SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test

FOR PROFESSIONAL USE ONLY

Product Name

SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test

Intended Use

The SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test is intended for in vitro qualitative detection to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen, influenza A+B (Flu A+B) antigen and respiratory syncytial virus (RSV) antigen in human nasopharyngeal swab or oropharyngeal swab samples.

SARS-CoV-2 antigen reagent is used for SARS-CoV-2 Antigen test of novel coronavirus suspected populations appear symptoms within 7 days. Positive result of the antigen test can be used for early triage and rapid management of suspected populations, but it cannot be used as diagnosis basis of SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Further nucleic acid detection should be carried out for suspected population whose antigen test result is positive or negative.

This reagent is only for professional use, not suitable for family test. The test results are only for clinical reference and it is recommended to conduct comprehensive analysis of the disease condition in combination with clinical manifestations of patients and other laboratory tests; it is not suitable for screening of general population.

Test Principle

According to the gold immunochromatographic test principle, the double antibody sandwich immunochromato-graphic assay was used to detect SARS-CoV-2, Flu A+B and RSV antigen in the samples.

SARS-CoV-2:

When the sample contains SARS-CoV-2 antigen, the antigen binds with the corresponding gold labeled monoclonal antibody to form a compound, moving forward under the chromatography, then combines with the coated antibody in the test line to form Au-SARS-CoV-2 monoclonal antibody 1-antigen-SARS-CoV-2 monoclonal antibody 2 complex to condenses into a red band (Test line, T), indicating a positive result. When the sample does not contain SARS-CoV-2 antigen, complex cannot be formed in the test line, and no red band appears, indicating a negative result.

Flu A+B:

When the sample contains influenza A virus antigen, the antigen binds with the corresponding gold labeled monoclonal antibody to form a compound, moving forward under the chromatography, then combines with the coated antibody in the test line (T2) to form Au-influenza A virus monoclonal antibody 1-antigen-influenza A virus monoclonal antibody 2 complex to condenses into a red band (Test line, T2), indicating a positive result. When the sample does not contain influenza A virus antigen, complex cannot be formed in the test line (T2), and no red band appears, indicating a negative result.

When the sample contains influenza B virus antigen, the antigen binds with the corresponding gold labeled monoclonal antibody to form a compound, moving forward under the chromatography, then combines with the coated antibody in the test line (T1) to form Au-influenza B virus monoclonal antibody 1-antigen-influenza B virus monoclonal antibody 2 complex to condenses into a red band (Test line, T1), indicating a positive result. When the sample does not contain influenza B virus antigen, complex cannot be formed in the test line (T1), and no red band appears, indicating a negative result.

RSV:

When the sample contains RSV antigen, the antigen binds with the corresponding gold labeled monoclonal antibody to form a compound, moving forward under the chromatography, then combines with the coated antibody in the test line to form Au-respiratory syncytial virus monoclonal antibody 1-antigen-respiratory syncytial virus monoclonal antibody 2 complex to condenses into a red band (Test line, T), indicating a positive result. When the sample does not contain RSV antigen, complex cannot be formed in the test line, and no red band appears, indicating a negative result.

No matter whether the samples contain antigens or not, the gold labeled monoclonal antibody will combine with the coated goat anti-mouse IgG antibody at the control line to form a complex and condenses into a red band (Control line, C).

Components

1. Test cassette:

Components / Test cassette	Test line	Gold conjugate pad	Control line
SARS-CoV-2	SARS-CoV-2 monoclonal antibody 2	SARS-CoV-2 monoclonal antibody 1	Goat anti-mouse IgG antibody
Flu A+B	T1:Influenza B virus monoclonal antibody 2 T2:Influenza A virus monoclonal antibody 2	Influenza B virus monoclonal antibody 1; Influenza A virus monoclonal antibody 1	Goat anti-mouse IgG antibody
RSV	Respiratory syncytial virus monoclonal antibody 2	Respiratory syncytial virus monoclonal antibody 1	Goat anti-mouse IgG antibody

2. Extraction Reagent: Tris (hydroxymethyl) methyl aminomethane buffer with surfactant.

This product provides two different packaging forms, the packaging form 1 or 2 can be selected according to the demands.

