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Produktinformation

- Forschungsprodukte & Biochemikalien
- Zellkultur & Verbrauchsmaterial
- Diagnostik & molekulare Diagnostik
- Laborgeräte & Service

Weitere Information auf den folgenden Seiten!
See the following pages for more information!

Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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COVID-19 & Influenza A and B Rapid Test Cassette

Background

People infected with the 2019-Novel Coronavirus can cause a variety of respiratory symptoms. In severe cases, it can lead to pneumonia, severe acute respiratory syndrome, renal failure, and even death.

Influenza virus is a type of pathogen that can cause acute respiratory infections in humans. It is highly infectious, spreads quickly, has a high morbidity rate, and is accompanied by certain mortality.

Influenza A, influenza B, and COVID-19 viral antigens are generally detectable in upper respiratory specimens during the acute phase of infection.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Jiangsu Mole Bioscience Co.,Ltd.

Stock code 839185

Jiangsu Taizhou

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Tel: 0523-86080606

Zhejiang Hangzhou

Add: 4-5th Floor, Building No.5, Health Valley, No.1500 Wenyi xi Road, Yuhang District, Hangzhou, Zhejiang province, China

Tel: 0571-87209306 / 87209308

Detection Significance

Early diagnosis and early isolation can be achieved for the infection of the two pathogens, to block the transmission of pathogens, and reduce the risk of epidemic transmission.

In the period of the COVID-19 pandemic, it can help doctors distinguish between the novel coronavirus infection and influenza virus infection, and make a targeted treatment plan.

Test Principle

The COVID-19 Antigen and/or Flu A/B Combo Test Cassette is a qualitative membrane strip-based immunoassay for the detection of influenza A virus,and influenza B virus, COVID-19 virus in nasopharyngeal swab specimen.

Product Advantages

- **Simple Test Procedure** — NO laboratories or trained personnel request, easy-to-interpret results.
- **Complete Testing** — One sampling can Detect and differentiate of COVID-19 antigen, Influenza A and B virus.
- **Better Performance** — The sensitivity and specificity for Influenza A or B are both > 99%. The sensitivity for COVID-19 is 97.3% and the Specificity is 98.4%.
- **Fast Result** — Results in only 15 minutes.

Ordering Information

Ref	Product Name	Packing Size	Storge Condition	Certification
R218T020B0C0	Flu A/B + COVID-19 Antigen Combo Test Cassette Kit	20 Tests/Kit	2-30°C	CE
R084T020B0C0	Influenza A&B Rapid Test Cassette	20 Tests/Kit	2-30°C	CE

Specimen | Nasopharyngeal swab Kit Size | 20 tests/kit Shelf life: 2 years

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Flu A/B + COVID-19 Antigen Combo Test Cassette Kit
Instruction for Use

IVD

For Professional *Use Only.*
***For In Vitro* Diagnostic Use Only.**

INTENDED USE

The test is intended for use in the rapid detection and differentiation of influenza A virus, influenza B virus, and COVID-19 virus nucleocapsid protein antigen, but does not differentiate, between SARS-CoV and COVID-19 viruses and is not intended to detect influenza C antigens. Performance characteristics may vary against other emerging influenza viruses.
Influenza A, influenza B and COVID-19 virus antigens are generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
The In fluenza A , Influenza B and COVID-19 Antigen Combo Test Kit is intended for the influenza A,influenza B and COVID-19 antigens in the nasal swab and Nasopharyngeal swab samples.
The test provides preliminary test results. Negative results cannot exclude COVID-19 ,influenza A or influenza B virus infection and they cannot be used as the sole basis for treatment or other management decision.

BACKGROUND

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2,COVID-19 virus) epidemic is a public health emergency of international concern. At present, the COVID-19 virus is spreading all over the world. Due to the the emergence of vaccines, people's risk of contracting the virus has been reduced, but it is still impossible to completely avoid contracting the virus.Thus,it is necessary for people to conduct a rapid self-test.
According to the clinical data and the current epidemiological investigation, the general incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
Influenza is a highly contagious, acute, viral infection of the respiratory tract. It is a communicable disease that is easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months.Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while Type B infections are usually more mild.
Rapid diagnosis of influenza A and B or COVID-19 virus has become more important due to the availability of effective antiviral therapy. Rapid diagnosis of influenza can lead to reduced hospital stays, antimicrobial use and cost of hospital care.

