

SARS-CoV-2 Antigen Rapid Test Kit

A colloidal gold immunochromatography assay (rapid test) for the qualitative detection of SARS-CoV-2 antigen in nasal swab samples.

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (Nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β -coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

The viral infection causes a series of respiratory illness including severe respiratory syndrome, indicating the virus most likely infects respiratory epithelial cells and spreads mainly via respiratory tract from human to human¹. Current epidemiological assessments indicate that the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue, a dry cough and loss of taste and / or smell; with nasal congestion and other typical flu-like symptoms presenting in some cases.

The SARS-CoV-2 Antigen Rapid Test Kit detects the presence of SARS-CoV-2 nucleocapsid antigen in test samples. This antigen is generally detectable in samples from the upper respiratory tract of infected individuals during the acute phase of the infection. Rapid diagnosis of SARS-CoV-2 infections support early identification of infected individuals allowing healthcare professionals to treat patients more efficiently and effectively. Such rapid identification of those infected by SARS-CoV-2 may also support mass screening efforts and initiation of contact tracing to reduce the spread of the virus.

Features and benefits

- Qualitative detection of SARS-CoV-2 nucleocapsid antigen
- Fast and easy to use in point of care setting and near patient testing
- For use with nasal swab samples
- No specialised equipment needed
- Rapid determination of current infection with SARS-CoV-2
- Result within 15 minutes

Specifications

Format	Colloidal gold immunochromatography assay
Sensitivity	92.00%
Specificity	99.26%
Hands on time	< 3 minutes
Time to result	15 minutes
Sample type	Nasal swab
Reagent stability	The SARS-CoV-2 Antigen Rapid Test Kit and associated reagents are to be stored at 4-30°C. At this temperature they are stable until the expiration date printed on the box label

Performance characteristics


A total of 210 clinical samples with PCR test results were obtained; of which 75 were classified as positive and the remaining 135 negative. The samples were assessed using the SARS-CoV-2 Antigen Rapid Test Kit and the results summarised.


		SARS-CoV-2 Antigen Rapid Test Kit	
		Positive	Negative
RT-PCR	Positive	69	6
	Negative	1	134

Relative sensitivity: **92.00%**


Relative specificity: **99.26%**

Ordering information

 Product name	Size	Code
SARS-CoV-2 Antigen Rapid Test	25 tests/kit	20A010A027

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Complementary products

Type	 Product name	Code
ELISA	ErbaLisa® COVID-19 IgG	IME00136
	ErbaLisa® COVID-19 IgM	IME00137
Automated CLIA	TGS COVID-19 IgG*	CVCL100G
	TGS COVID-19 IgM*	CVCL100M
	TGS COVID-19 Control Set*	CVCLCSGM
Rapid	Coronavirus Ag Rapid Test Cassette [Swab]	GCCOV-502a

*for use on the IDS-iSYS Multi-Discipline Automated System

*Manufactured by Technogenetics

References

1. Xiao F, Tang M, Zheng X, Liu Y, Li X, Shan H, Evidence for gastrointestinal infection of SARS-CoV-2, Gastroenterology [2020], doi: <https://doi.org/10.1053/j.gastro.2020.02.055>.


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