

COVID-19 antibody test kits advisory and checklist



Peter D. Welin, John Gambill, William Beckley | Tuesday, April 21, 2020

It has been reported recently that some companies in Ohio are purchasing serological tests that detect antibodies, or proteins, found in the blood when the body responds to the virus that causes COVID-19. They plan to use the tests on staff and, in some cases, customers.

According to a checklist issued by the Ohio Department of Health, these tests detect the immune response to the virus, not the virus itself, and can help healthcare professionals identify individuals who have overcome an infection in the past and developed an immune response. In the future, this may potentially be used to help determine, alongside other clinical data, that patients are no longer susceptible to infection and can return to work, according to the U.S. Food and Drug Administration (FDA).

While valid information on whether employees may have already been infected or not is urgently needed, Ohio Department of Health Director Amy Acton, M.D., MPH, has strongly recommended that employers in Ohio review the following information before purchasing or using COVID-19 antibody test kits:

- In the early days of an infection when the body's immune response is still building, antibodies may not be detected. As such, antibody testing is one piece to the puzzle to determine whether employees can return to work. Antibody test results are not the sole answer.
- Some firms developing the tests are falsely claiming that their serological tests are approved by the FDA or falsely claiming that they can diagnose COVID-19.
- All employers looking to use the tests should ensure that they are buying only antibody tests approved

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by the FDA for Emergency Use Authorization (EUA). Without the FDA's EUA approval, there is no way to know if the test kits are valid. Testing companies that are EUA-approved are listed on the FDA [website](#), which is updated daily.

- Testing companies should obtain an FDA letter of authorization on their antibody test kit. These letters are proof that tests have been approved. They are posted on the FDA website.
- Many testing companies are in the queue at FDA for approval. Once approved, this will help expand availability.

For answers to your COVID-19 questions, contact the McDonald Hopkins attorneys below. Or, contact the Ohio Department of Health at 1-833-4-ASK-ODH (1-833-427-5634).



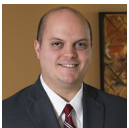
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