HGiA®

CE 1434

The SARS-CoV-2 Antigen Rapid Test Kit

HGiA COVID-19 and Variant of Concern

COVID-19 has continued to threaten human life through waves of variants due to fast viral gene mutations especially in the S protein and has killed over 800, 000 people alone in the U.S. The five variants of concerns (VoC) based on the WHO working definition, Alpha Beta, Gamma, Delta, and Omicron, have appeared at different times at one region and quickly spread to other regions or the rest of the world. Currently, the once dominant variant, the Delta variant, is being replaced with the newest omicron variant that has much faster transmission than Delta, with infection cases doubled every 1.5 to 3 days. The Omicron variant can evade the immune system and causes reinfection and infection of the vaccinated population. Although the early studies indicate that the Omicron variant has only caused less severe syndromes, it remains to be seen if Omicron will cause potential health problems.

HGiA Why a Rapid Antigen Test? When and How the Test is Used?

Antigen tests are based on instant antibody-antigen interaction without amplification procedure. The test can take only 15-20 minutes rather than a few hours for RT-qPCR.

Unlike RT-qPCR tests, the antigen tests do not need special instrument and can be performed anywhere outside the lab. With fast transmission of the SARS-CoV-2 in communities, fast antigen home test kits are necessary for screening tests at home, schools, workplaces, and other places where people gather.

A confirmation test by RT-qPCR may be needed for antigen test. A positive result from an antigen test needs confirmation by the molecular assay (RT-qPCR test). If an antigen test is negative, repeat testing is recommended to get more accurate results.

HGIA Introducing SARS-CoV-2 Antigen Rapid Test Kit

For self-testing
Submitted and CE/IVD Marked

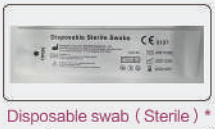
Reliable Results
in 15-20 Mins

Anterior Nasal Swab

Over the Counter (OTC)
use at home

Pack Size: 1 Test


Instruction For Use * 1


Disposable swab (Sterile) * 1

Test Cassette * 1


Extraction tube with solution * 1

Biohazard Specimen Bag * 1

Pack Size: 5 Tests


Instruction For Use * 1


Extraction Tube Holder
for 5–Test Kit * 1


Disposable swab (Sterile) * 5

Test Cassette * 5


Extraction tube with solution * 5

Biohazard Specimen Bag * 5

Pack Size: 20 Tests


Instruction For Use * 1


Extraction Tube Holder
for 20–Test Kit * 1


Disposable swab (Sterile) * 20

Test Cassette * 20


Extraction tube with solution * 20

Biohazard Specimen Bag * 20

HGIA How Does the SARS-CoV-2 Antigen Rapid Test Kit Work?

The SARS-CoV-2 Antigen Rapid Test Kit t is a rapid (approximately 15-20 minutes) antigen-capture immunoassay, detecting the presence of SARS-CoV-2 nucleocapsid protein (N Protein) in anterior nasal swab specimens. SARS-CoV-2 specific antibody and a control antibody are immobilized onto a membrane support as two distinct lines-Test line (T) and Control line (C). Combined with colloidal gold monoclonal antibody against SARS-CoV-2 antigen deposited on the conjugate pad, the test strip can test the presence of the SARS-CoV-2 using drops of nasal lysate specimen by visual color change.

A positive sample will generate a visible red violet line in test line due to N protein antigen binding to the conjugated antibody. However, a negative specimen does not contain SARS-CoV-2 N protein antigen or the SARS-CoV-2 N-protein antigen level is below the limit of detection, the test line will not change color.

Performance of the SARS-CoV-2 Antigen Rapid Test Kit

Analytical Sensitivity

Analytical sensitivity is critical for a test to be used as a reliable tool for routine testing of COVID-19. Although not as sensitive as the RT-qPCR method for detection of the presence of SRAS-CoV-2, the antigen test is still highly sensitive, especially for the patients within 7 days of syndrome onset.

The Limit of Detection (LoD) of the SARS-CoV-2 Antigen Rapid Test Kit was determined using serial dilutions of the heat-inactivated SARS-CoV-2. The confirmed LoD for the SARS-CoV-2 Antigen Test Kit was 2.0×10^3 $TCID_{50}$/mL.

Clinical sensitivity and specificity

To evaluate the clinical sensitivity of the SARS-CoV-2 Antigen Rapid Test Kit, we have examined the correlation between the antigen kit and the gold standard RT-qPCR kit:

SARS-CoV-2 Antigen Rapid Test Kit	SARS-CoV-2 Multiplex Test (RT-qPCR)			Sensitivity (%)	Specificity (%)	Total coincidence rate(%)
	Positive	Negative	Total			
Positive	106	1	107	92.2% (95%CI: 85.7% to 96.4%)	99.8% (95%CI: 98.8% to 100%)	98.2% (95%CI: 96.8% to 99.2%)
Negative	9	449	458			
Total	115	450	565			

Disclaimer:

The SARS-CoV-2 Antigen Rapid Test Kit is used for identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive, and 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 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, and confirmed with a molecular assay, if necessary, for patient management.