

	Molecular Test - Lab	Molecular Test – Point of Care	Anti-Body Test
Summary	Golden Standard – This is what all hospital systems, health departments, and major commercial labs are using.	Future – This testing is going to be the standard in which you can test active viral cases real time, with high accuracy.	Adjunctive – As this test gets more specific for antibodies it will be great to understand who has HAD EXPOSURE to the disease.
Specimen Source	Swab - Nasopharyngeal	Swab - Nasopharyngeal	Blood Sample
Test Pathway	Real time reverse transcriptase polymerase chain reaction (rRT-PCR) Assay	Real time reverse transcriptase polymerase chain reaction (rRT-PCR) Assay	Serological & Antigen Assay
Test Processing	24 Hours to 1 week+	Point of Care 5 to 60 minutes	Point of Care 1 to 15 minutes
Test Target	Viral RNA	Viral RNA, Nucleic Acid (genetic information)	Antibody. Most make Antibodies 5- 10 days post-infection.
Test Specificity	SARS-CoV-2 RNA	SARS-CoV-2 RNA	IgM and IgG in blood, plasma, and serum samples. Rapid Diagnostic Test (RDT), Enzyme linked Immunosorbent assay (ELISA), Neutralization assay
Virus Test	Yes – only detects virus that is present	Yes – only detects virus that is present	No – only detects antibodies and cannot detect the virus.
Vendors + FDA	<ul> <li>Hospital Labs</li> <li>State Health Departments</li> <li>Commercial Labs including Quest Diagnostics + LabCorp</li> <li>Vault Health (saliva test)</li> </ul>	<ul> <li>Cepheid Xpert SARS-CoV-2 (FDA)</li> <li>Credo VitaPC R COVID-19 (Pending)</li> <li>Microsens RapiPrep COVID- 19 (FDA)</li> <li>GenMark Diagnostics ePlex SARS-CoV-2 (FDA)</li> <li>Mesa Biotech Accula SARS- CoV-2 (FDA)</li> <li>Abbott ID Now COVID-19 (FDA)</li> </ul>	<ul> <li>Cellex (FDA) RDT</li> <li>ChemBio (FDA) RDT</li> <li>VITROS (FDA) RDT</li> <li>Multiple Vendors not FDA approved but used internationally</li> </ul>
Viral Load	Yes – Amplification rate can be a proxy to understand viral load. More accurate	Yes – Amplification rate can be a proxy to understand viral load.	No – Viral load is not understood as it does not measure for Virus
Test Error	<ul> <li>Negative results could be attributed to a poor-quality sample or early disease</li> </ul>	<ul> <li>Negative results could be attributed to a poor-quality sample or early disease</li> </ul>	<ul> <li>Negative Result even though patient is/was exposed to virus</li> <li>Positive Result even though patient is/was not exposed to virus</li> </ul>
Test Accuracy	• 99%	• 99%	• 50-85%+ for FDA approved testing for IgG/IgM specific

## References:

- Center for Evidence-Based Medicine Oxford University <u>https://www.cebm.net/wp-content/uploads/2020/04/POCT-Covid19-Tables.pdf</u>
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- Li Z et al. Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. Journal of Medical Virology 2020. <u>https://doi.org/10.1002/jmv.25727</u>.
- Johns Hopkins School of Public Health <u>https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html#sec2</u>