Package type 1:

Specification / Ingredients	20 tests/kit	25 tests/kit	40 tests/kit	Remark
Test cassettes and desiccants in a sealed foil pouch	20	25	40	
Extraction Reagent	6.5mL*2	7.5mL*2	6.5mL*4	
Extraction tube	20	25	40	Optional
Swab	20	25	40	Optional
IFU	1	1	1	

Package type 2:

Specification / Ingredients	20 tests/kit	25 tests/kit	40 tests/kit	Remark
Test cassettes and desiccants in a sealed foil pouch	20	25	40	
Extraction Reagent	0.5mL*20	0.5mL*25	0.5mL*40	
Swab	20	25	40	Optional
IFU	1	1	1	

MATERIAL NEEDED BUT NOT PROVIDED

1. Timer
2. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
3. Appropriate biohazard waste container and disinfectants.

Storage and Shelf-Life

Store in the sealed pouch at 4-30℃. DO NOT FREEZE. Valid for 24 months and avoid using expired products.

The reagent can be transported at room temperature for a short time. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. It must be used in one hour if opened (Humidity≤60%, Temp: 20℃-30℃). Please use immediately when the humidity ＞60%.

Sample Requirement

Sample Collection

Collection method of nasopharyngeal swab:

The operator holds the swab by the right hand and holds the head of the subject fixedly by left hand. Do not overexert to avoid traumatic hemorrhage. When the cusp of the swab touching the paries posterior of the pharyngonasal cavity, letting the swab remain in the place for a few seconds (about 3 seconds) and rotating the swab gently for one cycle, and then remove the swab slowly. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

Collection method of oropharyngeal swab:

The head of the person to be collected is slightly tilted and his mouth is wide open, exposing the pharyngeal tonsils on both sides. Wipe the swab across the root of the tongue. Wipe the pharyngeal tonsils on both sides of the person to be collected back and forth with a little force for at least 3 times, and then wipe up and down the posterior pharyngeal wall for at least 3 times. Avoid touching your tongue, cheeks or teeth when sampling. Just after drinking water or beverages, sampling samples cannot be used for testing.

Note: The sample should not be inactivated.

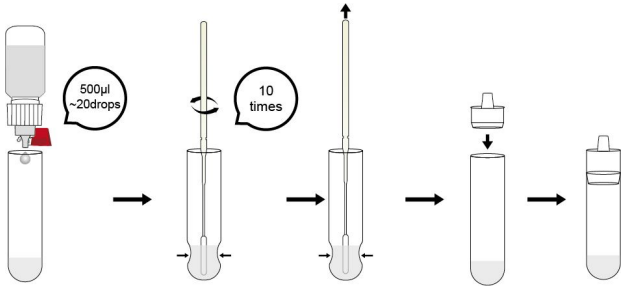
Sample preservation

After the samples of human nasopharyngeal swabs and oropharyngeal swabs are collected, the swabs should be processed as soon as possible and tested within 1 hour. If it cannot be tested immediately, it can be stored at 2-8°C for 4 hours and long-term storage is not recommended.

Sample Treatment

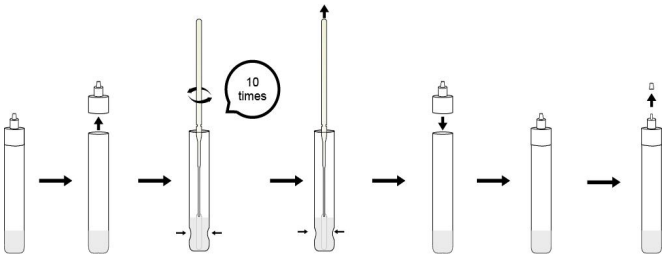
Package type 1 treatment method:

1. Add 500μL of sample extraction reagent into the sample extraction tube (add about 20 drops vertically if using a dropper).
2. Insert the swab after sampling into the reagent of the sample extraction tube, rotate and squeeze the swab against the inner wall of the tube for 10 times vigorously to make the sample dissolve in the solution as much as possible.
3. Squeeze swab head along the inner wall of the extraction tube to keep the liquid in the tube as much as possible. Take out and discard the swab, and the extracted solution will be used as test sample.
4. Cover the lid and wait for inspection.



