

PROOF OF MEETING THE CURRENT MINIMUM CRITERIA

We Joinstar Biomedical technology Co., Ltd hereby certified that our product: COVID-19 Antigen Rapid test(Colloidal Gold)

Specimen: Oropharyngeal Saliva

Article Number: FGCOVG400, FGCOVG500, FGCOVG600, FGCOVG700

1. Sensitivity and Specificity

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test (Colloidal Gold)	Results	Positive	Negative	
	Positive	98	4	102
	Negative	4	496	500
Total Result		102	500	602

The total sensitivity of COVID-19 Antigen is 96.1%; 95% CI:(90.26%-98.92%)

Total specificity of COVID-19 Antigen is 99.2%; 95%CI: (97.96%-99.78%)

Total agreement rate of COVID-19 Antigen is 98.7%; 95%CI: (97.40%-99.42%)

2. Cross-reactivity:

The following cross-reactive substances have been tested using COVID-19 Antigen Rapid Test (Colloidal Gold) and no cross-reactivity was observed.

HCoV-229E	HCoV-OC43	HCoV-NL63	MERS-CoV
HCoV-HKU1	Human RSV	Human Enterovirus	Human Rhinovirus
Human Metapneumovirus	Mycoplasma pneumoniae	Parainfluenza virus	Adenovirus
Influenza B virus (Victoria line)	H1N1 (2009) influenza virus	Influenza A H3N2 virus	Avian influenza virus H7N9
Influenza B virus (Yamagata series)	Seasonal Influenza A H1N1	Neisseria meningitidis	Streptococcus pneumoniae
Staphylococcus aureus			

3. Interfering Substances:

The following compounds have been tested using COVID-19 Antigen Rapid Test (Colloidal Gold) and no interference was observed.

Interfering substances	concentration
Aspirin	30ug/dL
Ascorbic Acid	20mg/dL
Ibuprofen	200ug/dL
Bilirubin	60mg/dL
Chloramphenicol	3ug/dL

Comply with the current minimum criteria of Paul Ehrlich Institute.