COVID-19 Antigen/FLU A+B Antigen Combo Rapid Test Cassette
(Colloidal Gold Method)

Intended Use

COVID-19 Antigen/FLU A+B Antigen Combo Rapid Test Cassette (Colloidal Gold Method) is a rapid test for the qualitative detection of antigens to SARS-CoV-2 and flu A+B 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. Therefor the negative results from an antigen test may need to be confirmed with a PCR test or virus culture 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 virus should meet the requirements of the "Technical Guidelines for Covid-19 Laboratory Testing" and "Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating" to do a better biosafety job.

Performance Characteristics

■ Clinical Performance

COVID-19 Antigen

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%）

FLU A Antigen and FLU B Antigen

Different samples from 436 patients were detected by the Influenza A/B Rapid Test and the cell culture.

A. Nasopharyngeal and Oropharyngeal Swab Specimen

FLU A		CELL CULTURE		Total
		Positive	Negative	
NDH testing kit	Positive	146	3	149
	Negative	5	282	287
Total		151	285	436

Sensitivity (PPA): 96.69% (146/151), （95% CI: 92.48%，98.58%）

Specificity (NPA): 98.95% (282/285), （95% CI: 96.95%，99.64%）

FLU B		CELL CULTURE		Total
		Positive	Negative	
NDH testing kit	Positive	160	3	163
	Negative	7	266	273
Total		167	269	436

Sensitivity (PPA): 95.81% (160/167), （95% CI: 91.60%，97.96%）

Specificity (NPA): 98.88% (266/269), （95% CI: 96.77%，99.62%）

B. Anterior nasal Swab Specimen (nose front)

FLU A		CELL CULTURE		Total
		Positive	Negative	
NDH testing kit	Positive	141	5	146
	Negative	10	280	290
Total		151	285	436

Sensitivity (PPA): 93.38% (141/151), （95% CI: 88.24%，96.36%）

Specificity (NPA): 98.25% (280/285), （95% CI: 95.96%，99.25%）

FLU B		CELL CULTURE		Total
		Positive	Negative	
NDH testing kit	Positive	152	4	156
	Negative	15	265	280
Total		167	269	436

Sensitivity (PPA): 91.02% (152/167), （95% CI: 85.71%，94.48%）

Specificity (NPA): 98.51% (265/269), （95% CI: 96.24%，99.42%）

C. Saliva/Sputum Specimen

FLU A		CELL CULTURE		Total
		Positive	Negative	
NDH testing kit	Positive	131	4	135
	Negative	20	281	301
Total		151	285	436

Sensitivity (PPA): 86.75% (131/151), （95% CI: 80.43%，91.26%）

Specificity (NPA): 98.60% (281/285), （95% CI: 96.45%，99.45%）

FLU B		CELL CULTURE		Total
		Positive	Negative	
NDH testing kit	Positive	138	3	141
	Negative	29	266	295
Total		167	269	436

Sensitivity (PPA): 82.63% (138/167), （95% CI: 76.17%，87.63%）

Specificity (NPA): 98.88% (266/269), （95% CI: 96.77%，99.62%）

■ Limit of Detection

The study used cultured viruses, which is β-propiolactone and heat inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) was confirmed as follows:

Virus Lineage	Limit of Detection (LoD)
SARS-CoV-2	$5\times10^{2.55}$ $TCID_{50}$/mL
Influenza A(H1N1)	1.0×10^{3} $TCID_{50}$/mL
Influenza A (H3N2)	1.0×10^{3} $TCID_{50}$/mL
Influenza A (H1N1pdm09)	5.0×10^{3} $TCID_{50}$/mL
Influenza B (Yamagata)	1.0×10^{4} $TCID_{50}$/mL
Influenza B (Victoria)	1.0×10^{3} $TCID_{50}$/mL

■ Cross Reactivity

➢ The Cross Reactivity of COVID-19 Antigen Rapid Test

No cross-reactivity was observed with recombinant MERS-CoV NP protein when tested at the concentration of 50μg/ml. No cross-reactivity was observed with the following viruses when tested at the concentration of 1.0×10^6 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 1.0×10^7CFU/ml: Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus.

➢ The cross reactivity of FLU A+B Antigen Rapid Test

To determine the analytical specificity of the Influenza A/B Test, 69 commensal or pathogenic microorganisms (24 viruses, 45 bacteria) that may be present in the upper respiratory tract were tested.

Positive and negative specimens were spiked with these microbes. Bacterial or yeast isolates were evaluated at a concentration of 10^7- 10^8 org/ml. Viral isolates were inoculated at a concentration of 10^4-10^8 $TCID_{50}$/ml. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 $TCID_{50}$/ml. None of the microorganisms tested yielded a positive result with the influenza-negative samples or interfered with detection of the influenza A or B positive samples. Both the negative and positive respiratory specimens were positive when spiked with influenza A strain A2/Aichi/2/68(H3N2) or influenza B strain Hong Kong 5/72.

Virus other than Influenza A/B viruses

Human adenovirus B, C	Adenovirus type 10, 18
Human coronavirus OC43	Coxsackie virus A9, B5
Human herpesvirus 2, 5	Echovirus 2, 3, 6
Herpes simplex virus 1	Human rhinovirus 2, 14, 16
Measles	Sendai virus
Parainfluenza virus 2,3	Respiratory syncytial virus
Varicella-Zoster	

Bacteria

Acinetobacter calcoaceticus	Bacteroides fragilis	Bordetella pertussis
Bacillus cereus	Bacillus subtilis	Bordetella parapertussis
Branhamella catarrhalis	Chlamydia pneumoniae	Corynebacterium diphtheria
Citrobacter freundii	Enterobacter cloacae	Enterococcus faecalis
Escherichia coli	Gardnerella vaginails	Haemophilus influenzae
Klebsiellaoxytoca	Klebsiella pneumoniae	Lactobacillus casei

Lactobacillus plantarum	Legionella pneumophila	Listeria monocytogenes
Moraxella catarrhalis	Mycobacterium avium	Mycobacterium intracellulare
Mycobacterium tuberculosis	Mycoplasma pneumoniae	Neisseria meningitides
Neisseria sicca	Neisseria subflava	Nocardia asteroids
Proteus vulgaris	Pseudomonas aeruginosa	Serratia liquifaciens
Staphylococcus aureus	Staphylococcus epidermidis	Streptococcus Groups A, B, C, F,
Streptococcus mutants	Streptococcus pneumoniae	Streptococcus salivaris
Streptococcus sanguis	Yersinia enterocolitica	

■ Interference

The following potential interference substances were evaluated with the COVID-19 Antigen/FLU A+B Antigen Combo 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	$1,0\times10^6$ PFU/ml
Oropharyngeal swab containing respiratory syncytial virus	$1,0\times10^6$ PFU/ml	Nasopharyngeal swab containing influenza virus	$1,0\times10^6$ PFU/ml
Oropharyngeal swab containing influenza virus	$1,0\times10^6$ PFU/ml		