

Issue Brief » Antibody Testing for SARS-CoV-2/COVID-19

SUMMARY » The SARS-CoV-2 global pandemic has had far reaching implications for people across the globe. In the United States, this outbreak has exposed widespread failures in the ability of our nation to respond to a major infectious disease threat. The spread of SARS-CoV-2 has been exacerbated by long-term dysfunction not only our health care system but also our social safety nets. Trillions of dollars have been spent in attempts to sustain corporate profits and stock market values. With so many out of work and business revenues stalled there is an aggressive push to “reopen the country”. Steps taken towards this goal must be guided by scientific evidence and prioritize protecting public health. The national and international discourse has turned to wide-spread antibody testing as a possible pathway to ending social distancing measures. Frontline health care workers are slated to be among the first to be tested. It is paramount that any steps taken are carefully weighed against the potential far-reaching consequences. For those who may be expected to enter the workforce, premature reliance on serology testing could have deadly consequences and undermine efforts to control the spread of infection.

BACKGROUND

The novel coronavirus, SARS-CoV-2, was identified in December 2019 as the cause of an outbreak of viral pneumonia. The virus spread rapidly around the world and a global pandemic was declared on March 11, 2020. The response has varied widely between countries and, within the United States, between states. While some countries have successfully prevented widespread outbreaks, the United States now has the most cases and deaths.¹

The United States’ response to SARS-CoV-2 has been inadequate in many ways. Testing has been largely unavailable, contributing to delays in surveillance, diagnosis, and isolation. Widespread shortages and rationing of personal protective equipment (PPE) have led to high rates of infection in health care workers and

other essential workers. Many but not all states have issued stay-at-home orders, an essential step in preventing transmission. Delays in implementing social distancing policies by some models may have increased the death toll during this first-wave of infection by up to 60 percent.² Trillions of dollars have been funneled into Wall Street while millions of unemployed have yet to receive any relief. The United States’ response to SARS-CoV-2 has failed and continues to fail by any number of measures.

In contrast, other nations were prepared for the SARS-CoV-2 virus. Several countries acted with a robust and coordinated response that adeptly contained the spread of infection and are now seeing rapid declines in new cases.³

Objectively, the inability to produce and implement widespread diagnostic testing has created one of the biggest obstacles to a successful response in the United States. With SARS-CoV-2 now wide-spread throughout the United States, limited availability of diagnostic tests, and high rates of false negative test results the window for actively surveilling how many people have been infected with SARS-CoV-2 has largely passed in the first wave of infections. This situation creates several challenges in the ability to move forward. It is essential that eagerness to move forward does not once more ignore basic scientific principles.

This issue brief explores the current narrative on plans to “reopen the economy,” which largely focus on using antibody testing.

POLICY MAKERS FOCUS ON ANTIBODY TESTING AS KEY ELEMENT IN PLANS TO “REOPEN THE ECONOMY.”

Recently, much of the discussion has turned to how stay-at-home orders will be lifted and businesses reopened. This discussion relies heavily on widespread antibody testing. Antibody testing measures antibodies that may be produced in response to pathogens, which is part of the immune response to the virus. These antibody tests are distinct from the RT-PCR tests used so far that measure viral particles and determine active infection only. There are different types of antibodies that emerge at different points in an infection and play different roles in the immune response.⁴ The immune system is complicated and not fully understood. This is especially true for SARS-CoV-2.

Important points to know:

- » Antibody testing is not the same as establishing immunity.
- » It may be years before we understand immunity to the novel pathogen, SARS-CoV-2.
- » We are already seeing misuse of the terms. Policy makers are acting as

though antibody testing and establishing immunity are interchangeable.

