ROW Version

Coronavirus Ag Rapid Test Cassette (Swab)

A lateral flow assay (rapid test) for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal swabs.

SARS-CoV-2 is a single-stranded RNA coronavirus[1]. Coronaviruses are composed of several proteins including the spike (S), envelope (E), membrane (M), and nucleocapsid (N)[2]. The spike glycoprotein of SARS-CoV-2 is a trimeric protein with each 180 kDa monomer consisting of 2 subunits (S1 and S2) which facilitate attachment and binding to the target cell[3].

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 human[1]. 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; nasal congestion and other typical flu-like symptoms are also present in some cases.

The Coronavirus Ag Rapid Test Cassette (Swab) detects 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 allowing faster initiation of contact tracing to help 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 nasopharyngeal swab samples
- No specialised equipment needed
- Rapid determination of current infection with SARS-CoV-2
- Result within 15 minutes

Specifications

Format	Lateral flow cassette
Sensitivity	96.72%
Specificity	99.22%
Hands on time	< 3 minutes
Time to result	15 minutes
Sample type	Nasopharyngeal swab
Reagent stability	The Coronavirus Ag Rapid Test Cassette (Swab) kit and associated reagents are to be stored at 2-30°C. At this temperature they are stable until the expiration date printed on the box label

Performance characteristics

A total of 317 nasopharyngeal swab samples were collected and tested across 7 non-laboratory sites by 24 non laboratorian healthcare workers. The results of the Coronavirus Ag Rapid Test Cassette (Swab) were compared with an EUA approved RT-PCR SARS-CoV-2 method. The results are as follows:

		Coronavirus Ag Rapid Test Cassette (Swab)	
		Positive	Negative
RT-PCR	Positive	**59**	2
	Negative	2	**254**

Relative sensitivity: **96.72%** Relative specificity: **99.22%**

Ordering information

Product name	Size	Code
Coronavirus Ag Rapid Test Cassette (Swab)	20 tests/kit	GCCOV-502a

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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	SARS-CoV-2 Antigen Rapid Test	20A010A027

*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.
2. Li, F., Li, W., Farzan, M., & Harrison, S. (2005). Structure of SARS coronavirus spike receptor-binding domain complexed with its 10.2210/pdb2ajf/pdb
3. Ou, X., Liu, Y., Lei, X. et al. Characterization of spike glycoprotein of SARS-CoV-2 on virus entry and its immune cross-reactivity with SARS-CoV. Nat Commun 11, 1620 (2020). https://doi.org/10.1038/s41467-020-15562-9

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