COVID-19& Influenza A/B& RSV Antigen Nasal Test Kit （Nasal）

REF: MI-S34001

INTENDED USE

The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit is an *in vitro* immunoassay. The assay is for the direct and qualitative detection of viral nucleocapsid proteins of SARS-CoV-2, Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) from nasal secretions. The test is for professional use. Negative results do not preclude these viral infections. Testing results should not be the sole basis for treatment or other management decisions.

PRINCIPLE

The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit detects viral antigens through visual interpretation of color development on the three internal test strips for COVID-19, FLU A/B and RSV respectively.

For COVID-19 test:

Anti-SARS-CoV-2 antibodies are immobilized at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colored particles are immobilized on the conjugated pad.

The nasal secretions, collected by the intended user, are supposed to be mixed with the extraction buffer, which is individually packed in the kit.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to anti-SARS-CoV-2 antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 antibodies immobilized at the Test Region. Excess colored particles will be captured at the Control Region of the NC membrane.

The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

For Influenza A/B test:

Anti-Influenza A virus antibodies and anti-Influenza B virus antibodies are immobilized at two separate test regions of the nitrocellulose membrane. Anti-Influenza A virus antibodies and anti-Influenza B virus antibodies conjugated to colored particles are immobilized on the conjugated pad.

The nasal secretions, collected by the intended user, are supposed to be mixed with the extraction buffer, which is individually packed in the kit.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the antibodies immobilized at the two Test Regions. Excess colored particles will be captured at the Control Region of the NC membrane.

The presence of a colored band in the test region indicates a positive result for the Influenza A/B viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

For RSV test:

Anti-respiratory syncytial virus antibodies are immobilized at the test region of the nitrocellulose membrane. Anti-respiratory syncytial virus antibodies conjugated to colored particles are immobilized on the conjugated pad.

The nasal secretions, collected by the intended user, are supposed to be mixed with the extraction buffer, which is individually packed in the kit.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to anti-respiratory syncytial virus antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the anti-respiratory syncytial virus antibodies immobilized at the Test Region. Excess colored particles will be captured at the Control Region of the NC membrane.

The presence of a colored band in the test region indicates a positive result for the respiratory syncytial viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- Individually packed test
- Package insert

Materials Required but Not provided

- Clock, timer or stopwatch

PRECAUTIONS

- For *in vitro* Diagnostic Use Only.
- Caution should be taken when inserting the sample collector into the nasal cavity.
- DO NOT ingest.
- Read the *Package Insert* prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin or eyes contact with buffer before, during or after testing.
- If infections with SARS-CoV-2, Influenza A virus, Influenza B virus and/or respiratory syncytial virus are suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- Do not puncture the sealing membrane in the extraction tube before testing.
- Viral isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2, Influenza A virus, Influenza B virus or respiratory syncytial virus are NOT recommended, except in a BSL3 laboratory using BSL3 work practices.

STORAGE AND STABILITY

- Store The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit at 2~30℃ when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

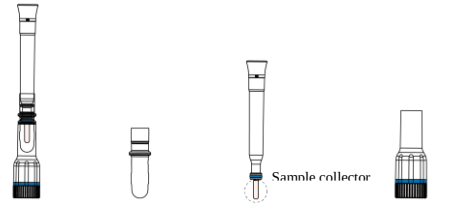
TEST PROCEDURE

Bring devices, reagents and specimens and/or controls to room temperature (15~30℃) before use.

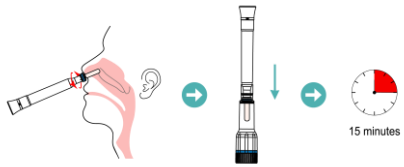
1. Remove the test from its packing. Label the device with the patient's identification. For best results, the assay should be performed within one hour.
2. 1) Take the test device out of the extraction tube.
   2) Remove the protector.
3. Gently insert the sample collector (the circle part in the picture) until resistance is met (about 1-2 cm into the nostril).
4. Rotate the collector five times against the nasal wall and remove from the nostril.
5. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen be collected from both nasal cavities.

Note: 1. It is important to obtain as much secretion as possible.
2. This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance.

