Clinical Performance

1 Sensitivity and Specificity

The performance of Medomics COVID-19 Antigen Test Kit (LFIA) was established with 340 nasopharyngeal swabs collected from clinical patients who were suspected of COVID-19. Two nasopharyngeal swabs were collected from patients and one swab was tested directly using Medomics COVID-19 Ag Test Card. The real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was used as the comparator method to confirm the status of samples for this study.

The results are shown in the following table.

	RT-PCR		
Medomics COVID-19 Ag test	Positive	Negative	Total
Positive	115	2	117
Negative	4	219	223
Total	119	221	340

Sensitivity: 96.64% (91.62%-99.08%)

Specificity: 99.10% (96.77%-99.89%)

PPV: 98.29% (93.96%-99.79%)

NPV: 98.21% (95.47%-99.51%)

Accuracy: 98.24% (96.20%-99.35%)

Explanation of terms

Sensitivity = True Positives / (True Positives + False Negatives)

Specificity = True Negatives / (True Negatives + False Positives)

PPV (Positive Predictive Value) = True Positives / (True Positives + False Positives)

NPV (Negative Predictive Value) = True Negatives / (True Negatives + False Negatives)

Accuracy = (Tue Negatives + True Positives) / Total Samples

2 Limit of Detection (LoD) Study Results

Medomics COVID-19 Ag Test Card LoD was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus. LoD studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. The results are shown in the following table.

Concentration $TCID_{50}$/mL	Number Positive/Total	% Detected
10	20/20	100%

The Medomics COVID-19 Ag Test Card LoD was confirmed as 10 $TCID_{50}$/mL.

3 High Dose Hook Effect

The high dose hook effect studies determine the level at which false negative results can be seen when samples containing very high concentration of SARS-CoV-2 virus are tested in triplicate. Increasing concentrations of inactivated SARS-CoV-2 virus tested up to a concentration of 10^5 TCID50/mL to ensure if any high dose hook effect exists in the test using Medomics COVID-19 Ag Test Card.

Concentration Tested	High Dose Hook Effect (Yes/No)
1.0 x 10^5 $TCID_{50}$/mL	No
1.0 x 10^4 $TCID_{50}$/mL	No
1.0 x 10^3 $TCID_{50}$/mL	No

No color intensity decreasing and high dose hook effect on test performance was observed up to a concentration of 105 TCID50/mL of inactivated SARS-CoV-2 virus with the Medomics COVID-19 Ag Test Card.

4 Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of Medomics COVID-19 Ag Test Card was evaluated by testing commensal and pathogenic microorganisms listed in the following table that may be present in the clinical samples. Each of the bacterium, viruses, and yeast were tested in triplicate in the absence or presence of inactivated SARS-CoV-2 virus.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Influenza A H1N1	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H3N2	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H5N1	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H7N9	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B Victoria	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B Yamagata	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus Type 1	1.0 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL	No
Enterovirus CA16e	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Staphylococcus aureus	1.0 x 10^6 CFU/mL	No
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Haemophilus influenzae	1.0 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	No
Candida albicans	1.0 x 10^6 CFU/mL	No

5 Endogenous Interfering Substances Effect

A study was performed to evaluated and demonstrated that the endogenous substances naturally present or drugs that may be artificially introduced into in clinical samples do not inference with the detection of SARS-CoV-2 in the Medomics COVID-19 Ag Test Card at the concentrations listed below.

Substance	Potential Interfering Substances	Concentration	Interference (Yes/No)
Endogenous	Mucin	2 % w/v	No
	Whole Blood	5 % v/v	No
Nasal spray or drops	Phenylephrine	0.05 mg/ml	No
Nasal steroids	Dexamethasone	0.8 mg/ml	No
	Triamcinolone acetonide	0.8 mg/ml	No
	Budesonide	0.5 mg/ml	No