October 8, 2020

Dear Dr. Azzam, Dr. Pandori, Administrator Sherych, and Ms. Kinsinger:

This is in response to your October 2, 2020 letter to healthcare providers and long-term-care facilities. Your letter can only be based on a lack of knowledge or bias, and will endanger the lives of our most vulnerable.

Under federal law, Nevada may not prohibit or effectively prohibit such testing at congregate facilities. While we welcome the opportunity to discuss your concerns with those two tests, the U.S. Department of Health and Human Services will take appropriate steps if you do not cease the improper unilateral prohibition.

Your letter directs healthcare providers and long-term-care facilities "to immediately discontinue the use of *all* COVID-19 point of care (POC) antigen tests until the accuracy of the tests can be better evaluated." (Emphasis added). Your letter specifically questions the positive predictive value of the Quidel Sofia and BD Veritor antigen POC tests. Your letter does not question the negative predictive value of those tests. As discussed below, your action is inconsistent with and preempted by federal law and, as such, must cease immediately or appropriate action will be taken against those involved.

The Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for both the Quidel Corporation (Quidel) Sofia and Becton, Dickinson and Company (BD) Veritor antigen POC tests for use on individuals suspected of COVID-19 by their healthcare provider, as set forth in those EUAs, and concluded, "Based on the totality of scientific evidence available to FDA, it is reasonable to believe that [those products] may be effective in diagnosing COVID-19, and that the known and potential benefits of [those] product[s] when used for diagnosing COVID-19, outweigh the known and potential risks of [those] product[s]."

The instructions for use for these tests reflect that the sensitivity and specificity of the Quidel Sofia and BD Veritor antigen POC tests are as follows:

- Quidel Sofia: 96.7% sensitivity and 100% specificity[1]
- BD Veritor: 84% sensitivity and 100% specificity.[2]

Your letter complains that the FDA relied on "extremely limited data," and directs all providers and facilities to immediately cease using *all* antigen POC tests. That directive was based on 39 positive antigen test results where the confirmatory RT-PCR test yielded negative results in 23 of the 39 instances. Your letter speculates—but does not verify—that those "conflicting test results" could have been due to "lack of compliance with the manufacturer's protocols[,] inadequate training on the testing

[1] https://www.fda.gov/media/137885/download (Nevada's October 2 letter incorrectly noting "87% sensitivity").
[2] https://www.fda.gov/media/139755/download. (Nevada's October 2 letter incorrectly noting "97.5% sensitivity").

procedure, or false negatives with the confirmation RT-PCR test especially if the confirmatory PCR test could not be performed within 48 hours of the positive antigen test."

Your letter correctly notes the scientific truth that "low prevalence and incidence of COVID-19 within a community may result in higher rates false positive tests." But your letter neglects to mention that such false positives will occur with *any* test, including PCR tests. Basic clinical science and guidance from the Centers for Disease Control and Prevention (CDC) underscores the unsound basis for your prohibition. *See* Attached. Additionally, your prohibition ignores the overwhelming preponderance of models demonstrating that frequent POC results—even with lower sensitivity and specificity—are superior to infrequent or long turnaround PCR tests at preventing infections and deaths. Lastly, your prohibition ignores the recent data on the superiority of antigen tests at predicting actual infectivity—the key issue.

In short, your directive to prohibit *all* POC antigen testing at long-term-care facilities and to seemingly call into question the FDA's conclusions in its EUAs for two POC antigen tests are based on speculation. Your prohibition conflicts with the August 31, 2020 issuance from the Office of the Assistant Secretary for Health,[3] which extended coverage under the Public Readiness and Emergency Preparedness Act (PREP Act)[4] to licensed health-care practitioners prescribing or administering POC COVID-19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the nation. Such tests must be authorized, approved, or cleared by the FDA (collectively, FDA-authorized COVID-19 tests).

The Quidel Sofia and the BD Veritor tests are FDA authorized. Furthermore, FDA has provided information to health care providers who are using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals. And the Centers for Medicare & Medicaid Services (CMS) has set forth guidelines for using antigen tests at congregate-care settings on both symptomatic and asymptomatic individuals.

