



**Statement to the Clinical Laboratory Improvements Advisory Committee on the
Expansion of Point-of-Care Testing, Self-Collection, and
Self-Testing in the Age of COVID-19**

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Clinical Laboratory Improvements Advisory Committee (CLIAC) on the topic of Expansion of Point-of-Care Testing (POCT), Self-Collection, and Self-Testing in the Age of COVID-19. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating for excellence in the practice of pathology and laboratory medicine worldwide.

No test is so simple and straightforward to perform that erroneous results cannot occur, or an incorrect result is "risk free" or inconsequential with regard to potential harm. However, point-of-care testing, self-collection, and at-home tests are important tools for helping slow the virus over the next few months until most Americans can get the vaccine. Among these rapid tests, each plays a role in helping frontline workers diagnose COVID-19 from POCT used in urgent care clinics and doctors' offices to at-home testing used in telehealth services. Detection in a variety of settings is needed since spill-over infections in the local community or across state borders can cause clusters or outbreaks of COVID-19 occurring. These tests can help detect infections in these settings that may go unnoticed for some time, posing a risk to the individuals in the setting, particularly those who are more vulnerable to SARS-CoV-2, and to the wider community. Early identification of clusters, isolation of cases and notification of contacts can prevent further spread within these settings and to the wider community.

CLIA requirements for POCT are clearly established, but at-home testing has caused some confusion because there are some tests that are approved for "at-home" collection, but the sample itself is sent to a central laboratory facility for actual testing. Some tests are now authorized for at-home collection and testing, and these tests include antigen tests and nucleic acid amplification tests, or molecular tests.

To further complicate matters, the Centers for Medicare and Medicaid Services (CMS) released guidance providing a temporary waiver for some of these tests, exempting them from certain aspects of CLIA. For example, SARS-CoV-2 surveillance testing can be performed in a facility that is NOT CLIA certified provided that patient-specific results are not reported. However, if patient specific results are reported, CLIA certification and compliance is required. Given the settings requiring COVID-19 testing, confusion abounds as to the appropriate testing as well as regulatory requirements associated with testing for certain settings.

CLIA should be required for POCT testing regardless of the settings. At home specimen collection and at home tests should have clear labeling prohibiting their use in settings outside of the home since many of these results will not be in the patient's medical records. We support wider and earlier SARS-CoV-2 testing of clusters, to isolate cases and notify contacts to prevent further spread within these various settings and to the wider community, but more guidance is needed that is tailored for non-laboratorian communities defining each type and use of these tests, explaining the differences, and the regulatory implications associated with them.

Thank you for the opportunity to comment and the CAP looks forward to working with CLIAC, federal officials, and the clinical laboratory community to develop solutions for COVID-19 and any future pandemics.