TEST PRINCIPLE

The Flu A/B + COVID-19 Antigen Combo Test kit is a rapid chromatographic immunoassay for the qualitative detection of influenza A virus, and influenza B virus, COVID-19 virus in nasal swab , nasopharyngeal swab specimen.
For Influenza A/B Test Cassette: In this test procedure, anti-influenza A antibody, and anti-influenza B antibody is immobilized in the different test line regions of the device. After a swab specimen is placed in the sample well, it reacts with anti-influenza A antibody, or anti-influenza B antibody coated particles that have been applied to the conjugate pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-influenza A antibody or anti-influenza B antibody.
If the specimen contains influenza A virus, or influenza B virus, a colored line will appear in the corresponding test line region indicating a positive result. If the specimen does not contain influenza A virus and influenza B virus, a colored line will not appear in these regions indicating a negative result. If the specimen contains influenza A and influenza B virus, two colored line will appear in the test line region.To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.
For COVID-19 Antigen Test Cassette: In this test procedure, anti-COVID-19-N antibody is immobilized in the different test line regions of the device. After a nasopharyngeal swab or nasal swab specimen is placed in the specimen well, it reacts with anti-COVID-19-N protein antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-COVID-19-N antibody.
If the specimen contains COVID-19 virus, a colored line will appear in the corresponding test line region indicating a positive result. If the specimen does not contain COVID-19 virus, a colored line will not appear in the region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Material Provided

- Test Cassette.....20
- Disposable swab.....20
- Workstation.....1
- Instructions for use.....1
- Extraction tube with buffer solution.....20

Materials Required but Not Provided
Timer, sealed bag and disinfectant;

STORAGE AND STABILITY

1. Store at 2-30°C ,the validity period of the product is 24 months. Do not freeze.
2. The test cassette should be used within 1 hour after opening the sealed pouch.
3. Kit contents are stable until the expiration date printed on the package.
4. Keep away from sunlight, moisture and heat.

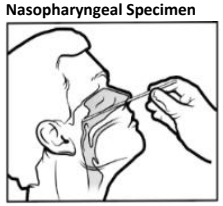
WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens and kits are handled.
4. Handle all specimens as if they contain infectious agents.
5. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Follow standard biosafety guidelines for handling and disposal of potential infective material.
8. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION

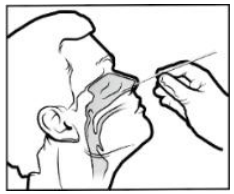
Please read the instructions for use carefully before use.
Allow the test cassette, buffer to reach room temperature 15-30 °C (59-86 °F) before testing.

Nasopharyngeal Specimen



- Tilt patient's head back 70 degrees.
- Gently and slowly insert the swab provided through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
- Gently rub and roll the swab for at least 5 times to absorb secretions, then slowly remove swab while rotating it.
- Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection.
- The swab collected with the specimen should be tested as soon as possible. If immediate testing is not possible, the swab should be placed in a sterile plastic tube labeled with patient's information and closed tightly at room temperature (15-30°C) for up to 1 hour before testing.

Nasal Specimen

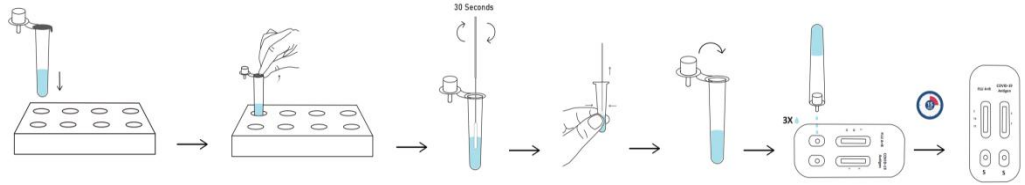


- Tilt patient's head back 70 degrees.
- While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril parallel to the palate (not upwards) until there is resistance at the turbinates.
- Rotate the swab at least 5 times against nasal wall, then slowly remove swab while rotating it.
- Repeat the above steps on the other nostrils using the same swab. The swab collected with the specimen should be tested as soon as possible. If immediate testing is not possible, the swab should be placed in a sterile plastic tube labeled with patient's information and closed tightly at room temperature (15-30°C) for up to 1 hour before testing.

