

Principles of the Test

The *CareStart*[™] COVID-19 Antigen test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider.

Direct nasopharyngeal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the swab sample migrates in the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 nucleocapsid protein antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

Test results are interpreted at 10 minutes. The presence of two colored lines in the control line region “C” and test line region “T” indicates COVID-19 positive. The presence of one colored lines in the control line region “C” indicates COVID-19 negative. No appearance of a colored line in the control region “C” indicates an invalid test.