

**SARS-CoV-2 Antigen Test Kit (LFIA)**  
**Jiangsu Medomics Medical Technology Co., Ltd.**  
**Analytical Performance Evaluation Report**

**Date of Issue:** Oct. 15, 2020

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### 1. Limit of Detection (LoD) Study Results

Medomics COVID-19 Ag Test kit LoD was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus at Jiangsu Provincial Center for Disease Control and Prevention (Jiangsu CDC). LoD studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. Dilute the SARS-CoV-2 virus with lysis buffer to a final concentration gradient of 10, 50, 100, 200, 1000 TCID<sub>50</sub>/mL.

Medomics SARS-CoV-2 Antigen Test Kit (LFIA) Lot Number: 2020072201, expiration DATE: 20220722

The results are shown in the following table.

SARS-CoV-2 tested (TCID <sub>50</sub> /mL)	Test Result
1000	20/20 positive
200	20/20 positive
100	20/20 positive
50	20/20 positive
10	20/20 positive

The Medomics COVID-19 Ag Test Card LoD was confirmed as 10 TCID<sub>50</sub>/mL.

### 2. High Dose Hook Effect

The high dose hook effect studies were performed at Jiangsu Provincial Center for Disease Control and Prevention (Jiangsu CDC). The study determines 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<sup>5</sup> TCID<sub>50</sub>/mL to ensure if any high dose hook effect exists in the test using Medomics COVID-19 Ag Test Card.

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Concentration Tested	High Dose Hook Effect (Yes/No)
1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
1.0 x 10 <sup>4</sup> TCID <sub>50</sub> /mL	No
1.0 x 10 <sup>3</sup> TCID <sub>50</sub> /mL	No

No color intensity decreasing and high dose hook effect on test performance was observed up to a concentration of 10<sup>5</sup> TCID<sub>50</sub>/mL of inactivated SARS-CoV-2 virus with the

Medomics COVID-19 Ag Test Card.

**3. Cross Reactivity (Analytical Specificity) and Microbial Interference**

Cross reactivity and microbial interference studies were performed at Institute of Microbiology, Chinese Academy of Sciences. 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.

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Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Human coronavirus OC43	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Human coronavirus NL63	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
MERS-coronavirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
SARS-coronavirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza A H1N1	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza A H3N2	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza A H5N1	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza A H7N9	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza B Victoria	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza B Yamagata	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Parainfluenza virus Type 1	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Respiratory syncytial virus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Enterovirus CA16e	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Adenovirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
<i>Mycoplasma pneumoniae</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Staphylococcus aureus</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Staphylococcus epidermidis</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Bordetella pertussis</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Legionella pneumophila</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Streptococcus pneumoniae</i>	1.0 x 10 <sup>6</sup> CFU/mL	No

<i>Haemophilus influenzae</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Streptococcus pneumoniae</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Mycobacterium tuberculosis</i>	1.0 x 10 <sup>6</sup> CFU/mL	No
<i>Candida albicans</i>	1.0 x 10 <sup>6</sup> CFU/mL	No

#### 4. Endogenous Interfering Substances Effect

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

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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