# Serious Issues With At-Home Tests Pamela A. Popper, President Wellness Forum Health

On July 21, 2021, the Centers for Disease Control (CDC) announced that on December 31 the agency would be withdrawing its request to the FDA for Emergency Use Authorization (EUA) for the PCR test for detection of SARS-CoV-2, the virus that causes COVID-19. The CDC wrote that the agency was providing advance notice so that laboratories and institutions would have enough time to choose other tests approved by the FDA.<sup>1</sup>

On another CDC site, the agency promotes home tests for COVID-19 for people who have symptoms, or asymptomatic people who have been exposed to a person who has COVID-19, stating that home tests are "especially important" before gatherings with unvaccinated children, the elderly, or others at risk of serious disease. The CDC states several times on this site that testing is necessary even for vaccinated people, and that people who test positive should isolate and wear a mask if they are in contact with others regardless of their vaccination status.<sup>2</sup>

The CDC site recommends consulting the FDA's website for a list of at-home tests approved under an Emergency Use Authorization.<sup>3</sup> The tests are available at drug stores like Walgreens and CVS, and also can be obtained free from local health departments. One of the tests listed on the FDA's site is the BinaxNOW COVID-19 Antigen Self-Test, made by Abbott Labs.

#### **Major Concerns**

There are many reasons to be concerned about this test. A document called "Healthcare Provider Instructions for Use" includes this statement:

"Individuals should report their test result through the NAVICA app (created by Abbott and downloadable for free) and provide all results to their healthcare provider in order to receive appropriate care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities..."

In other words, if you test positive and notify a physician or other healthcare provider, your local health authorities will likely know about your positive test results too. Health departments might be collecting test results just because collecting data is one of the things they are supposed to do. They might be collecting this data in order to continue to generate fear by reporting cases to the media every day. Or they might be planning something else, such as monitoring people who test positive in order to make sure that they quarantine at home; or even removing people from their homes and taking them to a quarantine camp. This is already happening in other countries, and after having

our rights and freedoms taken away for almost two years now, it's no longer possible to trust government and health officials. Anything is possible.

But that's not all. The instructions document also includes this statement about the reagent solution used in the test:

"The Reagent Solution contains a harmful chemical...If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice."<sup>5</sup>

The chemical is sodium azide, and here are excerpts from a CDC website providing facts about sodium azide:

"Sodium azide is a rapidly acting, potentially deadly chemical that exists as an odorless white solid."

Sodium azide is best known as the chemical found in automobile airbags. An electrical charge triggered by automobile impact causes sodium azide to explode and convert to nitrogen gas inside the airbag.

Sodium azide is used as a chemical preservative in hospitals and laboratories. Accidents have occurred in these settings. In one case, sodium azide was poured into a drain, where it exploded and the toxic gas was inhaled (breathed in)

Sodium azide is used in agriculture (farming) for pest control.

Sodium azide is also used in detonators and other explosives

Following release of sodium azide into the air, you could be exposed by breathing in the dust or the gas that is formed.

Sodium azide can also enter the body and cause symptoms through skin contact.

An explosion involving sodium azide may cause burn injury as well as expose people to the toxic gas, hydrozoic acid.

Sodium azide prevents the cells of the body from using oxygen. When this happens, the cells die.

Sodium azide is more harmful to the heart and the brain than to other organs, because the heart and the brain use a lot of oxygen." $^6$ 

There's more, but I think you get the idea. Exposure to even a small amount of this substance may be harmful.

The first time I reviewed the instructions document, the directions for use were extremely confusing. Consumers must have complained, because within a few days eleven pages of instructions with pictures were added. I still found the directions very confusing.<sup>7</sup>

### **Efficacy**

If you can figure out how to test yourself without being harmed by the reagent, what can you expect?

Consumers are instructed that if their test is negative, they should wait 24 hours and take another test. Apparently you keep looking for COVID until you find it!

"...a negative test does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions... Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management."

"Positive test results do not differentiate between SARS-CoV and SARS-CoV-2." (In other words, you may test positive and NOT have SARS-CoV-2, the virus that causes COVID-19)

"Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing." Again, we look and look and look for COVID until we find it!!

There are several caveats about interpretation of results if the consumer is unable to follow the directions exactly, which, as I mentioned before, are complicated:

"False negative results may occur if a specimen is improperly collected or handled."

"False negative results may occur if inadequate extraction buffer is used (e.g., < 6 drops)."

"False negative results may occur if specimen swabs are not twirled within the test card."

"False negative results may occur if swabs are stored in their paper sheath after specimen collection."8

#### **Information Submitted to the FDA**

After reading this section, one might wonder why the FDA even bothered to pretend to review any data:

"The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations." The problem is that these are specific applications for which the test is being used – asymptomatic people and serial testing.

The PCR test was used as the comparator method. I have written extensively about limitations of the PCR test, which include a very high risk of false positives. For example, in 2006, massive PCR testing was performed at the Dartmouth Hitchcock Medical Center when it was thought that the medical center was experiencing an epidemic of whooping cough. Almost 1000 healthcare workers were furloughed until their test results were returned. Over 140 employees were told that they had whooping cough, and thousands of others who tested positive were given antibiotics and/or a vaccine for whooping cough.

Almost eight months later, employees received an email from the hospital administration which stated that the entire episode was due to PCR testing error. Not even one case of whooping cough was confirmed with a more reliable follow-up test, and it was determined that the employees just had a common cold, not whooping cough.<sup>9</sup>

In other words, the error rate was 100%.

## Mr. Fauci admitted such $\,$ limitations of the PCR test in a podcast in July 2020. $^{10}$

"The performance of BinaxNOW COVID-19 Antigen Self Test was established with 53 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19."11

There is more "evidence" for the validity of the test in the document, but none of it justifies approving the use of this test in any situation, let alone for mass distribution.

#### The Bottom Line

There are significant risks associated with taking this test:

If you report your meaningless results, your status might be used by the government to regulate your activity or confine you; or perhaps even to force vaccinate you or make your return to regular life contingent on a booster shot.

Your meaningless test results may also be used by your local health department to determine the rules and restrictions in your area.

A negative test is meaningless, and you may be mandated to repeat the test or subject yourself to other tests in a medical setting. The intent seems to be to record as many "cases" as possible.

A positive test also is meaningless since the test cannot distinguish between SARS-CoV-2 and SARS-CoV.

People falsely thought that ending the use of PCR testing would put a stop to some of the COVID nonsense, including the false positives that allow the government to justify its tyrannical actions. Not true. It appears that the new tests are as bad or worse.

<sup>&</sup>lt;sup>1</sup> Centers for Disease Control Division of Laboratory Systems. 7/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing. <a href="https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-changes">https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-changes</a> CDC RT-PCR SARS-CoV-2 Testing 1.html

<sup>&</sup>lt;sup>2</sup> https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

<sup>&</sup>lt;sup>3</sup> https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

<sup>4</sup> https://www.fda.gov/media/147254/download

5 IRIC

<sup>6</sup> Centers for Disease Control. Facts About Sodium Azide. Emergency Preparedness and Response. <a href="https://emergency.cdc.gov/agent/sodiumazide/basics/facts.asp">https://emergency.cdc.gov/agent/sodiumazide/basics/facts.asp</a>

<sup>7</sup> https://www.fda.gov/media/147254/download

8 IBID

<sup>9</sup> Kolata G. "Faith in Quick Test Leads to Epidemic That Wasn't." New York Times Jan 22 2007

<sup>10</sup> https://www.youtube.com/watch?v=a Vy6fgaBPE&feature=youtu.be&t=260

https://www.fda.gov/media/147254/download