

# AMA to Congress: Antibody tests not the path back to “normal life”

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Serology tests used to detect the presence of COVID-19 antibodies should not be used to guide individual decisions that could put a person at higher risk of exposure and infection. That is the clear message that AMA experts are sending to Congress and the nation.

“We know that many are anxious to return to ‘normal life’ and discontinue physical distancing,” said Jesse Ehrenfeld, MD, immediate past chair of the AMA Board of Trustees. “But given that antibody tests too often return false-positive results and we know very little about what immunity a COVID-19 infection actually confers, we currently do not recommend that antibody tests be used by individuals to make decisions about their path forward.”

Dr. Ehrenfeld, an anesthesiologist and senior associate dean at the Medical College of Wisconsin, spoke during an online video briefing held by the U.S. House Committee on Oversight and Reform’s Subcommittee on Economic and Consumer Policy.

“We recognize that serology tests have a number of limitations that may result in actual harm to public health,” Dr. Ehrenfeld said. “In particular, the AMA is concerned about the possibility of COVID-19 serology tests returning false-positive results, leading individuals into thinking they may have immunity to COVID-19 when they in fact do not.”

The briefing, entitled “COVID-19 antibody testing: Uses, abuses, limitations and the Federal Response,” detailed the tests’ valid public health uses, the lack of normal Food and Drug Administration (FDA) regulatory scrutiny and how new Centers for Disease Control and Prevention (CDC) guidelines align with those developed by the AMA.

“When used properly, accurate, reliable antibody tests hold great promise,” said Rep. Raja Krishnamoorthi, D-Ill., chair of the subcommittee, who noted that demand for these tests “is sky high,” even though that demand is being met by 192 products being sold without the standard FDA review.

“The truth is many people mistakenly view antibodies as a ‘Get out of jail free card’ to return to daily life,” Krishnamoorthi said. “People who mistakenly think that they are immune will stop taking precautions—risking infection to themselves and risking the spread of disease to others.”

Keep current on the public health emergency with the AMA's COVID-19 resource center, which offers a library of resources from JAMA Network, the CDC and the World Health Organization.

## **CDC, AMA align on testing guidelines**

The AMA released guidance on the use of serology testing that noted its limitations and the high risk of false-positive results. Read more about the three big limitations of SARS-CoV-2 serology tests that doctors must understand.

In the briefing, Dr. Ehrenfeld discussed how points raised by the AMA were incorporated into the CDC's updated serology test guidelines.

“In its update, the CDC notes ongoing concerns about poor performance among many of the serology tests currently available on the market, including the significant possibility for false-positive results,” he said. “The AMA concurs with CDC recommendations that serology tests not be used as the basis for making policy, returning to work, or for decisions about housing or congregating groups of people.”

Dr. Ehrenfeld added that the AMA would fully support the FDA incorporating these concerns into the fact sheets it distributes to physicians and patients.

## **Appropriate uses for serology tests**

The three uses for serology testing the AMA considers “important and appropriate” were outlined in Dr. Ehrenfeld's remarks:

- | Population-level seroprevalence studies.
- | Evaluation of convalescent plasma donors.
- | Medically necessary, well-defined testing plans for patients working with physicians.

The other speakers at the hearing noted that, while the utility of serology testing for individuals is currently low, it does have value in the realm of public health—especially for tracking the spread of COVID-19 and its impact on populations in terms of hospitalizations and deaths.

The tests also hold potential for public health decision-making such as allocation of personal protection equipment, mitigation efforts and “ultimately, vaccine procurement and prioritization,” said Gigi Gronvall, PhD, senior scholar and associate professor at the Johns Hopkins Bloomberg School of Public Health’s Center for Health Security.

Questions raised by the AMA regarding the level of protection provided by antibodies were noted at the hearing. These include how it’s still not clear when an immune response develops after a COVID-19 infection, how strong this immune response may be and how long the immune response may last.

Read how providing additional guidance and education to physicians and the public regarding serological testing, its performance limitations and the risk for false positives is part of the AMA national strategy for COVID-19 testing.