Package type 2 treatment method:

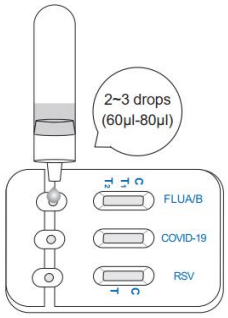
1. Open the sample extraction tube.
2. Insert the swab after sampling into the reagent of the sample extraction tube, rotate and squeeze the swab against the inner wall of the tube for 10 times vigorously to make the sample dissolve in the reagent as much as possible.
3. Squeeze the swab head along the inner wall of the extraction tube to keep the solution in the tube as much as possible. Take out and discard the swab, and the extracted solution will be used as test sample.
4. Close the lid and open the cap for inspection.



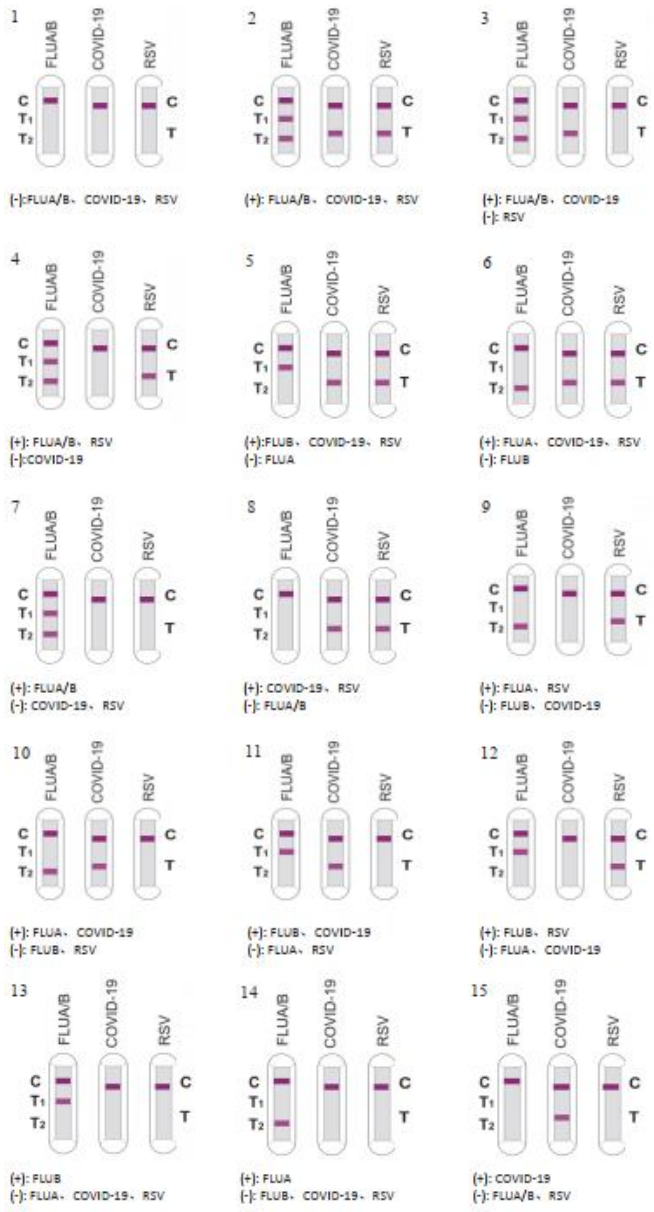
Test Procedure

Instructions must be read entirely before taking the test. Leave the reagent and sample at room temperature for 30 minutes before use. Return to room temperature. Do not open the inner packing until it is ready. Use it as soon as possible after opening the inner packing.

1. Open the tear hole of the aluminum foil bag, take out the test cassette and lay it flat.
2. Add 2-3 drops of the treated sample extract solution (about 60μL-80μL) vertically into the sample well of the test cassette.
3. The results should be observed after 15 minutes and showed invalid after 20 minutes.