According to FDA, [f]or licensed health care providers who are prescribing or ordering an authorized SARS-CoV-2 diagnostic test to be used off-label (outside the authorization) to screen asymptomatic individuals not suspected of having COVID-19, we recommend they consider the information below, as well as HHS guidance on PREP Act coverage.

Although the current available literature suggests that symptomatic individuals with COVID-19 and asymptomatic individuals without known exposure may have similar levels of viral genetic material, there is limited data on the distribution of viral loads in individuals with and without symptoms across demographics, different settings, and specimen types. Therefore, when screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as "off-label"). For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times.[5]

[3] https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf.
[4] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 Fed. Reg. 15198 (Mar. 17, 2020).
[5] General FAQs, Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?, available at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general, (last visited Oct.. 2, 2020).

CMS, which enforces the Clinical Laboratory Improvement Amendments of 1988 (CLIA), has concluded that [it] requires facilities with a CLIA Certificate of Waiver to follow the manufacturer's instructions (Instructions For Use) when performing laboratory testing. The FDA has granted EUAs to certain antigen tests for testing specimens from individuals who are suspected of COVID-19 by their health care provider within a number of days after the onset of symptoms, specific to each authorized test's validated performance. The FDA has provided recommendations for health care providers who are ordering authorized tests outside their authorization (e.g., antigen tests for asymptomatic individuals)—see FDA's FAQ on Testing for SARS-CoV-2 ("Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?") for further information.

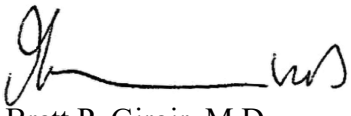
CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the FDA FAQ.[6]

Consistent with the above, the Assistant Secretary for Health extended PREP Act coverage to licensed health-care practitioners prescribing or administering FDA-authorized COVID-19 tests, including for off-label (outside the authorization) use to screen asymptomatic individuals in congregate facilities. Under federal law, that PREP Act coverage preempts any state or local provision of law or legal requirement that prohibits or effectively prohibits such licensed health-care practitioners from administering or prescribing FDA-authorized COVID-19 tests to symptomatic or asymptomatic individuals at congregate facilities.[7]

The nation needs more, not less testing, especially in congregate settings. And, as the FDA has stated, "For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times."

Your Department's across-the-board ban on POC antigen tests in such settings is based on speculation. It may cost lives. And it is also improper under the PREP Act. We will inform the relevant stakeholders in Nevada.