For example, Governor Newsom of California said in his April 6 briefing that antibody testing will be “foundational, fundamental” to sending Californians back to work.⁵ Governor Cuomo of New York and others have made comments along these same lines.⁶

Along with antibody testing, policy makers are discussing rolling out “immunity documentation,” including immunity certificates, passports, or cards. Under these proposals, people would be required to carry with them “immunity documentation” to prove their antibody test status. Dr. Fauci, director of the National Institute of Allergy and Infectious Diseases and member of the White House Coronavirus Task Force, recently discussed antibody testing on CNN:

“Within a period of a week or so, we are going to have a rather large number of tests that are available,” Dr. Anthony S. Fauci, the leading infectious disease expert in the U.S., said Friday morning on CNN. He said the White House coronavirus task force was discussing the idea of “certificates of immunity,” which could be issued to people who had previously been infected. “As we get to the point of considering opening the country,” Dr. Fauci said, “it is very important to understand how much that virus has penetrated society.” Immunity certificates, he said, had “some merit under certain circumstances.”⁷

Similar programs have been proposed in Italy, the United Kingdom, Germany, and other countries.^{8 9 10}

These decisions are being made on a very short timeframe and with inadequate information. The ways that antibody testing is being discussed raise several serious concerns that are outlined in this issue brief.

1. A positive antibody test does not mean someone is immune. There is still a lot we do not yet know about how SARS-CoV-2 impacts the immune system.

Knowledge about SARS-CoV-2 is growing but there is insufficient information available especially regarding the immune response to this virus. The virus was identified in December 2019 and has only been studied for four months. There is, therefore, no information available on long-term immune response or immunity.

There are some questions that must be asked about this virus before antibody testing is used to inform policies that relax physical distancing protections:

How long do symptoms last?	Information is still being gathered. ¹¹
How long can someone be infectious?	People with SARS-CoV-2 can be infectious without symptoms, before symptoms manifest, and possibly for several days to several weeks following recovery. ^{12 13 14}
Does having antibodies mean someone is not infectious?	No, having antibodies does not mean someone is no longer infectious for SARS-CoV-2. ^{15 16 17}
Does having antibodies mean someone is immune?	A positive antibody test does not necessarily mean a person is immune to SARS-CoV-2. ^{18 19 20}
Once someone has recovered from a SARS-CoV-2 infection, can they get it again?	There are multiple reports of people testing positive after recovery and negative tests for SARS-CoV-2. We do not yet know if this is due to re-infection or recurrence of prior infection. ^{21 22 23 24 25}

2. Oversight of antibody tests is lacking. Test results may not be reliable.

Unlike RT-PCR tests, the U.S. Food and Drug Administration (FDA) does not require review and approval for new SARS-CoV-2 serological tests, including tests for antibodies.²⁶ This lack of oversight means that it is unclear how reliable the tests are. Tests may produce high numbers of false negatives or high numbers of false positives. Some tests are not specific to SARS-CoV-2 and may measure antibodies to any coronavirus, including those that cause the common cold.

Companies conducting the test are supposed to include a statement with the results with some disclaimers, but enforcement of this minimal requirement is unclear and there are reports that it is not happening: “Promotional emails sent to hospitals and reviewed by The Associated Press failed to include required disclaimers. Some kits sold on websites promote themselves as ‘FDA-approved’ for home testing. The agency has not yet approved any COVID-19 home test.”

The CEO of the Association of Public Health Laboratories, Scott Becker, told CNN that his labs would not use the antibody tests on the market due to concerns about inaccurate results and lack of FDA oversight. “It could be quite dangerous,” he said.

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the market due to concerns about inaccurate results and lack of FDA oversight. “It could be quite dangerous,” he said.²⁸

Further, the type of antibody that the test measures matters. Different antibodies show up at different points in an infection.²⁹ Not all tests measure the same antibodies and most tests do not measure everything. Some tests are not even specific to SARS-CoV-2 and instead measure antibodies for any coronavirus, including those that cause the common cold.

In short, antibody tests may not even effectively measure antibodies for SARS-CoV-2.

3. Misuse of antibody tests may have dangerous ramifications for containing spread of SARS-CoV-2.

Equating a positive antibody test result with immunity is an irresponsible and unscientific way to use antibody tests given current scientific knowledge. However, in the push to reopen businesses and release stay-at-home orders, many policymakers continue to make this assumption. Using antibody tests to indicate immunity status may lead to unsafely returning workers to work because they are considered “immune”:

- » Could lead to exposure to workers who are not immune, which will result in further spread of the virus.
- » Could lead to exposure to others from workers who are still infectious. Testing for antibodies in the first ten days or so of infection will not identify that the worker has an active infection and is infectious. Antibody testing to determine return-to-work would not identify asymptomatic or pre-symptomatic infections.