Interpretation of Result



Number	FLUA/B		SARS-CoV-2	RSV	Interpretation of Result
	T1	T2	COVID-19		
1	-	-	-	-	Samples did not contain FLUA/B,SARS-CoV-2 and RSV antigens or the content was lower than the minimum detection limit of corresponding product
2	+	+	+	+	Samples contain FLUA/B,SARS-CoV-2 and RSV antigens
3	+	+	+	-	Samples contain FLUA/B and SARS-CoV-2 antigens, not contain RSV antigen or the content was lower than the minimum detection limit
4	+	+	-	+	Samples contain FLUA/B and RSV antigens, not contain SARS-CoV-2 antigen or the content was lower than the minimum detection limit
5	+	-	+	+	Samples contain FLUB,SARS-CoV-2 and RSV antigens, not contain FLUA antigen or the content was lower than the minimum detection limit
6	-	+	+	+	Samples contain FLUA,SARS-CoV-2 and RSV antigens, not contain FLUB antigen or the content was lower than the minimum detection limit
7	+	+	-	-	Samples contain FLUA/B antigens, not contain SARS-CoV-2 and RSV antigens or the content was lower than the minimum detection limit of corresponding product
8	-	-	+	+	Samples contain SARS-CoV-2 and RSV antigens, not contain FLUA/B antigens or the content was lower than the minimum detection limit of corresponding product
9	-	+	-	+	Samples contain FLUA and RSV antigens, not contain FLUB and SARS-CoV-2 antigens or the content was lower than the minimum detection limit of corresponding product
10	-	+	+	-	Samples contain FLUA and SARS-CoV-2 antigens, not contain FLUB and RSV antigens or the content was lower than the minimum detection limit of corresponding product
11	+	-	+	-	Samples contain FLUB and SARS-CoV-2 antigens, not contain FLUA and RSV antigens or the content was lower than the minimum detection limit of corresponding product
12	+	-	-	+	Samples contain FLUB and RSV antigens, not contain FLUA and SARS-CoV-2 antigens or the content was lower than the minimum detection limit of corresponding product

13	+	-	-	-	Samples contain FLUB antigen, not contain FLUA,SARS-CoV-2 and RSV antigens or the content was lower than the minimum detection limit of corresponding product
14	-	+	-	-	Samples contain FLUA antigen, not contain FLUB,SARS-CoV-2 and RSV antigens or the content was lower than the minimum detection limit of corresponding product
15	-	-	+	-	Samples contain SARS-CoV-2 antigen, not contain FLUA/B and RSV antigens or the content was lower than the minimum detection limit of corresponding product
16	-	-	-	+	Samples contain RSV antigen, not contain FLUA/B and SARS-CoV-2 antigens or the content was lower than the minimum detection limit of corresponding product
17	Any other results without quality control lines				Invalid result: both in FLUA/B, SARS-CoV-2,or RSV, it is recommended to repeat the test with the same sample

Limitation

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2. If the virus antigen level in the sample is lower than the detection limit, the test result may be negative.
3. As the duration of the disease increases, the number of antigens in the sample may decrease. After the sample is collected, compared with RT-PCR analysis, 7 days after the onset of symptoms, the result may be negative.
4. Due to the limitation of the detection method, the negative result can not exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis.
5. This reagent can only qualitatively detect SARS-CoV-2 antigens, influenza A/B antigen and respiratory syncytial virus antigen in human nasopharyngeal swab, oropharyngeal swab. It cannot determine the certain antigen content in the samples.
6. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample transportation and storage or freezing and thawing of the sample will affect the test results.
7. It is optimum when eluting swabs with the matched samples extraction solution. Using other diluents may result in wrong results.
8. The solution and test cassette must be equilibrated to room temperature (20℃-30℃) before used, otherwise the results may be incorrect.
9. Sensitivity maybe decrease if the sample did not test directly. Please test the sample as soon as possible.
10. Positive results may be found in SARS-CoV infection patients in the SARS-CoV-2 antigen reagent.
11. Analysis the possibility of false negative results:
1) Inappropriate sample collection, using other non-matching solution, sample transfer time is too long, the volume of solution added when eluted the swab are too much, non-standardized elution operation, low virus titer in the sample, these may all lead to false negative results.
2) Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.
12. Analysis the possibility of false positive results:
1) Inappropriate sample collection, using other non-matching solutions, non-standardized elution operation, these may all lead to false positive results.
2) Cross-contamination of samples may lead to false positive results.
3) Excess blood or mucin on the swab sample may interfere with test performance and may yield a false positive result.
13. Analysis the possibility of invalid result:
1) If the sample volume is not enough, the chromatography cannot be carried out successfully.
2) The test cassette would invalid if the package was broken. The packaging status must be carefully checked before use.
14. In different stages of infection, samples of different viral load may have different coincidence rates with nucleic acid test results.
15. When sampling a nasopharyngeal swab, both nostrils need to be sampled with the same swab. If you only take it once, it may cause wrong results.