TEST PROCEDURE

Nasal and Nasopharyngeal Specimen Test Procedure

1. Allow the test cassette, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.
2. Place the extraction tube in the workstation. Tear off the seal of the extraction tube.
3. After the specimen collection, insert the swab into the extraction tube which contains buffer, and rotate the swab for approximately 30 seconds to dissolve the sufficient specimen in the buffer.
4. Remove the swab while squeezing the swab head to screw the remaining specimen out.
5. Discard the swab according to your biohazard waste disposal protocol.
6. Remove a test cassette from the foiled pouch by tearing at the notch and place it on a clean and horizontal surface.
7. Cover the extraction tube with the dropping tip and add 3 drops of the specimen vertically into the each specimen well of the cassette.
8. Read the result after 15 minutes. The test result should not be read and interpreted after 20 minutes.



RESULT INTERPRETATION

Interpretation of Flu A/B results

Influenza A Virus POSITIVE: * Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the Test line region(Flu A line region,line 2).

Influenza B Virus POSITIVE: * Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the Test line region (Flu B line region ,line 1).

COVID-19 Virus POSITVIE: * Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the Test line region (COVID-19 virus line region ,line 3).

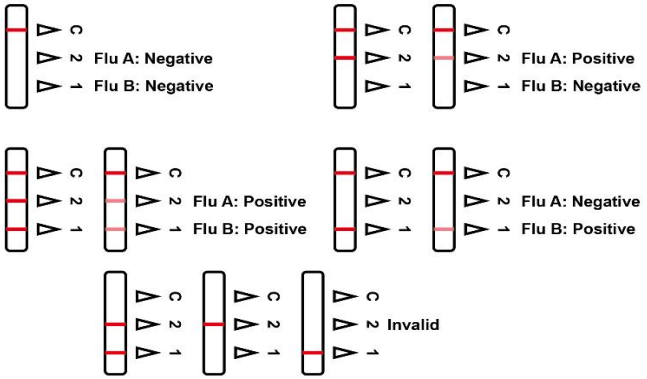
Influenza A Virus and Influenza B Virus POSITIVE: * Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the Flu A line region (2) and Flu B line region (1).

Influenza A Virus ,Influenza B Virus and COVID-19Vi

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of influenza A virus and influenza B virus present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

Negative: One colored line appears in the control region(C). No apparent colored line appears in the test line regions.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



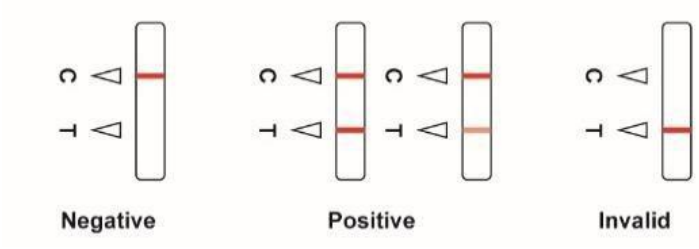
Interpretation of COVID-19 antigen results

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region(T).

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antigen present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

Negative: One colored line appears in the control region(C). No apparent colored line appears in the test line region(T).

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice .

LIMITATIONS OF THE TEST METHOD

1. This test detects both viable (live) and non-viable, Flu A/B and COVID-19. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of Flu A/B + COVID-19 Antigen Combo Test Kit was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. False results may occur if specimens are tested past 2 hour of collection. Specimens should be test as quickly as possible after specimen collection.
6. Positive test results do not rule out co-infections with other pathogens.
7. COVID-19 Positive test results do not differentiate between SARS-CoV and COVID-19.
8. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
9. Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
10. If the differentiation of specific influenza A virus, influenza B virus and COVID-19 viruses and strains is needed, additional testing, in consultation with local public health departments, is required.

