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BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

BinaxNOW antigen testing can be used in asymptomatic individuals. Is it ready for prime time?

A vital component of the public health response to covid-19, in addition to the ongoing vaccination process, is reducing transmission of SARS-CoV-2 between those who have not yet been vaccinated. Identifying sources of infection is imperative to achieve this goal, but as we have learned, those infected with SARS-CoV-2 can remain asymptomatic.

However, a possible breakthrough comes in BinaxNOW, a rapid antigen test that has received Emergency Use Authorization from the US Food and Drug Administration for testing those *with symptoms* concerning for covid-19. Now, a study published in the US Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report* this week addressed how well the test performed among asymptomatic individuals. (Note: we have written a ***glossary*** below to clarify some the necessary but technical terminology used when comparing the performance of diagnostic tests). The important thing to realize is that antigen tests like BinaxNOW are not meant to diagnose SARS-CoV-2 infection but, rather, to determine whether person taking the test is *contagious*.

If one were to ask the wrong question (i.e. how does BinaxNOW fare in diagnosing a coronavirus infection), the test would appear only half as good as the PCR test in asymptomatic individuals. Six out of 10 individuals with symptoms who were positive by the PCR test were also positive by the BinaxNOW test. Three out of 10 individuals without symptoms who were positive by the PCR test were also positive by the BinaxNOW test. That all sounds unimpressive. But when you look at whether or not the samples taken from test subjects were able to grow "culturable virus," (i.e. enough to be contagious) suddenly BinaxNOW does much better. The researchers found that the BinaxNOW was positive in 92.6 percent of the specimens that also were able to create culturable virus among symptomatic subjects. This means that the rapid test found 92.6 percent of the contagious cases. Meanwhile, the number was 78.6 percent in samples taken from asymptomatic persons. And that's on a single test. Test regimens that instruct people to do more than one test before drawing any conclusion would mean that the devices might correctly identify even more, and maybe nearly all, contagious people.

So, as long as the BinaxNOW test is understood and used properly, it could lead people to safely conclude they are not contagious, allowing more freedom of movement. Other advantages over the PCR (which are often positive for days or weeks after covid-19 patients are no longer contagious include the fact that it can be performed in 15-30 minutes; it also costs less than the PCR test. One drawback of the study is that it was performed by healthcare professionals. But it is plausible that individuals could perform the swabs themselves at homes.

Regarding the BinaxNOW and its overall ability to diagnose *any* infection, the authors point out that the Binax test does not go as deep into the nose as the PCR test. That alone may explain the superior performance of the PCR. We also note that the testing methodology is different (i.e. they test for different parts of the virus). The authors, nevertheless, conclude, that the speed of the test may help identify asymptomatic carriers in the community despite its relative lack of sensitivity in detecting infections. They should *not* be relied on to rule out infection. And one negative test is not enough, based on these data. Two or more in close succession would make the results even better.

***Glossary*:**

PCR Testing: Polymerase chain reaction (PCR) testing is a type of nucleic acid amplification test (NAAT). PCR amplifies DNA, meaning it increases the concentration of DNA in a sample. SARS-CoV-2 is an RNA virus, so first the sample must be cleaned and then converted to DNA. The conversion step (usually about an hour) and amplification steps (generally about 90 minutes) explain why PCR tests take longer than antigen tests.

Antigen: An antigen is a **foreign substance**, such as the coronavirus, that provokes the body to make reactive antibodies against the antigen. The antigen could in theory be anything, although it is often a protein fragment. **Antigen test**s look for the presence of the foreign substance. There are no conversion or amplification steps. This makes antigen tests quicker than PCR tests. But if there isn't enough antigen it can be as difficult to detect.

Antibody: An antibody is a **protein** that the body makes in response to a foreign substance. The antibody binds to the antigen, which makes it more attractive to the immune system. The binding of an antibody to an antigen is a form of "opsonization," which roughly translates to, "making a tasty side dish," in Greek.

—Michael Chary, MD PhD

POLICY BRIEFING

President Biden takes aim at coronavirus policies on day one.

President Biden wasted no time in taking aim at President Trump's covid-19 inchoate and ineffectual policies. Among the first executive actions signed by newly inaugurated President Biden yesterday was a mask mandate on federal property, a reversal from the Trump administration's stance. He also extended the federal eviction freeze, an action that newly sworn-in Director of the US Centers for Disease Control and Prevention Dr. Rochelle Walensky supported via Twitter later in the evening.

Biden installed Jeff Zeints as coronavirus response coordinator, a role intended to supervise vaccine and medical supply distribution and other aspects of the government's covid-19 response. The creation of this position comes as the United States reached another grim milestone: 400,000 deaths due to covid-19.

Another effort put forth by President Biden is his pledge to vaccinate 100 million people within the first 100 days of his administration. To come close to achieving this, improved manufacturing and distribution of the currently approved vaccines is needed. He may invoke the Defense Production Act (DPA), which many Senate Democrats have already called for in order to boost production of medical and testing supplies, personal protective equipment and vaccines. The Biden Administration will likely also call on states to expand the categories for residents eligible to receive a covid-19 vaccine.

After reversing many of the Trump administration's executive actions on his first day in office, including policies on immigration, the environment, and public health, it is clear that the Biden presidency will take a very different tack in many areas, including our course in the fight against covid-19. Clearly, the new administration sees a more active role for the federal government in fighting this pandemic. Now, we await the results.

—Miranda Yaver, PhD

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