Quality Control

The test device has a test line (T) and a control line (C) on the surface. Neither the test line nor the control line is visible in the result window before applying a sample. The control line is used for quality control and should always appear if the test procedure is performed properly and the test reagents of the control line are working. If no line appears on the quality control line, it indicates operation error or reagent failure.
The appearance of control line (C) is confirmed sufficient sample volume, adequate membrane wicking and correct procedural technique.

Performance Characteristics

Clinical performance

SARS-CoV-2 test:

The performance was established with 500 oropharyngeal swabs collected from 500 patients who were suspected of SARS-CoV-2, including 100 positive samples and 400 negative samples. PCR was selected as the comparison method, and the comparison results are shown in the table below.
Also both nasopharyngeal swab and oropharyngeal swab were collected from the above135 patients and the results were consistent.

Table 1 SARS-CoV-2 Antigen Rapid Test Performance against with PCR

SARS-CoV-2 Antigen Rapid Test	PCR		Total
	Positive	Negative	
Positive	95	1	96
Negative	5	399	404
Total	100	400	500

PPA: 95.00% (95%CI: 88.83%-97.85%)
NPA: 99.75% (95%CI: 98.60%-99.96%)
OPA: 98.80% (95%CI: 97.41%-99.45%)

Influenza A test:

Results showed in table 2 have been obtained by using SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test and one commercially available immunochromatographic reagent.
189 respiratory samples have been used for Influenza A evaluation, including 43 positive samples and 146 negative samples. The results were as follows:

Table 2 Influenza A Rapid Test Performance against with Comparator Method

Influenza virus A Antigen Rapid Test	Similar reagent		Total
	Positive	Negative	
Positive	40	4	44
Negative	3	142	145
Total	43	146	189

PPA: 93.02% (95%CI: 81.39%-97.60%)
NPA: 97.26% (95%CI: 93.17%-98.93%)
OPA: 96.30% (95%CI: 92.55%-98.19%)

Influenza B test:

Results showed in table 3 have been obtained by using SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test and one commercially available immunochromatographic reagent.
186 respiratory samples have been used for Influenza B evaluation, including 47 positive samples and 139 negative samples. The results were as follows:

Table 3 Influenza B Rapid Test Performance against with Comparator Method

Influenza virus B Antigen Rapid Test	Similar reagent		Total
	Positive	Negative	
Positive	44	3	47
Negative	3	136	139
Total	47	139	186

PPA: 93.62% (95%CI: 82.84%-97.81%)
NPA:97.84% (95%CI:93.85%-99.26%)
OPA: 96.77% (95%CI: 93.14%-98.51%)

RSV test:

Results showed in table 4 have been obtained by using SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test and one commercially available immunochromatographic reagent.
192 respiratory samples have been used for Respiratory syncytial virus Antigen evaluation, including 51 positive samples and 141 negative samples. The results were as follows:

Table4 RSV Rapid Test Performance against with Comparator Method

RSV Antigen Rapid Test	Similar reagent		Total
	Positive	Negative	
Positive	48	3	51
Negative	3	138	141
Total	51	141	192

PPA: 94.12% (95%CI: 84.08%-97.98%)
NPA:97.87% (95%CI: 93.93%-99.27%)
OPA: 96.88% (95%CI: 93.35%-98.56%)
EXPLANATION OF TERMS:
PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives
NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives.
OPA: Overall Percent Agreement = True Positives + True Negatives / Total
CI: Confidence Interval

Limit of Detection

SARS-CoV-2: The limit of Detection (LOD) of the SARS-CoV-2 test is 1.6×10^2 $TCID_{50}$/mL.
Flu A+B: National Reference Panel for Influence A/B Viral Antigens Detection Kit of National Institutes for Food and Drug Control was used to detect the minimum detection limit: when S1 is 1.22×10^4 $TCID_{50}$/L, the test results are positive for influenza A virus and negative for influenza B virus; when S2 is 3.25×10^4 $TCID_{50}$/L, the test results are positive for influenza A virus and negative for influenza B virus; when S3 is 5.25×10^5 $TCID_{50}$/L, the test results are positive for influenza B virus and negative for influenza A virus; when S4 is 1.00×10^4 $TCID_{50}$/L, the test results are positive for influenza B virus and negative for influenza A virus; when S5 is 1.25×10^3 $TCID_{50}$/L, the test results are positive for influenza A virus and negative for influenza B virus.
RSV: The LOD of RSV antigen (type A) is 1.0×10^4 $TCID_{50}$/mL. The LOD of RSV antigen (type B) is 1.0×10^4 $TCID_{50}$/mL.