PERFORMANCE CHARACTERISTICS

1 Sensitivity and Specificity

1.1 Sensitivity and Specificity of Flu A

1.1.1 The Influenza A/B Test Kit (nasopharyngeal Swab Specimen) was compared with a commercial PCR.

Method		PCR		Total
	Results	Positive	Negative	
Rapid Test Influenza A/B	Positive	82	0	82
	Negative	1	386	387
Total		83	386	469

The relative sensitivity of Flu A is 98.80% ; (95% CI:97.9%~ 100.0%)

The relative specificity of Flu A is 99.4%; (95%CI: 99.01%~100.0%)

1.1.2 The Influenza A/B Test Kit (nasal Swab Specimen) was compared with a commercial PCR.

Method		PCR		Total
	Results	Positive	Negative	
Rapid Test Influenza A/B	Positive	81	0	81
	Negative	2	386	388
Total		83	386	469

The relative sensitivity of Flu A is 97.59%(95%CI:91.63%~99.34%)

The relative specificity of Flu A is>99.00% (95%CI:99.01%~100.00%)

1.2 Sensitivity and Specificity of Flu B

1.2.1 The Influenza A/B Test Cassette (nasopharyngeal Swab Specimen) was compared with a commercial PCR.

Method		PCR		Total
	Results	Positive	Negative	
Rapid Test Flu A/B	Positive	86	0	86
	Negative	1	382	383
Total		87	382	469

The relative sensitivity of Flu B is 98.85% ; 95% CI:(93.77%~ 99.80%)

The relative specificity of Flu B is >99.00%; 95%CI: (99.00%~100.0%)

1.2.2 The Influenza A/B Test Cassette (nasal Swab Specimen) was compared with a commercial PCR.

Method		PCR		Total
	Results	Positive	Negative	
Rapid Test Flu A/B	Positive	84	0	84
	Negative	3	382	385
Total		87	382	469

The relative sensitivity of Flu B is 96.55%(95%CI:90.35%~98.82%)

The relative specificity of Flu B is >99.00% (95%CI:99.00%~100.0%)

1.3 Sensitivity and Specificity of COVID-19

1.3.1The SARS-CoV-2 Antigen Test Cassette (nasopharyngeal Swab Specimen)was compared with a commercially available gold standard reagent(PCR),the results showed that the clinical sensitivity and specificity.

Assessment reagent		PCR (gold standard reagent)		Total
		Positive	Negative	
SARS-CoV-2 Antigen Test Cassette	Positive	96	0	96
	Negative	2	371	373
Total		98	371	469

The relative Sensitivity (Positive coincidence rate) is 97.96% ;(95%CI：92.86%~99.44%)

The relative Specificity (Negative coincidence rate)is >99.00%; （95%CI：98.98~100.00%）

1.3.2The SARS-CoV-2 Antigen Test Cassette(nasal Swab Specimen) was compared with a commercially available gold standard reagent (PCR), the results showed that the clinical sensitivity and specificity.

Assessment reagent		PCR (gold standard reagent)		Total
		Positive	Negative	
SARS-CoV-2 Antigen Test Cassette	Positive	95	0	95
	Negative	3	371	374
Total		98	371	469

The relative Sensitivity (Positive coincidence rate) is 96.94% ;(95%CI：91.38%~98.95%)

The relative Specificity (Negative coincidence rate)is >99.00%;(95%CI:98.98~100.00%)

2.Limit of Detection(LOD)

The limit of detection of FluA/B+COVID-19 Combo Antigen Test Kit is showed on the follow tables.

Item	Concentration	Positive/result	Agreement rate
COVID-19 NP-protein	0.1ng/ml	30/30	100%
COVID-19 inactivated virus culture	50 $TCID_{50}$/ml	10/10	100%
Flu A NP-protein	2ng/ml	30/30	100%
Flu A inactivated virus culture (Aichi/2/68)	1.25×10^3 CEID/test	10/10	100%
Flu B NP-protein	3ng/ml	30/30	100%
Flu B inactivated virus culture(Hong Kong5/72)	0.5 x 10^2CEID/Test	10/10	100%

The test Limit of detection for the Influenza Strain.The Influenza Strain is come from ATCC and The Influenza Strain ATCC # Concentration is showed on the follow table.