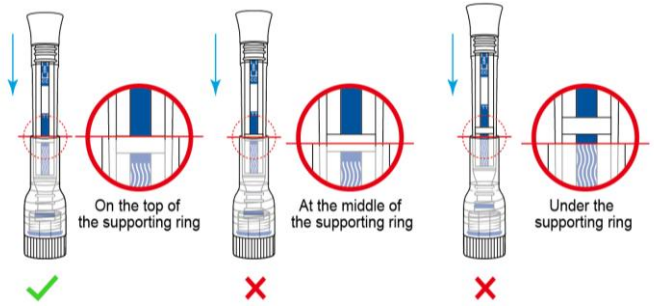
6. Place the test device vertically into the extraction tube until the top edge of the extraction tube reach the top of the supporting ring.
7. Read the results at 15 minutes.



Test **(a) Protector** **(b)Test Device** **(C)Extraction tube**

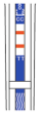


Note:
When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

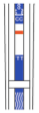


RESULT INTERPRETATION

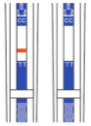
For COVID-19 test:



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

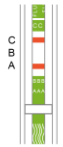


NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

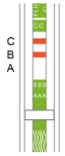


INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

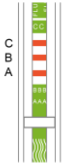
For Influenza A/B test:



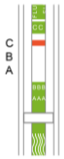
Influenza A Positive: One colored band appears in the control region (C), and another colored band in the A region (A).



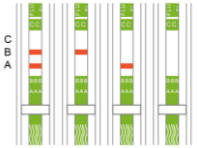
Influenza B Positive: One colored band appears in the control region (C), and another colored band in the B region (B).



Influenza A+B Positive: One colored band appears in the control region (C), and two other colored bands appear in both A region (A) and B region (B).
NOTE: Co-infection with influenza A and B is rare. A clinical specimen that generates positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.

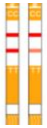


Negative: Only one colored band appears in the control region (C), and band appears neither in the A region (A) nor B region (B).



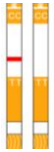
Invalid: No colored band appears in the control region (C), whether a test band(s) is present or not. Repeat invalid tests with a new sample, new test device and reagent. Insufficient sample volume, inaccurate operating procedure or expired tests may yield an invalid result. Contact your local distributor if the problem continues.

For RSV test:



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region(s) may vary depending on the concentration of analytes present in the specimen. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

QUALITY CONTROL

Internal Procedural Controls

The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit has built-in (procedural) controls. Each test has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

External Positive and Negative Controls

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

LIMITATIONS OF THE TEST

1. The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of viral antigens specific for SARS-CoV-2, Influenza A virus, Influenza B virus and respiratory syncytial virus. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. Both viable and nonviable viruses are detectable with the kit.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
5. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
6. Negative results do not preclude viral infections and should be confirmed via molecular assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity:

The limit of detection(LOD) of COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit, defined as the concentration of influenza virus and SARS-CoV-2 virus that produces positive COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit results approximately 95% of the time, was identified by evaluating different concentrations of inactivated Flu A(H3N2, H1N1), inactivated Flu B(Victoria, Yamagata), inactivated respiratory syncytial virus (type B) and inactivated SARS-CoV-2 in The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit.

20 tests were run at each concentration. The results identify a concentration of 1.0×10^4 $TCID_{50}$/ml as the LOD for Flu A(H3N2), 4.3×10^4 $TCID_{50}$ as the LOD for Flu A(H1N1), 2.2×10^5 $TCID_{50}$ for Flu B(Victoria), 2.5×10^5 $TCID_{50}$ for Flu B(Yamagata), 1.35×10^3 $TCID_{50}$/mL for inactivated respiratory syncytial virus (type B) and $1\times10^{2.4}$ $TCID_{50}$/mL as the LOD for SARS-CoV-2.

Clinical Evaluation:

For COVID-19 Test:

A total of 151 clinical specimens were collected to verify the performance of COVID-19 Antigen Test. Individuals who are suspected of COVID-19 were enrolled in this study.32 positive specimens and 119 negative specimens were confirmed by RT-PCR.

Table 1: Clinical Summary of COVID-19 Antigen

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Test	Positive	31	0	31
	Negative	1	119	120
	Total	32	119	151

Relative Sensitivity:96.9% (84.3%~99.4%)*
Relative Specificity: 99.9% (96.9%~100.0%)*
Overall Agreement: 99.3 % (96.3%~99.9 %)*
*95% Confidence Interval

For FLU A/B Test:

For Influenza A Test:

A total of 151 clinical specimens were collected, to verify the performance of Influenza A/B Antigen Test. 25 were found to be positive by RT-PCR and 126 were found to be negative by RT-PCR.