Analytical specificity

1. SARS-CoV-2:

1) Cross-reactivity
By testing 26 viruses and 14 other microorganisms, except for the Human

SARS-coronavirus Nucleoprotein, other viruses and microorganisms have no effect on the test results.

Cross Reaction Substance	Concentration	Results
HCoV-NL63	1 x 10^5TCID$_{50}$/mL	Negative
HCoV-OC43	8 x 10^5TCID$_{50}$/mL	Negative
HCoV-229E	1 x 10^5TCID$_{50}$/mL	Negative
HCoV-HKU1	10ug/mL	Negative
MERS	4 x 10^4TCID$_{50}$/mL	Negative
Human SARS-coronavirus Nucleoprotein	25ng/mL	Positive
Adenovirus Type3	1 x 10^6TCID$_{50}$/mL	Negative
Adenovirus Type7	1x 10^6TCID$_{50}$/mL	Negative
Adenovirus Type1	2 x 10^5TCID$_{50}$/mL	Negative
Adenovirus Type5	3 x 10^5TCID$_{50}$/mL	Negative
Adenovirus Type8	2.5 x 10^5TCID$_{50}$/mL	Negative
Adenovirus Type11	3 x 10^5TCID$_{50}$/mL	Negative
Adenovirus Type21	3 x 10^5TCID$_{50}$/mL	Negative
Adenovirus Type55	3 x 10^5TCID$_{50}$/mL	Negative
Echovirus	4 x 10^5PFU/mL	Negative
Influenza virus A (H1N1)	2.5 x 10^5PFU/mL	Negative
Influenza virus A(H3N2)	8 x 10^4PFU/mL	Negative
Influenza virus B Strain	3 x 10^5TCID$_{50}$/mL	Negative
Parainfluenza Type 1	1 x 10^5TCID$_{50}$/mL	Negative
Parainfluenza Type 2	1 x 10^5TCID$_{50}$/mL	Negative
Parainfluenza Type 3	1 x 10^5TCID$_{50}$/mL	Negative
Parainfluenza Type 4	1 x 10^5TCID$_{50}$/mL	Negative
Respiratory syncytial virus (RSV) type A	4 x 10^5TCID$_{50}$/mL	Negative
Respiratory syncytial virus (RSV) type B	4 x 10^5TCID$_{50}$/mL	Negative
Rhinovirus A16	1 x 10^5TCID$_{50}$/mL	Negative
Human Metapneumovirus (hMPV) 16 Type A1	1 x 10^5 TCID$_{50}$/mL	Negative
Candida albicans	1.8 x 10^6 CFU/mL	Negative
Legionella pneumophila	1 x 10^6 CFU/mL	Negative
Streptococcus pneumoniae	1x 10^6 CFU/mL	Negative
Pseudomonas aeruginosa	1 x 10^6 CFU/mL	Negative
Staphylococcus epidermidis	1 x 10^6 CFU/mL	Negative
Staphylococcus salivarius	1 x 10^6 CFU/mL	Negative
Mycoplaa Pneumoniae	1 x 10^6 CFU/mL	Negative
Chlamydia Pneumoniae	1 x 10^6 CFU/mL	Negative
Streptococcus pyogenes	1 x 10^6CFU/mL	Negative
Mycobacterum tuberculosis	1 x 10^6 CFU/mL	Negative
Hemophilus influenzae	1 x 10^6 CFU/mL	Negative
Bordetella pertussis	5 x 10^6 CFU/mL	Negative
Pneumocystis	1 x 10^6 CFU/mL	Negative
Pooled human nasal wash	NA	Negative

2) Microbial Interference Studies

By testing 10 other microorganisms, it was found that other microorganisms have no effect on the test results.

