TECHNICAL REPORT

IVD Test Assay Evaluation of NEWGENE COVID-19 Antigen Detection Kit

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Material Tested:

NEWGENE COVID-19 Antigen Detection Kit

Manufactured by:

Distributed by:

TECHNICAL REPORT

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REPORT TS4-0535-R

Evaluation of COVID-19 In Vitro Diagnostics Medical Devices

Product Details

Product:	NEWGENE COVID-19 Antigen Detection Kit
Product code:	NG-08
Lot number:	2021082001
Manufacturer:	New Gene (Hangzhou) Bioengineering Co. Ltd., China
Requested by:	Universal Therapeutics Sdn. Bhd.
Address:	S-15-12 Wisma YNH (Kiara 163 SOVO), No. 8, Jalan Kiara, 50480 Mont Kiara, Kuala Lumpur
Contact number:	+60 3 9213 0318
Email:	sas@universal-therapeutics.com
Date of request:	27th September 2021
Type of sample tested:	Nasal swab, saliva
Intended use:	Self-test

Executive Summary

The evaluation study was performed to determine the performance of the self-test kit, the NEWGENE COVID-19 Antigen Detection Kit in detecting SARS-CoV-2 antigen from nasal swab as well as saliva specimens. The testing was performed on 30 SARS-CoV-2 positive/30 SARS-CoV-2 negative nasal swab samples and 30 SARS-CoV-2 positive/30 SARS-CoV-2 negative saliva samples. The comparator used was real-time RT-PCR. The nasal positive samples consisted of samples with Ct values 13.70-29.88 while the saliva samples consisted of samples with Ct values 12.10-29.90. Results showed that the NEWGENE COVID-19 Antigen Detection Kit was able to detect SARS-CoV-2 antigen in all of the tested nasal swab samples (n=30) and in 29 out of 30 tested saliva samples with no false positives detected in the negative specimens. The evaluation showed that the tested device displayed a 100% sensitivity and specificity in detecting SARS-CoV-2 antigen in the tested nasal swab samples; and 96.7% sensitivity and 100% specificity when tested on saliva samples.

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1. Purpose and scope

The present evaluation was performed to determine the performance of the self-test kit, the NEWGENE COVID-19 Antigen Detection Kit in detecting SARS-CoV-2 antigen from nasal swab as well as saliva samples. The evaluation is a partial requirement for the product recommendation of use by the Medical Device Authority (MDA).

2. Materials and methods

2.1 Description of device and intended use

The NEWGENE COVID-19 Antigen Detection Kit is an *in vitro* immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid (N) antigen. It is intended for self-test use, suitable for people with symptoms of COVID-19. It can also be used on those without symptoms for the monitoring of their health status.

The test device uses monoclonal antibodies to detect SARS-CoV-2 N protein in nasal or saliva specimens. It is composed of the sample pad, reagent pad, reaction membrane and an absorbing pad. The reagent pad contains colloidal gold-conjugated monoclonal antibodies against the N protein; the reaction membrane contains the secondary antibodies for the N protein and the whole strip is placed in a plastic device. When sample is added, the gold-conjugated monoclonal antibody in the reagent pad is rehydrated and moves along the test strip together with the sample. If there is presence of SARS-CoV-2 antigen in the sample, it will bind to the conjugated antibodies and forms antigen-antibody complexes. These complexes are then captured by the immobilized antibodies at the T line on the strip forming a visible red band indicating a positive result. If SARS-CoV-2 antigen is absent in the sample, no red band will appear at the T line. As a procedural control, a line will always appear at the C region to indicate that sample has been added and membrane wicking has occurred.

2.2 Panel of samples

The samples used were archived saliva samples and nasal swab samples in viral transport medium (VTM). These samples were obtained from COVID-19 patients and were stored in -80 °C to ensure their integrity. They were tested for SARS-CoV-2 using real-time RT-PCR with amplification Ct values of 13.70-29.88 for the nasal swab samples and 12.10-29.90 for the saliva samples. A total of 30 SARS-CoV-2 positive and 30 negative nasal swab samples as well as 30 SARS-CoV-2 positive and 30 negative saliva samples were used for the present evaluation.