And yet, some testing manufacturers make broad claims about antibody test results. For example, one lab tailors materials to “Employers who would like to see what portion of their workforce is potentially immune/non-infectious.”³⁰ It is worth noting that this lab also states, “Positive results may be due to past or

present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.”

4. Targeting health care workers for antibody testing raises ethical concerns. Health care employers must not use antibody testing to remove or downgrade protections for nurses and other health care workers.

Many reported plans to roll out and study antibody testing have singled out health care workers as priority:

- » The director of the CDC, Robert Redfield, indicated in an interview with media that antibody tests could be used by hospitals to select and place health care workers during a second wave of COVID-19 patients expected later this year.³¹
- » Codirector of the clinical lab at a large hospital in San Francisco stated: “If a health care worker has the antibodies, then they would be at [a decreased] risk of acquiring the virus, so they could potentially be more on the frontline of fighting this and helping those that are infected acutely.”³²
- » The Chief Medical Officer of a laboratory company, which is performing testing for a health care system and university in Utah, stated, “At this point, I think the target is health care workers who have been exposed perhaps to the disease...To try to determine if they have become infected with the virus and likely developed immunity in case they have not presented symptoms. That will allow us to identify individuals who have developed immunity against the infection, who could potentially go back to work.”³³
- » A large health care system in Michigan is also focusing on health care workers in rolling out antibody testing.³⁴

- » Large health care systems in Minnesota also reported making plans to use antibody tests for statewide surveillance and starting using them with health care workers.³⁵

This trend echoes what we have seen in other countries using and proposing wider antibody testing. Health care workers in Italy were the first to be tested for antibodies.³⁶ United Kingdom had proposed a similar program to roll out antibody testing for health care workers first, but have since announced that none of the 17.5 million antibody tests purchased work well enough to be used.^{37 38}

Lacking and inadequate personal protective equipment (PPE) has been a significant and ongoing issue that jeopardizes the health and safety of nurses, their patients, colleagues, and families, and ultimately our communities. Throughout the pandemic, nurses and other health care workers have identified a clear pattern where their employers move to the lowest possible standard of protection.

Hospitals and other health care employers may use a positive antibody test result, equated inappropriately with immunity, to rationalize removing or downgrading protections for nurses and other health care workers. This is unacceptable.

There is, in fact, a history of employers using presumed immunity to excuse removing protections. During the 2014-15 Ebola outbreak in West Africa, survivors who had recovered from Ebola were sent into Ebola Treatment Centers, without full PPE, to provide care to patients with Ebola (see photo where a survivor with no PPE works alongside a worker with full PPE).³⁹
⁴⁰ Even with Ebola, recovering from an infection does not guarantee immunity.⁴¹

The targeting of health care workers in these studies to learn more about immunity and antibody testing raises serious ethical concerns. The lack of protective PPE plus concerted targeting of antibody testing essentially amounts to a widescale experiment being conducted on nurses and other health care workers without their consent.



5. The use of any form of “immunity documentation” to determine return-to-work or lifting of stay-at-home orders would further deepen racial and economic disparities in the United States.

The use of “immunity documentation,” including immunity certificates, passports, cards, etc., has been proposed in other countries and is being discussed in the United States as a way to reopen the economy faster. “Immunity documentation” policies rely on the inappropriate assumption that a positive antibody test means immunity for SARS-CoV-2; this is a novel virus and currently insufficient scientific knowledge exists to support this assumption.