Other microorganism	Concentration	Results
Staphylococcus aureus	1 x 10^6CFU/mL	Negative
Escherichia coli	1 x 10^6CFU/mL	Negative
Streptococcus salivarius	1 x 10^6CFU/mL	Negative
Proteus mirabilis	1 x 10^6CFU/mL	Negative
Klebsiella pneumoniae	1 x 10^6CFU/mL	Negative
Staphylococcus haemolyticus	1 x 10^6CFU/mL	Negative
Mumps Virus Ag	2 x 10^3TCID$_{50}$/mL	Negative
Avian Influenza Virus（H7N9）	8 x 10^4PFU/mL	Negative
Measles virus	2 x 10^3TCID$_{50}$/mL	Negative
Norovirus	1 x 10^5TCID$_{50}$/mL	Negative

3) Interfering substances

The test results showed no interference with the following drug concentrations:

Name	Concentration	Results
Mucin	0.5%	Negative
Blood (human)	5%	Negative
Guaiacol glyceryl ether	1ug/mL	Negative
Arbidol Hydrochloride Hydrate	1mg/mL	Negative
Zanamivir	2mg/mL	Negative
Meropenem	1mg/mL	Negative
Oseltamivir	3mg/mL	Negative
Ritonavir	1mg/mL	Negative
Peramivirtrihydrate	3mg/mL	Negative
Ribavirin	1mg/mL	Negative
Histamine hydrochloride	2mg/mL	Negative
Levofloxacin	1mg/mL	Negative
Oxymetazolin hydrochloride	1mg/mL	Negative
Ceftriaxone sodium	1mg/mL	Negative
Cefradine	100mg/mL	Negative
Cefalexin	100mg/mL	Negative
Benzocaine	5mg/mL	Negative
Tobramycin	2mg/mL	Negative
Lopinavir	1mg/mL	Negative
Azithromycin	3mg/mL	Negative
Watermelon frost buccal tablets	100mg/mL	Negative
Dexamethasone	0.5mg/mL	Negative
Flunisolide	2mg/mL	Negative
Beclomethasone	10mg/mL	Negative
Sodium chloride	0.9%	Negative
Alpha-interferon	1mg/mL	Negative
Phenylephrine hydrochloride	5mg/mL	Negative
Acetaminophen	10mg/mL	Negative
Ibuprofen	1mg/mL	Negative
Aspirin	5mg/mL	Negative
Acetylsalicylic acid	5mg/mL	Negative
Hydrocortisone	1mg/mL	Negative
Albuterol	1mg/mL	Negative
Chlorpheniramine	5mg/mL	Negative
Diphenhydramine	5mg/mL	Negative
Budesonide	10mg/mL	Negative
Mometasone	1mg/mL	Negative
Fluticasone	1mg/mL	Negative
NeilMed	5mg/mL	Negative
Menthol	0.15mg/mL	Negative
Quinine	150uM	Negative
Lamivudine (retroviral drug)	1mg/mL	Negative
Biotin	100ug/mL	Negative
Human Anti-mouse Antibody	600ng/mL	Negative

2. Flu A+B:

1) There was no cross reaction with respiratory adenovirus, respiratory syncytial virus and mycoplaa pneumoniae. There was no interfer reaction with haemophilus influenzae, pseudomonas aeruginosa, staphylococcus aureus, staphylococcus epidermidis, streptococcus pyogenes, streptococcus salivarius, proteus singularis and candida albicans.

2) The test results showed no interference with the following drug concentrations:

Name	Concentration	Results	
		Flu A	Flu B
Mucoprotein	0.5%	Negative	Negative
Blood	5%	Negative	Negative
Oxymetazoline Hydrochloride	0.5mg/mL	Negative	Negative
Dexamethasone acetate	0.5mg/mL	Negative	Negative
Budesonide nasal spray	0.5 mg/mL	Negative	Negative
Tobramycin eye drops	1mg/mL	Negative	Negative
N-acetaminophen	2 mg/mL	Negative	Negative
Aspirin	5mg/mL	Negative	Negative
Cefalexin	50mg/mL	Negative	Negative
Chloramphenicol eye drops	0.5mg/mL	Negative	Negative
Cefradine	10mg/mL	Negative	Negative
Oseltamivir	5mg/mL	Negative	Negative
Zanamivir	1mg/mL	Negative	Negative
Ribavirin	0.1mg/mL	Negative	Negative
Levofloxacin	1mg/mL	Negative	Negative
Meropenem	1mg/mL	Negative	Negative
Watermelon frost slice	2mg/mL	Negative	Negative
Mupirocin	0.75mg/mL	Negative	Negative
Amoxicillin	5mg/mL	Negative	Negative
Cefixime	2mg/mL	Negative	Negative
Clarityne	2mg/mL	Negative	Negative

