

FAQs for CoviDx™ SARS-CoV-2 Rapid Antigen Test

What is the CoviDx™ SARS-CoV-2 Rapid Antigen Test targeting?

CoviDx™ SARS-CoV-2 Rapid Antigen Test is targeting the nucleocapsid protein antigen of SARS CoV-2 virus.

What is the storage requirement of CoviDx™ SARS-CoV-2 Rapid Antigen Test?

CoviDx™ SARS-CoV-2 Rapid Antigen Test should be stored at 2-30°C (35.6-86°F) out of direct sunlight. If stored at 2-8°C (35.6-46.4°F), ensure that the test device is brought to room temperature (15-30°C/59-86°F) before testing.

What patient samples can be used on CoviDx™ SARS-CoV-2 Rapid Antigen Test?

CoviDx™ SARS-CoV-2 Rapid Antigen Test is intended to be used with freshly collected nasal, oropharyngeal, and nasopharyngeal swab samples.

Can the patient swabs be stored frozen for retrospective testing?

The patient swab samples should be tested as soon as possible after collection. All samples should be tested within 1 hour of collection.

When can the CoviDx™ SARS-CoV-2 Rapid Antigen Test results be interpreted?

CoviDx™ SARS-CoV-2 Rapid Antigen Test results should be read at 20 minutes. Positive results can be read as early as 15 minutes. Do not read the test results after 30 minutes.

The test line is quite weak.

Does this affect the interpretation of results?

Even if the test line is faint in color or incomplete it should be interpreted as positive. A positive result indicates the presence of SARS-CoV-2 antigen.

The test(s) line is visible but the control line is absent.

Can I still report the results?

A red control line must appear in the result window for the test to be valid. The absence of the control line indicates an invalid result and the patient must be retested with a new test.

How sensitive is the CoviDx™ SARS-CoV-2 Rapid Antigen Test?

When compared to a highly sensitive PCR SARS-CoV-2 test, the overall positive percent agreement (PPA) between CoviDx™ SARS-CoV-2 Rapid Antigen Test and PCR was 93.75%. With samples that had Ct values of < 30, PPA was 100%.

How specific is the CoviDx™ SARS-CoV-2 Rapid Antigen Test?

When compared to a highly sensitive PCR SARS-CoV-2 test, the overall negative percent agreement (NPA) was 100%.

Has the CoviDx™ SARS-CoV-2 Rapid Antigen Test undergone testing with the new SARS CoV-2 variant strains?

CoviDx™ SARS-CoV-2 Rapid Antigen Test has been tested and proven effective with the new SARS CoV-2 variant strains from UK (B 1.1.7), Denmark, and South Africa.

Does a negative CoviDx™ SARS-CoV-2 Rapid Antigen Test result rule out COVID-19?

Negative results should be considered presumptive and do not preclude infection. Negative results should not be used as the sole basis for diagnosis, treatment, or other clinical and patient management decisions and should be confirmed with a molecular test for SARS-CoV-2.