Influenza strain	Concentration	Influenza strain	Concentration
Influenza A/Aichi/2/68(H3N2)	1.25×10^3 CEID/test	Influenza A/Netherlands/12/00(07/336)(H7N3)	3ug/test
Influenza A/NWS/33(H1N1)	2.67×10^4 CEID/test	Influenza A/Cambodia/R0405050/2007(08/216)(H5N1)	1.5ug/test
Influenza A/Hong Kong/8/68	5.35×10^4 CEID/test	Influenza A/Brazil/11/78(79/560)	60ug/test
Influenza A/Port/Chalmers/1/73(H3N2)	1.90×10^4 CEID/test	Influenza A/Vietnam/1194/2004(09/184)(H5N1)	15ug/test
Influenza A/WS/33(H1N1)	4.74×10^2 CEID/test	Influenza A/Taiwan/1/86(94/510)	60ug/test
Influenza A/New Jersey/8/76(Hsw N1)	2.67×10^2 CEID/test	Influenza B Brigit	4.75×10^4 CEID/test
Influenza A/Mal/302/54	2.65×10^5 CEID/test	Influenza B B/R5	0.75CEID/test
Influenza A/panama/2007/99	10.5ng/test	Influenza B Hong Kong/5/72	0.5×10^2 CEID/test
Influenza A/New Caledonia/20/99	15ng/test	Influenza B/Russia/69	1.78×10^2 CEID/test
Influenza A/Hong Kong/1073/99/(08/208)(H9N2)	6ug/test	Influenza B/Lee/40	1.58×10^3 CEID/test
Influenza A/Mississippi/1/85(86/576)	750ug/test		

3.Cross-reactivity

3.1 The cross-reactivity for COVID-19 Test Kit

The COVID-19 Test Cassette was tested with various microorganisms for possible cross-reactivity. No cross-reactivity was seen with the following microorganisms when tested at the concentration presented in the table below.

Microorganism	Concentration	Microorganism	Concentration
Arcanobacterium bernardiae	1×10^7 CFU/ml	Staphylococcus epidermidis	1×10^7 CFU/ml
Arcanobacterium haemolyticum	1×10^7 CFU/ml	Streptococcus pneumoniae	1×10^7 CFU/ml
Candida albicans	1×10^7 CFU/ml	Streptococcus salivarius	1×10^7 CFU/ml
Corynebacterium	1×10^7 CFU/ml	Streptococcus sp. Group F	1×10^7 CFU/ml
Moraxella catarrhalis	1×10^7 CFU/ml	Human Coronavirus OC43	2.45×10^6 $TCID_{50}$/ml
Neisseria lactamica	1×10^7 CFU/ml	Coronavirus NL63	1×10^5 $TCID_{50}$/ml
Pseudomonas aeruginosa	1×10^7 CFU/ml	Influenza A H1N1	3.16×10^5 $TCID_{50}$/ml
Staphylococcus aureus subspaureus	1×10^7 CFU/ml	Influenza A H3N2	1×10^5 $TCID_{50}$/ml
Influenza B (Yamagata and Victoria) virus	3.16×10^6 $TCID_{50}$/ml	Parainfluenza virus 2	1.58×10^6 $TCID_{50}$/ml
Human Rhinovirus 2	2.81×10^4 $TCID_{50}$/ml	Parainfluenza virus 3	1.58×10^7 $TCID_{50}$/ml
Human Rhinovirus 14	1.58×10^6 $TCID_{50}$/ml	Respiratory syncytial virus	8.89×10^4 $TCID_{50}$/ml
Human Rhinovirus 16	8.89×10^6 $TCID_{50}$/ml	MERS-coronavirus	10^5 PFU/ml
Measles virus	1.58×10^4 $TCID_{50}$/ml	Epstein-Barr virus	10^5 PFU/ml
Adenovirus 3	$1.58\times10^4$$TCID_{50}$/ml	human metapneumovirus (hMPV)	2.25×10^5 $TCID_{50}$/ml
Human coronaviruses 229E	2.35×10^6 $TCID_{50}$/ml	Coronavirus HKU1	1×10^5 $TCID_{50}$/ml

3.2 The cross-reactivity for FluA/B Test Kit

The FluA/B Test Kit was tested with various microorganisms for possible cross-reactivity. No cross-reactivity was seen with the following microorganisms when tested at the concentration presented in the table below.

