COVID-19 Serology Tests Approved for Emergency Use Authorization by the FDA

There are two kinds of tests available for COVID-19: diagnostic tests and serologic (antibody) blood tests.

- A diagnostic test will tell if a person has a current infection.
- A serologic test (or antibody test) tell if a person had a previous infection.

A small (but growing) number of tests have received Emergency Use Authorization by the FDA for clinical care and are becoming increasingly available for use through healthcare providers to check for SARS-CoV-2 antibodies in individuals.

- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Depending on when someone was infected and the timing of the test, the test may not find antibodies in someone with a current COVID-19 infection.
- It typically takes one to two weeks after someone becomes sick with COVID-19 for their body to make antibodies; some people may take longer to develop antibodies.
- It is unknown yet if having antibodies to the virus can protect someone from getting infected with the virus again, or how long that protection might last.
- The presence of immunoglobulin M (IgM) antibodies indicate recent exposure to COVID-19, while the presence of immunoglobulin G (IgG) antibodies indicate later-stage infection.

Sensitivity vs Specificity

- Unless an Emergency Use Authorization (EUA) has also been submitted and reviewed, the FDA has not reviewed the validation of tests offered by certain developers.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.
- Test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate). Sensitivity of both nucleic acid tests and antibody tests is affected by number of variables. The likelihood of a false-negative result depends on both the timing of sample collection and the type of specimen collected.
- Test specificity is the ability of the test to correctly identify those without the disease (true negative rate). Specificity of available antibody tests may vary by assay. It is important to check the validation data provided by the manufacturer and/or performing laboratory. A high specificity (>93%) means a low false positive rate.

FDA Recommendations for Healthcare Providers

- Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.
- Be aware not all marketed serological tests have been evaluated by the FDA. The FDA's authorized tests, including serological tests, are listed on the **Emergency Use Authorization (EUA) page**. Tests are being offered under a policy outlined in the FDA's **COVID-19 Diagnostic Policy Guidance** and listed on the FDA **FAQ page**. Such tests have not been reviewed by the FDA, unless an EUA has also been submitted and reviewed by FDA.
- See FDA approved **laboratories**.

Serology Test Assessment & Description

Rapid Diagnostic Test (RDT)

Authors/Company	What it Tells Us	What it Cannot Tell Us	Time to Results
Cellex, Inc. ChemBio	The presence or absence (qualitative) of antibodies against the virus present in patient serum.	The quantifiable amount of antibodies in the patient serum, or if these antibodies are able to protect against future infection	10-30 minutes

Description

RDT, lateral flow assay, which detects IgM and IgG to the nucelocapside protein of SARS-CoV-2. The sensitivity is 93.8% and specificity is 95.6%, when tested at 2 Chinese hospitals in a total of 128 COVID19 positive patients, and 250 COVID19 negative patients (as detected by RT-qPCR). This test detects IgM and IgG antibodies to the nucleocapsid (N) protein of SARS-CoV-2. Sensitivity and specificity values were not released.

Enzyme Linked Immunosorbent Assay (ELISA)

Authors/Company	What it Tells Us	What it Cannot Tell Us	Time to Results
VITROS Immunodiagnostic Products Mount Sinai Laboratory	The presence or absence (quantitative) of antibodies against the virus present in patient serum	If the antibodies are able to protect against future infection	1-5 Hours

Description

This test is a proprietary ELISA, and detects total IgM and IgG, but does not discern between the two. The target antigen is SARS-CoV-2 spike protein. Sensitivity was 83% when tested in 36 samples known positive, and sensitivity was 100% out of 400 known SARS-CoV-2 negative samples. Sensitivity increases as day from symptom onset increases. This must be used on the platform VITROS® XT 7600 Integrated System, the VITROS® 3600 Immunodiagnostic System, the VITROS® 5600 Integrated System and VITROS® ECi/ECiQ Immunodiagnostic systems.

This test detects, qualitatively, IgG present in the serum of patients. The ELISA based method uses a 1:50 dilution of human serum that is flowed over a plate coated with the spike protein receptor binding domain (RBD). Sensitivity and specificity are not yet available

Neutralization Assay

Authors/Company	What it Tells Us	What it Cannot Tell Us	Time to Results
	The presence of active antibodies in patient serum that are able to inhibit virus growth ex vivo, in a cell culture system. Indicates if the patient is protected against future infection.	It may miss antibodies to viral proteins that are not involved in replication.	3-5 Days

References:

FAQs on Diagnostic Testing for SARS-CoV-2 . (2020, April 24). Retrieved from Emergency Situations (Medical Devices)

Johns Hopkins Bloomberg School of Public Health. (2020, April 24). Retrieved from Center for Health Security