TECHNICAL REPORT

IVD Test Assay Evaluation of ProDetect®
COVID-19 Antigen Rapid Test (Oral fluid)

Prepared by:

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Material Tested:

ProDetect® COVID-19 Antigen Rapid Test (Oral fluid)

Manufactured and Distributed by:

TECHNICAL REPORT

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REPORT TS4-0425-R
Product Evaluation Study

Product Details

Product:	ProDetect® COVID-19 Antigen Rapid Test (Oral fluid)
Product code:	PR-CVDCAgO
Lot number:	PR-CVDCAgO21JUL01
Manufacturer:	Medical Innovation Ventures Sdn. Bhd.
Requested by:	Medical Innovation Ventures Sdn. Bhd.
Address:	Level 4, Biopharmaceutical Block, IPHARM, NIBM, MOSTI, Block 5-A, Halaman Bukit Gambir, 11700 Gelugor, Penang, Malaysia
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Date of request:	15 July 2021

Executive Summary

The evaluation study was performed to determine the performance of a self-test kit - the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) in detecting SARS-CoV-2 antigen from saliva samples. The testing was performed on 30 SARS-CoV-2 positive and 30 SARS-CoV-2 negative saliva samples by real-time RT-PCR. The positive samples were samples with Ct values between 17.79 – 29.52. The present evaluation showed that the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) was able to detect SARS-CoV-2 antigen in all of the positive samples indicating 100% sensitivity. No false positives were detected among the negative samples, indicating the test 100% specificity in detecting SARS-CoV-2 antigen in saliva samples.

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1. Purpose and scope

The present evaluation was performed to determine the performance of a self-test kit – the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) in detecting SARS-CoV-2 antigen from saliva samples. The evaluation is a partial requirement for the product recommendation of use by the Medical Device Authority (MDA) and the Ministry of Health Malaysia.

2. Materials and methods

2.1 Description of device and intended use

The ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) is a rapid lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human oral fluid specimens. It serves as an aid in the diagnosis of COVID-19 for individuals suspected of SARS-CoV-2 infection. It is intended for home use only.

In principle, when the specimen is added to the device and it contains SARS-CoV-2 antigen, the antigen will react with the SARS-CoV-2 nucleocapsid antibody-coated particles at the T line region of the test cassette. A coloured line will appear. If the specimen does not contain SARS-CoV-2 antigen, no coloured line will appear indicating a negative result. 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 obtained from COVID-19 patients. They have been in storage for about 1 month in -80 °C. These samples have been previously tested for SARS-CoV-2 using real-time RT-PCR with amplification Ct values of 17.79 – 29.52. A total of 30 SARS-CoV-2 positive and 30 SARS-CoV-2 negative samples were used for the present evaluation.

2.3 Detection of SARS-CoV-2 Antigen using the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid)

Materials provided in the kit are the test device, the collection device, a biosafety bag, single-use buffer, a procedure card and an instructions for use. 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 saliva sample was mixed with 50 µl of the buffer. The mixture was mixed well and all of it was transferred to the test device sample well.
- The test device was incubated at room temperature for about 15-20 min following which the result was read. Results read after 30 min were considered invalid. 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.

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3. Results

A total of 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 ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) was able to detect SARS-CoV-2 antigen in all 30 positive samples tested resulting in a sensitivity of 100% (Table 1 & 2). No false positive was detected among the SARS-CoV-2 negative specimens indicating the product specificity of 100%.

Concordance analysis showed that there was a perfect agreement (κ=1.000; p<0.001) between the test product and the real-time RT-PCR used as the comparator assay.

Limitation of the evaluation.
As a self-test kit, it would be ideal for the evaluated product to be tested in the field. However, due to the testing laboratory's limitation of resources, this was not performed. Instead, archived saliva samples were used. Integrity of these samples were ensured by their storage in -80 °C for and minimizing their freeze-thaw cycles.

Table 1. Detection of SARS-CoV-2 antigen in saliva samples using the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid).

		Real-time RT-PCR		
		Pos	Neg	Total
Tested Product	Pos	30	0	30
	Neg	0	30	30
Total		30	30	60

Table 2. Analysis of SARS-CoV-2 antigen detection using the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) on saliva samples.

Pos	Neg	Sensitivity (95% CI[a])	Specificity (95% CI)	PPV[b] (95% CI)	NPV[c] (95%CI)	Concordance (Kappa value, κ)
30	30	100% (88.6-100)	100% (88.6-100)	100% (88.6-100)	100% (88.6-100)	1.000 (p<0.001)

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

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4. Conclusion

Evaluation of the ProDetect® COVID-19 Antigen Rapid Test (Oral fluid) was successfully completed. The tested product showed that it was able to detect the presence of SARS-CoV-2 antigen in all of the tested saliva samples (100% sensitivity) and displayed 100% specificity.

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Date: 22nd July 2021	**Date: 22nd July 2021**

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