may have significant risks of exposure to COVID-19. POC antigen tests are not currently recommended in outbreak settings, because of the importance of having a very sensitive test to detect and isolate asymptomatic infectious individuals.
The use of POC antigen testing for screening of asymptomatic individuals who work in general (non-health care, non-congregate) employment settings is not currently recommended.

Performing Point of Care Tests

All POC antigen tests authorized by the FDA under an EUA are deemed to be CLIA waived tests. CLIA waived facilities performing POC COVID testing are required to notify the Office of Health Care Quality (OHCQ) to add testing, have a test order from an authorized practitioner, follow the EUA manufacturer's instructions, and report all released results to MDH.
Facilities and practices that hold CLIA certification and a Maryland Laboratory Licensure should submit a change form to add the specific EUA test, signed by the CLIA director.

Facilities and practices that do **not** currently hold CLIA Certification and Maryland Laboratory Licensure (both of which are required), should apply for both well before they are ready to test, as both must be obtained before they begin testing in order to be in compliance. Both the State Compliance Application and the CLIA Certification are to be filled out and signed, with original signatures, by the director and mailed to the office address listed on the state application along with additional documentation outlined on the last page of the state application checklist. (For CLIA waived testing only clinical diploma and clinical practice license are required). Once an application is approved there is about a 24 hour period for processing after which the lab will be invoiced by CMS $180 for a CLIA waiver. Once the CMS invoice is paid, the lab will receive a state license and a CLIA Certificate of Waiver, after which the lab can begin testing.

There are no fees for state licensure or renewal, and the state license is non-expiring. The CMS CLIA certification is renewed every two years currently at a fee of $180. CMS has stated that a facility can begin testing with only the CLIA number assigned. To check for this before paying the CMS fee, call licensing at 410-402-8045. The CLIA number is available 24 hours after the applications are approved.

Guidance Related to Test Results

MDH has developed Interim Guidance for Use and Interpretation of SARS-CoV-2 (COVID-19) Point of Care Tests, attached to this guidance. At this point, the guidance is more specific to rapid antigen tests as they are being distributed within the State, describes scenarios for patients presenting to clinicians, and provides recommendations for the interpretation of their POC tests. Additional guidance on other tests will be provided as the tests become more widely available.

At this time, MDH strongly recommends a confirmatory RT-PCR test for a **positive** rapid antigen test in **asymptomatic** individuals, regardless of community prevalence or the reason for the test. Due to the absence of published literature and data on the use of rapid antigen tests in asymptomatic individuals, MDH believes that at this time it is prudent to confirm the tests with an RT-PCR test. For similar reasons, MDH also recommends consideration of a confirmatory RT-PCR if a rapid antigen test is negative in an asymptomatic individual, particularly if there are indications of recent exposure. MDH also strongly recommends a confirmatory RT-PCR in a symptomatic individual who has a negative rapid antigen test.

MDH will also be evaluating the performance of rapid antigen testing as it is implemented on a larger scale, to determine its most appropriate role in the overall framework of COVID-19 testing in the State. To that end, MDH will work with institutional recipients of the tests to collect information on test performance, which may include the collection of confirmatory RT-PCR tests on a sample of negative as well as positive antigen tests. MDH will contact institutional recipients directly regarding this confirmatory testing.

Management of children excluded from school is guided by the most recent guidance for laboratory-confirmed cases of COVID-19 and persons with COVID-like illness, located on the web page, "Resources for Schools and Child Care." The performance of POC tests may be of particular concern to schools. It is important to consider the school context and this guidance when making testing decisions for return to school recommendations.

Reporting of Results

The Secretary's 10/1/2020 Amended Directive and Order Regarding Various Health Care Matters (MDH No. 2020-10-01-01), requires all tests for COVID-19 to be reported to the Department. POC tests do not all have the capacity to deliver results electronically, so for tests that are not automatically configured to report, the provider must provide an ongoing means to report the results. At this time, this may be accomplished by one of two 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); or (2) providers can also manually enter the results into the portal established by CRISP. A procedure to enter data manually into CRISP is attached to this document, and is available at https://crisphealth.org/guidance/providers/. A batch upload process under development will also be available in the near future.

Patient Education and Contact Tracing as a Result of POC Testing

Patients who test positive for COVID-19 using antigen tests should be advised to self-isolate, as noted in the guidance on interpretation and use of POC tests. Patients will be contact-traced according to existing processes for those who test positive using PCR and as such, patients should be informed about contact tracing and encouraged to "answer the call" ("MD COVID" on caller ID or 240-466-4488) and to cooperate in contact tracing processes. The guidance on

interpretation and use of POC tests also contains recommendations about release from quarantine or isolation.

There is also Guidance specifically for situations when employers are requesting that employees continue to work while in quarantine for exposures under the CDC guidance related to Critical Infrastructure Workers. In these cases, the employer should check with the local health department for recommendations.

Sincerely,

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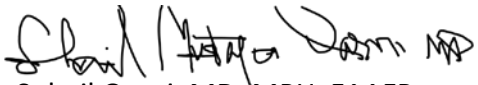

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Attachments:

1. MDH Order No. 2020-10-01-01
2. Interim Guidance for Use and interpretation of SARS-CoV-2 (COVID-19) Point of Care Tests