



U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
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Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States.¹ The United States Department of Health and Human Services (HHS) is the lead agency for the federal government’s response to the COVID-19 pandemic.

A key component of that response is rapidly expanding COVID-19 testing across America. Within HHS, the Office of the Assistant Secretary for Health leads federal efforts to support that expansion. Enhancing the safety of nursing homes, assisted-living facilities, long-term-care facilities, and other facilities where people congregate to receive care or education or to work (collectively, “congregate facilities”) is critical for our Nation’s response to the COVID-19 pandemic. Testing for COVID-19, including those who are asymptomatic, is a key part of that effort.²

¹ The Secretary’s declaration of a public health emergency was retroactively effective on January 27, 2020.

² *See, e.g.*, Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel, available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html> (last visited Aug. 29, 2020) (explaining that, in addition to nursing homes, “testing residents with signs or symptoms of COVID-19 and testing asymptomatic close contacts should also be applied to other long-term care facilities (e.g., assisted living facilities, intermediate care facilities for individuals with intellectual disabilities, institutions for mental disease, and psychiatric residential treatment facilities)”); Testing in Institutions of Higher Education, available at <https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html> (last visited Aug. 29, 2020) (“In areas with [moderate to substantial community transmission](#) where resources allow, local health officials and [institutions of higher learning] may consider testing some or all asymptomatic students, faculty, and staff who have no known exposure (e.g., students in congregate housing such as residence halls) to identify outbreaks and inform control measures.”); Testing asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings, available at <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html#testing-3> (last visited Aug. 29, 2020) (“Viral testing of workers without symptoms may be useful to detect COVID-19 early and stop transmission quickly, particularly in areas with [moderate to substantial community transmission](#).”).

Both the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have issued guidance and provided other information regarding screening asymptomatic individuals, including in congregate settings.

According to FDA,

For health care providers who are 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. 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.³

CMS 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 Emergency Use Authorizations (EUA) to certain antigen tests for testing specimens from individuals who are suspected of COVID-19 by their healthcare 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](#).⁴

Therefore, as an Authority Having Jurisdiction under the Secretary’s March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act),⁵ Assistant Secretary for

³ 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 Aug. 29, 2020).

⁴ 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).

⁵ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical

Health, Admiral Brett P. Giroir, M.D., extends coverage under the PREP Act to licensed health-care practitioners prescribing or administering point-of-care 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).

PREP Act coverage encompasses 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.⁶

In addition to the requirements set forth herein, licensed health-care practitioners must comply with the requirements of the PREP Act and the conditions of the Secretary's declaration under the PREP Act in order to receive PREP Act coverage.⁷

This 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.⁸

Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020).

⁶ FDA determines the scope of on-label authorization.

⁷ *See, e.g.*, Advisory Opinion 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/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Aug. 29, 2020).

⁸ *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).