Microorganism	Concentration	Microorganism	Concentration
Arcanobacterium bernardiae	1×10^7 CFU/ml	Staphylococcus epidermidis	1×10^7 CFU/ml
Arcanobacterium haemolyticum	1×10^7 CFU/ml	Streptococcus pneumoniae	1×10^7 CFU/ml
Candida albicans	1×10^7 CFU/ml	Streptococcus salivarius	1×10^7 CFU/ml
Corynebacterium	1×10^7 CFU/ml	Streptococcus sp. Group F	1×10^7 CFU/ml
Moraxella catarrhalis	1×10^7 CFU/ml	Human Coronavirus OC43	2.45×10^6 $TCID_{50}$/ml
Neisseria lactamica	1×10^7 CFU/ml	Coronavirus NL63	1×10^5 $TCID_{50}$/ml
Pseudomonas aeruginosa	1×10^7 CFU/ml	Parainfluenza virus 2	1.58×10^6 $TCID_{50}$/ml
Staphylococcus aureus subspaureus	1×10^7 CFU/ml	Parainfluenza virus 3	1.58×10^7 $TCID_{50}$/ml
Human Rhinovirus 2	2.81×10^4 $TCID_{50}$/ml	Respiratory syncytial virus	8.89×10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58×10^6 $TCID_{50}$/ml	MERS-coronavirus	10^5 PFU/ml
Human Rhinovirus 16	8.89×10^6 $TCID_{50}$/ml	Epstein-Barr virus	10^5 PFU/ml
Measles virus	1.58×10^4 $TCID_{50}$/ml	human metapneumovirus (hMPV)	2.25×10^5 $TCID_{50}$/ml
Adenovirus 3	$1.58\times10^4$$TCID_{50}$/ml	Coronavirus HKU1	1×10^5 $TCID_{50}$/ml
Human coronaviruses 229E	2.35×10^6 $TCID_{50}$/ml	SARS-CoV-2	$2.5\times10^5$$TCID_{50}$/ml
SARS-CoV	2.5×10^5 $TCID_{50}$/ml		

4. Interfering Substances

The following compounds had been tested using the FluA/B+COVID-19 Antigen Test Kit and no interference observed.

Analytes	Concentration	Analytes	Concentration
Whole Blood	20μl/ml	Naso Gel	5% (V/V)
Mucin	50μg/ml	Phenylephrine	12mg/ml
Budesonide Nasal Spray	200μl/ml	Relenza	282ng/ml
Dexamethasone	0.8mg/ml	Tamiflu	1.1μg/ml
Flunisolide	6.8ng/ml	Tobramycin	2.43mg/ml
Mupirocin	12mg/ml	CVS Nasal Spray(Cromolyn)	15% (V/V)
Oxymetazoline	0.6mg/ml	AZEP Nasal Spray(Azelastine)	10% (V/V)
Chloraseptic(Methol/Benzocaine)	1.5mg/ml	Mupirocin	10mg/ml
Sterimar Nasal Spray(Saline,)	1:1 (V/V)		

5. Precision

Repeatability: The results of testing the three batches of products with negative and positive solution, products have good color reading consistency. That is, the products have good repeatability.

Reproducibility: Different people use negative and positive solutions to test the three batches of products at different locations and at different times, the color rendering results of the products are all consistent. The products have good reproducibility.

Manufacturing Date and Expiration Date: view on label

INDEX OF SYMBOL

	Consult Instructions for Use		Contain <n> tests		Do not use if package is damaged and consult instruction for use
IVD	In vitro diagnostic medical device		Use-by date		Do not reuse
REF	Catalogue #	LOT	Lot Number	2°C 30°C	Temperature limit 2 to 30°C
	Manufacture Date		Manufacturer	CE	CE conformity marking
EC REP	Authorized Representative				

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EC REP

Lotus NL B.V.
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Accessory	Manufacturer	EC-Representative	CE Mark
Disposable swab	Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town, Guangling District, Yangzhou 225109 Jiangsu, P.R. China	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany	CE 0197

REF: R218T020B0C0
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REVISION HISTORY

Version	Date	Description
English VER 1.0	2022.09.30	First Release