Sincerely yours,

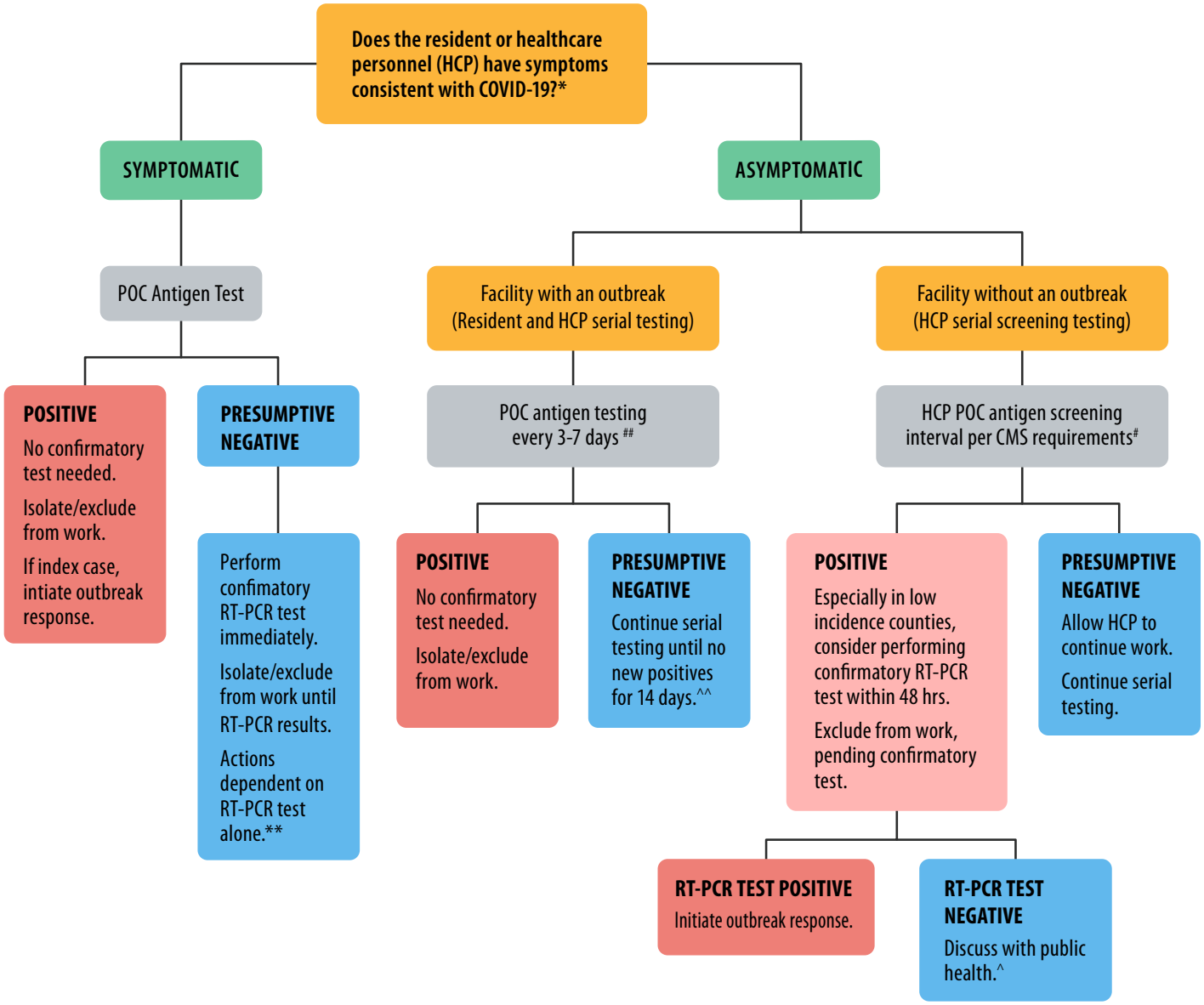


Brett P. Giroir, M.D
ADM, USPHS

[6] What is CMS's policy regarding laboratories performing antigen tests authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for use at the point of care (POC) or in patient care settings operating under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate of Waiver on asymptomatic individuals?, available at https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf (last visited Aug. 29, 2020).

[7] *See, e.g.*, Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, available at https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf (last visited Aug. 29, 2020).

CONSIDERATIONS FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES



This algorithm should be used as a guide, but clinical decisions may deviate from this guide if indicated. Contextual factors including community incidence, characteristics of different antigen testing platforms, as well as availability and turnaround times of RT-PCR, further inform interpretation of antigen test results.

RT-PCR: reverse-transcriptase polymerase chain reaction
POC: point-of -care
HCP: healthcare personnel
Index case: a newly identified case of SARS-CoV-2 infection in a resident or HCP in a nursing home facility with no known infections of SARS-CoV-2 infection in the previous 14-day period.
COVID-19 outbreak response in a nursing home is triggered when one nursing home-onset SARS-CoV-2 infection in a resident or one HCP SARS-CoV-2 infection.

* Asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing do not need to be retested. If an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

** Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if retesting by RT-PCR is warranted.

CMS recommendations for testing asymptomatic HCP in facilities without a case

CDC guidance on testing residents of nursing homes. CDC guidance on testing HCP

^ In discussion with the local health department, community incidence and time between antigen test and RT-PCR test can be utilized to interpret discordant results and determine when HCP can return to work.

^^ If an antigen test is presumptive negative in a facility with an outbreak, residents should be placed in transmission-based precautions or HCP should be allowed to continue working while monitoring for symptoms.

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cdc.gov/coronavirus