



OAKLAND COUNTY EXECUTIVE DAVID COULTER

HEALTH DIVISION

Leigh-Anne Stafford, Health Officer

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Dear Community Partner,

Please find enclosed guidelines for COVID-19 testing that describes the various options currently available. Information includes how tests are administered, if a test is under development or has restricted use. Most noteworthy is the reverse transcription polymerase chain reaction (RT-PCR) test is the only test currently approved to detect COVID-19 infection in individuals. It is the test being used by local hospitals, private labs and the Michigan Department of Health and Human Services to identify COVID-19 infections.

Oakland County Health Division is aware that some laboratories and vendors have made available rapid-result antibody tests for Covid-19. At this time, none of the antibody tests have received FDA approval for routine clinical use, despite claims to the contrary.

Antibody testing results should not be used to support “return to work” decisions for any employee. Any results from antibody testing should be confirmed with one of the approved RT-PCR tests. For information about testing available in Oakland County, call 1-800-848-5533.

Importantly, both the antibody tests and the molecular tests may provide a misleading “negative” result early in the clinical course of COVID-19 infection, especially before a person exhibits symptoms. If an individual has a known exposure to someone with COVID-19, CDC guidelines indicate that they must self-quarantine for 14 days and monitor symptoms twice daily. For information about quarantine, self-isolation, self-monitoring and a symptom tracking log visit <https://bit.ly/2xVLDrc>.

Additional information can be found at www.oakgov.com/COVID . If you have any questions, contact me at faustr@oakgov.com or 248-858-1276.

Sincerely,

OAKLAND COUNTY HEALTH DIVISION
Department of Health and Human Services

Russell Faust, MD, Ph D, FAAP
Medical Director

Molecular Test

RT-PCR test is a quantitative reverse transcription real-time polymerase chain reaction test and currently is the standard test for identifying COVID-19 infection. This method looks for the presence of SARS-CoV-2 viral RNA present in the throat and back of nose, collected by “nasopharyngeal swab.” RT-PCR tests most commonly provide fast throughput for large numbers of samples in a laboratory – from hundreds to thousands at a time.

If a person tests positive by RT-PCR, you are very likely infected with COVID-19; there are rare false positives. False negative results are possible if the virus present is at a low level due to infection very early or very late in the clinical course. As a result, levels of virus present in nasopharyngeal swab may not be high enough to be detected by this method. If you have been infected with COVID-19 and have recovered, this method may give a negative result.

Serologic

Serologic testing, more commonly known as an antibody test, only requires a drop of blood and identifies virus antibodies. It can detect if a person already had COVID-19 or was exposed to it at some point in the past and is now recovered. The test cannot detect whether a person presently has the virus, and as result should not be used to diagnose COVID-19. Serologic tests most commonly provide results for single samples at a time, intended for point of care applications.

Currently over 40 manufacturers have filed for FDA approval for point of care antibody tests. Some of these tests are being offered for sale now. None of the antibody tests are FDA approved for routine clinical use.

Currently, there is not enough data on the antibody levels during the clinical course of COVID-19 infection to make conclusions on the clinical value of these tests.

It is Important to note at this time:

- These tests are investigative (experimental);
- These tests are not diagnostic;
- Clinical decisions should not be based on these tests alone;
- Negative serologic test results do not rule out possible COVID-19 infection;
- Positive results may be due to past or present infection with non-SARS-CoV2 coronavirus strains, as these are common cause of “cold” symptoms (may include coronavirus strains: HKU1, NL63, OC43, 222E).

Antigen Tests

These tests look for the presence of a molecule specific to COVID-19, for example, a protein that is present on the surface of the virus. Like molecular tests, antigen tests reveal the presence of the virus. Once the infection has resolved, the antigen disappears.

Antigen tests are currently under development and may provide advantages over molecular tests when they become available.

These, and other, COVID-19 test methods are rapidly evolving, with additional methods under development.