

## COVID-19 Antigen Rapid Test Cassette (Colloidal Gold Method)

### Intended Use

COVID-19 Antigen Rapid Test Cassette (Colloidal Gold Method) is a rapid test for the qualitative detection of antigens to SARS-CoV-2 in human nasopharyngeal/oropharyngeal swab specimens or saliva/sputum specimens. It is intended for professional use only.

One of the main advantages of an antigen test is the speed of the test, which can provide results in minutes. We can potentially scale to test millions of people per day due to their simpler operation.

The antigen tests may not detect all active infections. Therefore, the negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative, the administration added.

The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests. Laboratory testing of 2019-nCoV should meet the requirements of the "Technical Guidelines for Covid-19 Laboratory Testing" to do a better biosafety job.

### Performance Characteristics

#### ■ Clinical Performance

Different samples from 436 patients were detected by COVID-19 Antigen Rapid Test and the RT-PCR.

#### A. Nasopharyngeal and Oropharyngeal Swab Specimen

COVID-19 antigen		RT-PCR		Total
		Positive	Negative	
NDH testing kit	Positive	103	2	105
	Negative	2	329	331
Total		105	331	436

Sensitivity (PPA): 98.10% (103/105), (95% CI: 93.32% , 99.48% )

Specificity (NPA): 99.40% (329/331), (95% CI: 97.82% , 99.83% )

### B. Anterior nasal Swab Specimen (nose front)

COVID-19 antigen		RT-PCR		Total
		Positive	Negative	
NDH testing kit	Positive	97	3	100
	Negative	8	328	336
Total		105	331	436

Sensitivity (PPA): 92.38% (97/105), ( 95% CI: 85.68% , 96.09% )

Specificity (NPA): 99.09% (328/331), ( 95% CI: 97.37% , 99.69% )

### C. Saliva/Sputum Specimen

COVID-19 antigen		RT-PCR		Total
		Positive	Negative	
NDH testing kit	Positive	93	2	95
	Negative	12	329	341
Total		105	331	436

Sensitivity (PPA): 88.57% (93/105), ( 95% CI: 81.08% , 93.34% )

Specificity (NPA): 99.40% (329/331), ( 95% CI: 97.82% , 99.83% )

#### ■ Limit of Detection

The study used cultured SARS-CoV-2 virus, which is  $\beta$ -propiolactone and heat inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) is  $5 \times 10^{2.55}$  TCID<sub>50</sub>/ml

### ■ High-dose Hook Effect

The COVID-19 Antigen Rapid Test was tested up to  $1.0 \times 10^{6.01}$  TCID<sub>50</sub>/ml of inactivated SARS-CoV-2 and no high-dose hook effect was observed.

### ■ Cross Reactivity

No cross-reactivity was observed with recombinant MERS-CoV NP protein when tested at the concentration of 50 µg/ml. No cross-reactivity was observed with the following viruses when tested at the concentration of  $1.0 \times 10^6$  PFU/mL: Influenza A (H1N1), Influenza A (H3N2), Influenza B (Yamagata), Influenza B (Victoria), Adenovirus (type 3), Human metapneumovirus, Parainfluenza virus (type 2), Respiratory syncytial virus, Enterovirus, Rhinovirus, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63. No cross-reactivity was observed with the following bacteria when tested at the concentration of  $1.0 \times 10^7$  CFU/mL: Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus.

### ■ Interference

The following potential interference substances were evaluated with the COVID-19 Antigen Rapid Test Cassette at the concentrations listed below and were found not to affect test performance.

Substance	Concentration	Substance	Concentration
3 OTC nasal sprays	10%	Guaiacol glycerol ether	20 mg/ml
3 OTC mouthwashes	10%	Mucin	1%
3 OTC throat drops	10%	Mupirocin	250 µg/ml
4-acetamidophenol	10 mg/ml	Oxymetazoline	10 mg/ml
Acetylsalicylic acid	20 mg/ml	Phenylephrine	10 mg/ml
Albuterol	20 mg/ml	Phenylpropanolamine	20 mg/ml
Chlorpheniramine	5 mg/ml	Relenza ® (zanamivir)	20 mg/ml
Dexamethasone	5 mg/ml	Rimantadine	500 ng/ml
Dextromethorphan	10 mg/ml	Tamiflu ® (oseltamivir)	100 mg/ml
Diphenhydramine	5 mg/ml	Tobramycin	40 mg/ml
Doxylamine succinate	1 mg/ml	Triamcinolone	14 mg/ml
Flunisolide	3 mg/ml	Nasopharyngeal swab containing respiratory syncytial virus	$1.0 \times 10^6$ PFU/ml
Oropharyngeal swab containing respiratory syncytial virus	$1.0 \times 10^6$ PFU/ml	Nasopharyngeal swab containing influenza virus	$1.0 \times 10^6$ PFU/ml
Oropharyngeal swab containing influenza virus	$1.0 \times 10^6$ PFU/ml		