COVID-19 Testing Comparison Table (5.27.20)*

Testing Type	Test Purpose & Information	When/ How to Initiate Testing in WI	Collection/Test Results
Viral (respiratory mucus test)	 Tests for current infection using sample from your upper respiratory system (i.e.: nose). Used to diagnose COVID-19, the disease caused by SARS-CoV-2 virus: Viral molecular nucleic acid detection: detects genetic material from the virus Viral antigen: detects viral proteins causing an immune response Conducted in consultation with a health provider (doctor's order) or public health official and processed through public health, commercial, or clinical laboratories using tests granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA).** 	 Symptoms and/or exposed to someone with COVID-19: Call your health provider or complete online health screening for referral to a testing site. Contact your local health department. Call a community testing site to get details and schedule. If drive-through/ walk-up option is available, check requirements and follow instructions. Contact a self-collection test kit vendor with an FDA EUA test and follow instructions. Coutbreak of COVID-19 cases within a work or community environment or at discretion of public health: Follow direction of local health department for contact-related or asymptomatic testing recommendations and administration. Discontinue COVID-19 Isolation with the Test-Based method: Method requires 2 negative FDA-authorized molecular viral tests at least 24 hours apart in addition to other criteria. Usually initiated by either health department or individual's health provider in follow-up to a COVID-19 diagnosis. 	 Depending on test type: Specimen collected by trained healthcare professional from the throat/ tonsillar area via the nose or mouth; the deep nose area; or the nostrils. OR Specimen collected by self from the deep nose area or nostrils under onsite supervision by a trained collection individual. OR Specimen collected by self from nostrils or saliva at home. Test swab placed in viral transport medium or packaged as directed and sent to lab for processing. Results within 2-4 days. OR Test kit processed at "point of care" (POC)*** using a high throughput mobile or facility-based platform. Results within minutes. POSITIVE = Isolate at home and consult with healthcare provider NEGATIVE = If asymptomatic/ exposed/ traveled, quarantine at home for at least 14 days. If symptomatic, follow isolation protocol. If asymptomatic, not exposed, no quarantine or isolation necessary. Continue with COVID-19 personal infection control strategies.

Antibody (blood/ "serology" test)	Tests for antibodies to a previous infection using a sample of blood (antibodies show up 1-3 weeks after infection). Also conducted in consultation with a	As more data are gathered and the performance characteristics of approved tests are better understood, serologic tests will play an important role in determining the prevalence of COVID-19 on a population level, and may inform local and state wide epidemiologic studies and future modeling efforts. • Check with your healthcare provider to see if they offer antibody testing. • May eventually be recommended/ provided by health department for certain individuals.	Specimen collected by trained healthcare professional via blood draw from patient's vein or capillary (finger stick). Blood specimen tube packaged and sent to CLIA certified lab for processing. Results within days.
	health provider or public health official using an <u>FDA EUA test</u> and processed in a lab. Used to determine who has been infected, how the body's immune system responds to the virus, and how it spreads; as well as detect potential donors of plasma that can be used to treat those with current infection. Not yet used to determine immunity to the virus and "inappropriate to use for the basis of any decisions related to returning to work or infection control practices within health care or other workplace settings." —WI DHS <u>Health Alert #7</u>		Currently there are no serology antibody tests approved for POC collection and testing by an FDA EUA. Future POC antibody tests will most likely be a finger stick blood specimen collected by a trained healthcare professional and tested for IgM and IgG antibodies. POSITIVE = Consult with provider regarding 2 nd antibody test recommendation. If asymptomatic/ at end of isolation period, return to usual routine. Continue with COVID-19 personal infection control strategies. If symptomatic, follow isolation protocol. NEGATIVE = You may not have had the virus or you may have had virus but antibodies have not developed yet. If exposed or symptomatic, follow provider recommendations for diagnostic testing and isolation protocol.

* Due to the rapidly changing information and testing becoming available, it is advisable to check the CDC testing guidance often to ensure the most current information.

** Section 564 of the Food, Drug & Cosmetic Act permits the FDA Commissioner to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency during the effective period of a declaration. EUA candidates include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the FD&C Act or section 351 of the Public Health Service Act. Having an EUA means the product developer has shown required scientific data to ensure safety and efficacy of the use of the product to diagnose, treat, or prevent the emergency.

*** There are regulatory considerations that must guide the use of POC instruments for SARS-CoV-2 diagnostic purposes. Testing sites operating a POC diagnostic instrument must have a current certificate via the Clinical Laboratory Improvement Amendments of 1988 (CLIA). During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will permit a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility. The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate and must be under the direction of the existing lab director. Frequently Asked Questions (FAQs) concerning CLIA Guidance during the COVID-19 Emergency is available here.



GUIDANCE ON INTERPRETING COVID-19 TEST RESULTS

	RESULT	INTERPRETATION	RECOMMENDED ACTION
VIRAL TESTING ⁺ (testing for current infection)	Positive	<i>Most likely</i> * you DO <u>currently</u> have an active COVID-19 infection and can give the virus to others.	<u>Stay home* and follow CDC guidance</u> on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Negative	<i>Most likely</i> * you DO NOT <u>currently</u> have an active COVID-19 infection.	If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again.
			If you don't have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and others</u> .
ANTIBODY TESTING [#] (testing for past infection with the virus)	Positive:	You <i>likely*</i> have HAD a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. <u>Take steps to protect yourself</u> and others.
	Negative	You <i>likely*</i> NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.	You could still get COVID-19. <u>Take steps to protect yourself and others</u> .
	Viral Positive, Antibody Positive :	<i>Most likely</i> * you DO <u>currently</u> have an active COVID-19 infection and can give the virus to others.	<u>Stay home* and follow CDC guidance</u> on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
вотн	Viral Positive, Antibody Negative	<i>Most likely</i> * you DO <u>currently</u> have an active COVID-19 infection and can give the virus to others.	<u>Stay home* and follow CDC guidance</u> on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
(antibody and viral testing)	Viral Negative, Antibody Positive	You <i>likely*</i> have HAD and RECOVERED FROM a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and</u> <u>others.</u>
	Viral Negative, Antibody Negative	You <i>likely*</i> have NEVER HAD a COVID-19 infection.	You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and others.</u>

•No test is ever perfect. All tests occasionally result in false positive results (the test result should be negative because you DO NOT have COVID-19 but comes back positive) or false negative results (the test result should be positive because you DO NOT have COVID-19, but comes back negative). Sometimes the results are not definitive (the result is unclear, and you don't know if it is positive or negative). For this and other reasons, results should always be reviewed by a healthcare professional.

t Viral tests are typically performed on respiratory specimens such as nasal swabs or throat swabs. They test for the presence of the virus, usually by testing for the virus's RNA or sometimes by testing for the virus's proteins ("antigen testing"). Antigen testing may be less sensitive than tests for the virus's RNA. If your antigen test is negative, please ask your healthcare provider if additional testing with an RNA test is needed and how long you should stay home. tAntibody testing, also called "serologic testing" or "serology", is typically performed on a blood sample. Ideally, the results show whether you have ever been infected with the virus in the past or may be currently infected. Antibody tests check for antibodies that appear in the blood between about one and three weeks after symptom onset and may remain as long as a lifetime. Antibody tests may be positive while a person is infected. It is not yet known whether these antibodies protect against reinfection with the COVID-19 virus. For many other similar viruses, antibodies are protective for years or longer, but we do not yet have adequate data to know for COVID-19.