3. RSV:
1) There was no cross reaction with Influenza viru A (H1N1, H3N2), Influenza viru B, respiratory adenovirus, and mycoplaa pneumoniae. There was no interfer reaction with haemophilus influenzae, pseudomonas aeruginosa, staphylococcus aureus, staphylococcus epidermidis, streptococcus pyogenes, streptococcus salivarius, proteus singularis and candida albicans.
2) The test results showed no interference with the following drug concentrations:

Name	Concentration	Results
Mucoprotein	0.5%	Negative
Blood	5%	Negative
Oxymetazoline Hydrochloride	0.5mg/mL	Negative
Dexamethasone acetate	0.5mg/mL	Negative
Budesonide nasal spray	0.5mg/mL	Negative
Tobramycin eye drops	1mg/mL	Negative
N-acetaminophen	2mg/mL	Negative
Aspirin	5mg/mL	Negative
Cefalexin	50mg/mL	Negative
Chloramphenicol eye drops	0.5mg/mL	Negative
Cefradine	10mg/mL	Negative
Oseltamivir	5mg/mL	Negative
Zanamivir	1mg/mL	Negative
Ribavirin	0.1mg/mL	Negative
Levofloxacin	1mg/mL	Negative
Meropenem	1mg/mL	Negative
Watermelon frost slice	2mg/mL	Negative
Mupirocin	0.75mg/mL	Negative
Amoxicillin	5mg/mL	Negative
Cefixime	2mg/mL	Negative
Clarityne	2mg/mL	Negative

Hook Effect:
SARS-CoV-2: No high dose hook effect was observed up to $1.6x10^5$ $TCID_{50}$/mL of SARS-CoV-2.
Flu A+B: No high dose hook effect was observed up to $4.9x10^8$$TCID_{50}$/mL of Influenza A virus; No high dose hook effect was observed up to $5.4x10^6$ $TCID_{50}$/mL of Influenza B virus.
RSV: No high dose hook effect was observed up to $1.0x10^6$$TCID_{50}$/mL of RSV (type A). No high dose hook effect was observed up to $1.0x10^6$$TCID_{50}$/mL of RSV (type B).

Precaution
1. The reagent is a disposable diagnostic reagent in vitro, which is only used for the detection of human nasopharyngeal swab, or oropharyngeal swab. The operation should be carried out strictly according to the instructions. Do not use expired and damaged products.
2. The strength of the quality control line does not mean the quality of the reagent, as long as its color is clear and visible, that means the reagent is effective.
3. The kit should be sealed and kept away from moisture. Reagents or samples stored at low temperature should be balanced to room temperature before they can be used.
4. Reagents should be used as soon as possible after removal from aluminum foil bags, so as to avoid exposure to air for too long and affecting test results due to dampness.
5. Do not use samples that have been placed for too long or contaminated.
6. Please operate in accordance with the laboratory testing procedures for infectious diseases. Waste after use should be treated in accordance with infectious substances and should not be discarded at will.
7. Incorrect operation may affect the accuracy of the results, such as sample extraction reagent insufficient or excessive, insufficient sample mixing, insufficient amount, inaccurate detection time, etc.
8. Components in different batch should not be mixed; Viral Transport Media (VTM) may affect the test result; extracted sample for PCR tests cannot be used for the test.
9. If the sample swab is not rotated and squeezed in the sample extraction tube for 10 times, false negative results may occur. If the swab is put into the packaging bag after sample collection, false negative results may occur.
10. There should be appropriate biosafety assurance procedures for those substances containing and suspected sources of infection. The following are relevant considerations:
1) Handle samples and reagents with gloves;
2) Do not suck samples with your mouth;
3) Do not smoke, eat, drink, cosmetic or handle contact lenses while handling these items;
4) Disinfect the spilled sample or reagent with disinfectant;
5) Disinfect and treat all samples, reagents and potential pollutants in accordance with relevant local regulations;
6) Each component of the reagent remains stable until the expiry date under proper handling and storage conditions. Do not use the expired reagent kit.
11. The extraction reagent contains sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with a large volume of water.

MANUFACTURER / POST-SALE SERVICE UNIT

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EUROPEAN REPRESENTATIVE

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CE

INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Keep dry
30℃ 4℃	Temperature limit	LOT	Batch code
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Use-by date	Σ	Contains sufficient for <n> tests
EC REP	European representative		Keep away from sunlight

IFU- SARS-CoV-2/Flu A+B/RSV Antigen , 2021-05, A/2, English