Test rapido Coronavirus (SARS-CoV-2) Antigene

Rapid chromatographic immunoassay



Rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in the human nasopharynx.

For professional in vitro diagnostic use only.

INTENDED USE

The Coronavirus Rapid Test Cassette (SARS-CoV-2) Antigen (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in association with clinical presentation and results of other laboratory tests.

The results refer to the detection of SARS-CoV-2 antigens.
An antigen is usually detectable in upper respiratory tract samples during the acute phase of the infection.
Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is required to determine the status of the infection.
Positive results do not rule out bacterial infection or packaging with other viruses.
The agent detected may not be the precise cause of the disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient treatment or management decisions.
Negative results should be treated as suspected and confirmed with a molecular test if necessary for patient management.
Negative results should be considered in the context of a patient's recent exposures, history, and presence of clinical signs and symptoms consistent with COVID-19.

PRINCIPLE

The Coronavirus Rapid Test Cassette (SARS-CoV-2) Antigen (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antigens in human nasopharyngeal swab specimens.

The test line region is coated with SARS-CoV-2 antibodies.
During testing, the sample reacts with the SARS-CoV-2 antibody coated particles in the test.
The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in the test line region.
If the sample contains SARS-CoV-2 antigens, a colored line will appear in the test line region as a result of this.
If the sample does not contain SARS-CoV-2 antigens, no colored line will appear in the test line region, indicating a negative result.

As a procedural control a colored line will always appear in the control zone, indicating that the correct amount of sample has been added and that migration to the membrane has occurred smoothly.

REAGENTS

The test contains anti-SARS-CoV-2 antibodies as the capture reagent and anti-SARS-CoV-2 antibodies as the detection reagent.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 ° C).
The test is stable until the expiration date printed on the sealed pouch.
The test must remain in the sealed pouch until use.
DO NOT FREEZE. Do not use beyond the expiration date.

Pack of 20 tests.

Code	Description
71031037	Test rapido Coronavirus (SARS-CoV-2) Antigene Rapid chromatographic immunoassay