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2.3 Detection of SARS-CoV-2 Antigen using the NEWGENE COVID-19 Antigen Detection Kit

Materials provided in the kit are the test cassette, a sample extraction tube and the cap, a specimen bag, an instruction for use and optionally, either a paper cup and a dropper (for saliva specimen) or a sampling swab (for nasal specimen). The test procedure was performed as follows:

- The test device was removed from its packaging pouch and placed on a level surface.
- About 50 µl of the nasal swab or the saliva sample was mixed with 50 µl of the provided buffer. The mixture was allowed to incubate for about one min before it was all transferred to the test cassette sample well.
- The test cassette was incubated at room temperature for about 15-30 min following which the result was read. The appearance of two lines at the T and C region indicated the presence of SARS-CoV-2 antigen in the tested sample and a negative result was indicated by the appearance of only one line at the C region.

All procedure was performed in a biosafety cabinet to minimize potential exposure to SARS-CoV-2.

3. Results

A total of 30 SARS-CoV-2 positive and 30 negative nasal swab samples as well as 30 SARS-CoV-2 positive and 30 negative saliva samples were used for the evaluation. Performance of the product was calculated using the Evidence-based Medicine (EBM) Diagnostic Test Calculator (https://ebm-tools.knowledgetranslation.net/calculator/diagnostic/; Table 2). Results showed that the NEWGENE COVID-19 Antigen Detection Kit was able to detect SARS-CoV-2 antigen in all of the tested nasal swab samples resulting in a sensitivity of 100% (Table 1 & 2); and in 29 out of the 30 tested saliva samples, resulting in a 96.7% sensitivity. No false positive was detected among the SARS-CoV-2 negative specimens indicating the product specificity of 100% in both the nasal and saliva samples.

Concordance analysis showed that there was a perfect agreement (κ=1.000; $p<0.001$) between the NEWGENE COVID-19 Antigen Detection Kit and the real-time RT-PCR used as the comparator assay when tested on nasal swab samples; and an almost perfect agreement (κ=0.967; $p<0.001$) when tested on saliva samples (Table 2).

Limitation of the evaluation

Due to constraint of time and resources, the device was not brought out for field testing. Only archived samples were used for the evaluation. To ensure samples' integrity, the samples were stored in -80 °C and were aliquoted to minimize their freeze-thaw cycles.

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Table 1. Detection of SARS-CoV-2 antigen in nasal swab and samples saliva samples using the NEWGENE COVID-19 Antigen Detection Kit.

(a)

		SARS-CoV-2 detection using Real-time RT-PCR (Nasal swab samples)		
		Pos	Neg	Total
Tested Product	Pos	30	0	30
	Neg	0	30	30
Total		30	30	60

(b)

		SARS-CoV-2 detection using Real-time RT-PCR (Saliva samples)		
		Pos	Neg	Total
Tested Product	Pos	29	0	29
	Neg	1	30	31
Total		30	30	60

Table 2. Analysis of SARS-CoV-2 antigen detection using the NEWGENE COVID-19 Antigen Detection Kit on nasal swab and saliva samples.

Sample type	Pos	Neg	Sensitivity (95% CI[a])	Specificity (95% CI)	PPV[b] (95% CI)	NPV[c] (95% CI)	Concordance (Kappa value, κ)
Nasal swab	30	30	100% (88.6-100)	100% (88.6-100)	100% (88.6-100)	100% (88.6-100)	1.000 (p<0.001)
Saliva	29	31	96.7% (83.3-99.4)	100% (88.6-100)	100% (88.3-100)	96.8% (83.8-99.4)	0.967 (p<0.001)

[a] Confidence Interval; [b] Positive predictive value; [c] Negative predictive value

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4. Conclusion

Evaluation of the NEWGENE COVID-19 Antigen Detection Kit was successfully completed. The device showed that it was able to detect the presence of SARS-CoV-2 antigen in the tested nasal swab samples with 100% sensitivity and 100% specificity. The device showed a performance of 96.7% sensitivity & 100% specificity in the tested saliva specimens.

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Date: 6th October 2021	**Date: 6th October 2021**

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