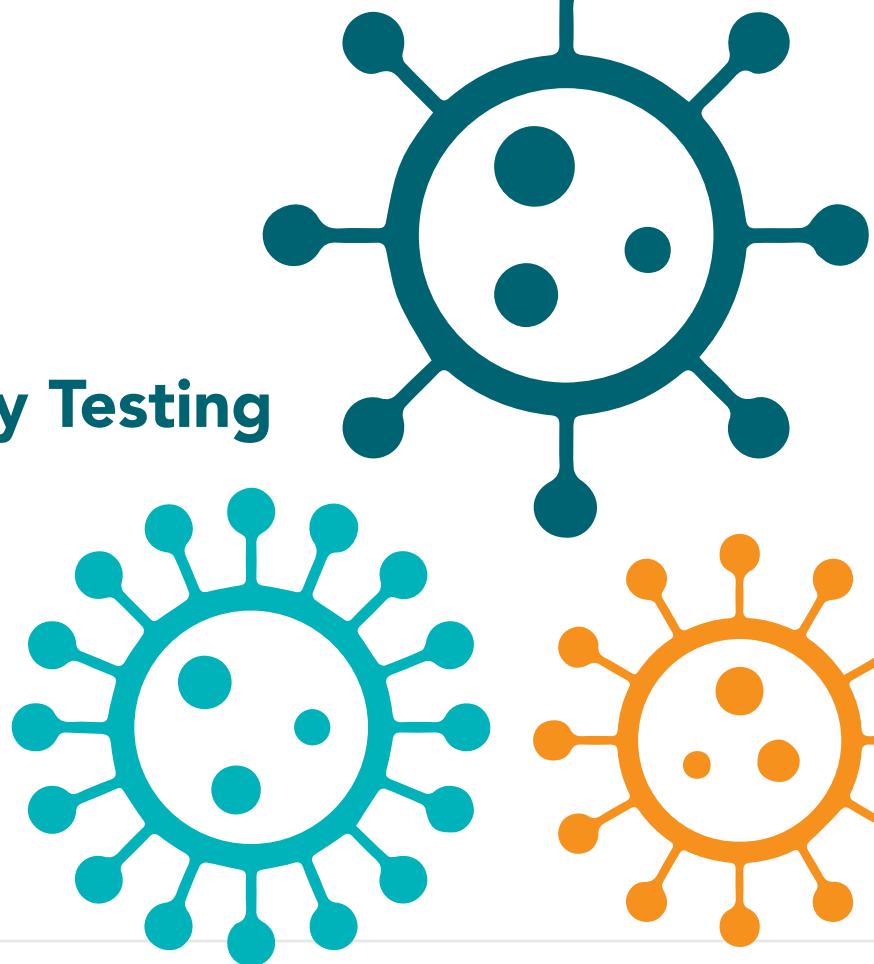


NOW AVAILABLE



SARS-CoV-2 Antibody Testing from ASPIRA Labs

The **COVID-19 Antibody testing** available measures both IgG and IgM antibodies allowing for the highest sensitivity and specificity.



Test Specifications



Sensitivity

100% (≥ 14 days post PCR confirmation)

Specificity

99.81%



Turnaround Time

2-3 days



Sample type

1 Tiger Top SST (serum separator tube)

Volume Requirements

2.0 mL Serum

What is the Intended Use?

The test is intended for use as an **aid in identifying individuals** with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown how long antibodies persist following infection and whether the presence of antibodies confers protective immunity.

The Elecsys Anti-SARS-CoV-2 assay **should not** be used to diagnose acute SARS-CoV-2 infection.

Interpreting the Test Results

What does a **positive** result mean?

- A positive test result for this test indicates that antibodies against SARS-CoV-2 **were detected**, and the individual has potentially been exposed to SARS-CoV-2.
- Antibodies are generally detectable several days following infection.
- A positive result can indicate recent or past infection but does not exclude recently infected individuals who are still contagious.
- It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.
- Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.



What does a **negative** result mean?

- A negative test result for this test means that anti-SARSCoV-2 specific antibodies **were not present** in the specimen above the limit of detection of the assay.
- Individuals tested early after infection may not have detectable antibody response despite active infection; in addition, not all patients will develop a detectable antibody response to SARS-CoV-2 infection.
- When testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19.
- Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19 regardless of Anti-SARS-CoV-2 Immunoassay results.

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