

## May 15, 2020: Advocacy spotlight on AMA cautions physicians, public about limitations of antibody testing for SARS-CoV-2

With a growing number of tests claiming to identify people who have been exposed to SARS-CoV-2 and potentially immune to COVID-19, the AMA announced guidance to help ensure physicians and the general public are aware of the limitations and potential uses of serological testing, also known as antibody testing. Through the new guidance, the AMA cautions physicians and the general public about using these tests to determine individual immunity and warns that the discontinuation of physical distancing should not be made on the basis of antibody test results. "Given that we do not yet have scientific evidence showing if, when and for how long individuals might become immune to COVID-19, physicians and the general public should not use antibody testing to consider anyone immune to the disease—doing so may lead individuals to falsely assume they can stop physical distancing and further the spread of illness," said AMA President Patrice A. Harris, MD, MA. "Although many are using these tests to determine whether an individual had COVID-19, we encourage physicians to only use antibody tests authorized by the Food and Drug Administration (FDA) and only for the purposes of population-level studies, evaluating recovered individuals for convalescent plasma donations, or along with other clinical information as part of a well-defined testing plan for groups or individuals." The AMA's new guidance provides physicians and the general public with an overview of the current state of antibody testing for SARS-CoV-2, including their limitations, potential uses, and how they are and are not regulated. This guidance can be found online as part of the AMA's COVID-19 Resource Center. While antibody tests may play an important role in determining the overall prevalence of COVID-19 in the U.S. population, including asymptomatic infection, inherent limitations exist in using them to identify prior infection in individuals. Many of the antibody tests currently on the market may return a significant number of false positive results, as well as show cross-reactivity—meaning the tests also identify antibodies for other coronaviruses, such as those causing the common cold. Given these limitations, the AMA recommends that currently available antibody tests not be used as the sole basis of diagnosing COVID-19, and not be offered to individuals as a method of determining immune status, and not be used to inform decisions such as returning to work, discontinuing physical distancing, or as the basis for "immunity certificates." Additionally, concerns continue to mount about the performance and fraudulent labeling of many of the SARS-CoV-2 antibody tests currently available. The vast majority of more than 120 tests on the market have not been authorized by the FDA, despite marketing claims to the contrary. The AMA urges physicians to pay close attention to the regulatory status of all available SARS-CoV-2 antibody tests. A list of all antibody tests authorized by FDA for SARS-CoV-2 can be found on FDA's website. The AMA continues to recommend physical

distancing to reduce the spread of COVID-19. However, there are marginalized and minoritized patient-communities disproportionately impacted by COVID-19 and their housing or employment status may make it difficult to adhere to physical distancing recommendations. The new guidance calls for providing messaging to medically underserved communities that explicitly takes into consideration the cultural and social features affecting their ability to make long-term choices on physical distancing and other COVID-19 precautions. The AMA will continue to provide resources to physicians and physicians-in-training to help prepare them to care for patients as the pandemic evolves and protect themselves and their patients from illness. These resources are available on the AMA COVID-19 Resource Center.

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