Antibody testing is likely to follow the same patterns that we have seen with RT-PCR testing, which has been fraught with issues since the beginning:

- » First, the CDC’s testing was extremely limited, then it was faulty.⁴²
- » Testing and testing materials have been of short supply and private companies have overpromised testing capacity and many states have seen tens of thousands of tests pending results for weeks.^{43 44}
- » With the limited supply of PCR tests, we have seen celebrities and government officials have easy access to testing while frontline health care workers and many patients have been denied tests.⁴⁵

Further, testing has not been equitably available across the United States:

- » In some places like Shelby County, Tennessee, RT-PCR testing has been available in white neighborhoods but not in black neighborhoods.⁴⁶
- » Philadelphia and other places across the United States have shown similar disparities in where testing has been made available, where suburban drive through testing centers have been set up and urban centers neglected.⁴⁷
- » African-Americans have been less likely to be referred for testing when they show up for care with signs of infection, which is part of a larger and long-standing pattern where Black and Indigenous People of Color are less likely to get needed care and more likely to have worse outcomes.⁴⁸
- » According to the U.S. Department of Health and Human Services, non-hispanic blacks are less likely to have health insurance and more likely to be uninsured than non-hispanic whites, which may additionally impact access to testing for SARS-CoV-2.⁴⁹

With use of “immunity documentation,” disparities in who has access to antibody testing may result in a disparities in who is allowed to return to work.

Increasing unemployment related to COVID-19 has been unequal. According to the U.S. Bureau of Labor Statistic, unemployment rates rose 6.7 percent for Blacks, 6.0 percent for Hispanics, and 4.0 percent for whites in March 2020 alone.⁵⁰ The stark racial disparities in COVID-19-related unemployment mean that testing disparities would further amplify economic disparities.

Even if employers were to offer or require antibody testing directly to employees, there would continue to be disparities in exposure, infections, and deaths.

- » We do not know that a positive antibody test means that a worker is immune.
- » We can expect that certain jobs will be pressured to use “immunity documentation” sooner, including health care, grocery workers, other food service workers, retail workers, and manufacturing workers.
- » There are already stark disparities in who can work from home: 30 percent of white workers can telework compared to 20 percent of Black or African American workers.⁵¹
- » Significant disparities in household wealth, with the median Black family owning just 2 percent of the wealth the median white family owns, mean there will be unequal pressure on Black workers to return to work sooner.⁵²
- » The use of “immunity documentation” will likely continue to mean increased exposure, infections, and deaths among these workers.

These disparate impacts on Black workers as compared to white workers with the use of “immunity documentation” would likely further amplify health disparities of COVID-19. The CDC recently reported data that showed that black populations are disproportionately affected by COVID-19. While 59 percent of the catchment population is white, 18 percent is Black, and 14 percent Hispanic, 45 percent of COVID-19 hospitalizations were White, 33 percent Black, and 8 percent Hispanic.⁵³ Several states have now started reporting data on COVID-19 deaths and race and Black patients are dying at higher rates than others from COVID-19.⁵⁴ These racial disparities in COVID-19 hospitalizations and deaths reflect long-standing health disparities where Black populations experience higher rates of diabetes, asthma, kidney disease, heart disease, lung disease, and other co-morbidities associated with increased severity of COVID-19, caused by racism, economic disparities, housing disparity, environmental pollution, and other causes of inequality.

CONCLUSION

In conclusion, antibody testing requires further analysis and discussion.

Before antibody testing is used to determine any policy, more investigation is needed to better understand the interactions between SARS-CoV-2 and the immune system, reliability of antibody tests, and other elements related to SARS-CoV-2.

Based on what we do currently know, nurses know the following measures must be put in place to better manage the SARS-CoV-2 pandemic and prevent further transmission:

- » Workplace protections for nurses and other health care workers, with the highest level of protection as determined by the precautionary principle.
- » Congress and the Trump Administration to invoke the Defense Production Act to mobilize a much broader and bigger manufacturing push to produce the N95s and other gear we need now and in the long term.
- » Widespread RT-PCR testing of both asymptomatic and symptomatic individuals to ensure prompt recognition and response to all possible COVID-19 infections.
- » Rigorous contact tracing to identify all people who may have been exposed to a confirmed case, ensuring that those individuals are isolated, and that further transmission is stopped.
- » Coverage of all treatment, care and services for people with potential COVID-19 infection who are uninsured or underinsured, including for insured patients who are denied coverage. This should include funding for widespread communication to the public that all testing, treatment, and other health care services related to COVID-19 will be paid for regardless of their insurance status.

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