COVID-19 Antigen Rapid Test Frequently Asked Questions (FAQ)

Q: What is Coronavirus?

A: Corona viruses are a large family of viruses which may cause illness in animals or humans. In humans, several corona viruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19.

Q: What is COVID-19?

A: COVID-19 is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before. COVID-19 is now a pandemic affecting many countries globally.

Q: What are the known symptoms to COVID-19?

A: The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Some patients may have aches and pains, nasal congestion, sore throat, or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but only have very mild symptoms. Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 5 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart and lung problems, diabetes, or cancer, are at higher risk of developing serious illness. However, anyone can catch COVID-19 and become seriously ill. Even people with very mild symptoms of COVID-19 can transmit the virus. People of all ages who experience fever, cough and difficulty breathing should seek medical attention.

Q: How does the SARS-CoV-2 Antigen Rapid Test work?

A: The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab specimens.

When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15 minutes based on the presence or absence of visually colored lines.

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Q: What do the test results mean?

A: Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results from patients more than seven days post symptom onset should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Q: What are the known limitations of the test?

A: The known limitations of the SARS-CoV-2 Antigen Rapid Test are:

- The SARS-CoV-2 Antigen Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal swab specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
- Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
- Use of viral transport media may result in decreased test sensitivity.
- A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
- Test results should be correlated with other clinical data available to the physician.
- A positive test result does not rule out co-infections with other pathogens.
- A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
- A negative test result is not intended to rule out other viral or bacterial infections.
- A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.
- If the differentiation of specific SARS viruses and strains is needed, additional testing is required.

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