For Influenza B Test:

A total of 151 clinical specimens were collected, to verify the performance of Influenza A/B Antigen Test.26 were found to be positive by RT-PCR and 125 were found to be negative by RT-PCR.

Table 2：Clinical Summary of Influenza A

		RT-PCR		Total
		Positive	Negative	
Influenza A Test	Positive	25	0	25
	Negative	0	126	126
	Total	25	126	151

Relative Sensitivity: 99.9% (86.7%~100.0%)*
Relative Specificity: 99.9 %(97.0%~100.0%)*
Overall Agreement: 99.9 % (97.5%~100.0%)*
*95% Confidence Interval

Table 3：Clinical Summary of Influenza B

		RT-PCR		Total
		Positive	Negative	
Influenza B Test	Positive	25	0	25
	Negative	1	125	126
	Total	26	125	151

Relative Sensitivity: 96.2% (81.1%~99.3%)*
Relative Specificity: 99.9 % (97.0%~100.0%)*
Overall Agreement: 99.3 % (96.3%~99.9%)*
*95% Confidence Interval

For Respiratory Syncytial Virus(RSV) test:

A total of 151 clinical specimens were collected, to verify the performance of Respiratory Syncytial Virus Antigen Test.18 were found to be positive by RT-PCR and 133 were found to be negative by RT-PCR.

Table 4:Clinical Summary of RSV

		RT-PCR		Total
		Positive	Negative	
Respiratory Syncytial Virus Test	Positive	18	1	19
	Negative	0	132	132
	Total	18	133	151

Relative Sensitivity:99.9% (82.4%-100.0%)*
Relative Specificity: 99.2% (95.9%-99.9%)*
Overall Agreement: 99.3% (96.3%-99.9%)
*95% Confidence Interval

Cross Reactivity:

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with The COVID-19&Influenza A/B&RSV Antigen Nasal Test Kit.

HCoV-229E	Adenovirus 4	*Candida albicans*
HCoV-OC43	Adenovirus 5	*Chlamydia pneumoniae*
HCoV-NL63	Adenovirus 7	*Group C Streptococcus*
Norovirus	Adenovirus 55	*Haemophilus influenzae*
Parainfluenza virus 1	Epstein-Barr virus	*Legionella pneumophila*
Parainfluenza virus 2	Enterovirus EV70	*Mycoplasma pneumoniae*
Parainfluenza virus 3	Enterovirus EV71	*Mycobacterium tuberculosis*
Parainfluenza virus 4	Enterovirus A16	*Staphylococcus aureus*
Rhinovirus A30	Enterovirus A24	*Staphylococcus epidermidis*
Rhinovirus B52	Enterovirus B1	*Streptococcus agalactiae*
Adenovirus 1	Echovirus 6	*Streptococcus pneumoniae*
Adenovirus 2	*Bordetellapara pertussis*	*Streptococcus pyogenes*
Adenovirus 3	*Bordetella pertussis*	

NOTE:

1) **For COVID-19 test:** COVID-19 detection has no across reactivity with influenza A , influenza B , respiratory syncytial virus, adenovirus.
2) **For FLU A/B test:** FLUA detection has no across reactivity with influenza B, respiratory syncytial virus, SARS-CoV-2. FLUB detection has no across reactivity with influenza A, respiratory syncytial virus, SARS-CoV-2.
3) **For RSV test:** RSV detection has no across reactivity with influenza A, influenza B and SARS-CoV-2.

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of the kit.

Substance	Concentration	Substance	Concentration
3 OTC nasal sprays	10%	Guaiacol glyceryl ether	20mg/mL
3 OTC mouth washes	10%	Mucin	1%
3 OTC throat drops	10%	Whole blood	4%
4-acetamidophenol	10 mg/mL	Mupirocin	250μg/mL
Acetylsalicylic acid	10 mg/mL	Oxymetazoline	25μg/mL
Albuterol	10 mg/mL	Phenylephrine	10 mg/mL
Chlorpheniramine	5 mg/mL	Phenylpropanolamine	1mg/mL
Dexamethasone	50μg/mL	Zanamivir	10mg/mL
Dextromethorphan	10μg/mL	Adamantanamine	500 ng/mL
Diphenhydramine	5 mg/mL	Oseltamivir phosphate	10mg/mL
Doxylamine succinate	1 mg/mL	Tobramycin	10mg/mL
Flunisolide	25μg/mL	Triamcinolone	14mg/mL

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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