INSTRUCTIONS FOR USE

NAME: SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (Lateral chromatography)

SUMMARY:

The novel corona viruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel corona virus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the 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 (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease 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 milder.

PRODUCT SPECIFICATION: 1Test/Kit, 5Tests/Kit, 25Tests/Kit

INTENDED USE:

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (Lateral chromatography) is suitable for qualitative detection of SARS-CoV-2 virus antigen, influenza A virus antigen and influenza B virus antigen in human nasopharyngeal swab or oropharyngeal swab samples.

For *In Vitro* Diagnostic use only. For professional use only.

PRINCIPLE:

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit is based on immunochromatographic assay to detect SARS-CoV-2 antigens and Influenza A/B antigens in human nasopharyngeal swab or oropharyngeal swab samples.

During the test, SARS-CoV-2 antigens and Influenza A/B antigens conjugate with SARS-CoV-2 antibodies and Influenza A/B antibodies labeled on colored spherical particles to form immune complex. Owing to capillary action, immune complex flow across the membrane. If the sample contains SARS-CoV-2 antigens and Influenza A/B antigens, it will be captured by the pre-coated test area and form visible test line.

To serve as a procedure control, a colored control line will appear if the test has been performed properly.

CAUTIONS:

1. This kit is for In Vitro Diagnostic use only.
2. For healthcare professionals and professionals at point of care sites.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not touch the reaction area of test cassette.
5. Please read all the information in this leaflet before performing the test.
6. The test kit should remain in the sealed pouch until use.
7. All specimen should be considered potentially hazardous and handled in the same manner as an infectious agent.
8. To avoid erroneous results, specimen must be processed as indicated in the test procedure section.
9. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
10. Do not reuse **test cassette, sample extraction solution or disposable swab of the kit.**
11. **The test result should be interpreted by the physician along with clinical findings and other laboratory test results.**
12. **Disposal: All specimen and the used kit have the infectious risk. The used test kit should be discarded according to federal, state and local regulations.**

MAIN COMPONENTS:

Materials provided	Quantity (1 Test/Kit)	Quantity (5Tests/Kit)	Quantity (25Tests/Kit)
Test Cassette	1 Test	5 Tests	25 Tests
Disposable Swab	1 Piece	5 Pcs	25 Pcs
Sample Extraction Solution	1 Bottle	5 Bottles	25 Bottles
Biohazard Disposal Bag	1 Piece	5 pcs	25 pcs
Instructions for Use	1 Piece	1 Piece	1 Piece

MATERIAL REQUIRED BUT NOT PROVIDED:

1. Appropriate biohazard waste container.
2. Timer

SPECIMEN COLLECTION AND PREPARATION:

Nasopharyngeal Swab Specimen Collection:

1. Tilt patient's head back 70 degrees.
2. Insert swab into nostril. (Swab should reach depth equal to distance from nostrils to outer opening of the ear.) Leave swab in place for several seconds to absorb secretions.

Oropharyngeal Swab Specimen Collection:

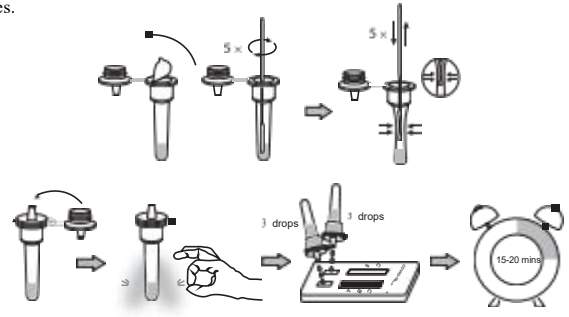
Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx at least 5 times. Then remove swab and avoid touching the tongue, teeth, and gums

Specimen Transport and Storage:

Freshly collected specimen should be processed as soon as possible. If specimens are to be transported, they should be packed in compliance with local regulations covering the transportation of etiological agents.

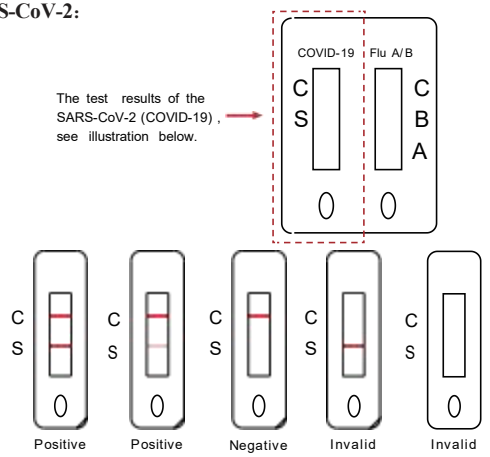
TEST PROCEDURE:

1. Sample collection: Collect nasopharyngeal swab or oropharyngeal swab samples, according to the method of sample collection.
2. Remove the cap from extraction solution tube.
3. Insert the sample swab into the tube (immerse the sample part in the sample extraction solution), make sure the sample is removed into the extraction solution by rubbing and stirring the sampled swab up & down for 5 times.
4. Squeeze the tube and the swab to leave the extraction solution on the swab completely in the extraction solution tube.
5. Take out the test cassette from the aluminum foil bag and place it on a horizontal and dry plane.
6. Mix the sample by gently turning the tube upside down, squeeze the tube to add 3 drops (about 100μL) to each sample well of the test cassette separately, and start counting.
7. Visually read the result after 15-20 minutes. The result is invalid after 20 minutes.



INTERPRETATION OF TEST RESULTS:

For SARS-CoV-2:



Positive Result:

Both the control line (C) and test line (S) appear indicates the presence of SARS-CoV-2 antigen. Any faint line in the test line (S) should be considered positive.

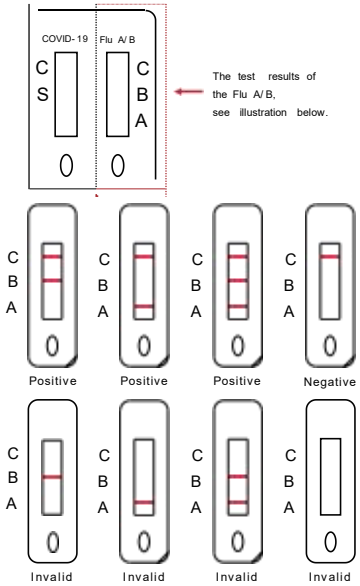
Negative Result:

Only the control line (C) and no test line (S) appear indicates no SARS-CoV-2 antigen was detected.

Invalid:

If the control line (C) fails to appear, the test result is invalid.

For Influenza A/B



Positive Result:

Influenza B Positive

Both the Control line (C) and test line (B) appear indicates the presence of Influenza B antigen.

Influenza A Positive

Both the Control line (C) and test line (A) appear indicates the presence of Influenza A antigen.

Influenza A and Influenza B Positive

Three bands appear, one appears in the control line (C) and the two others appear in the test line (A) and (B). The test result indicates the presence of Influenza A antigen Influenza B antigen.

Negative Result:

Only the control line (C) and no test line (B) or (A) appear indicates no Influenza A antigen or Influenza B antigen was detected.

Invalid:

No visible colored band appears at control line after performing the test, the test result is invalid. Retest the sample.

STORAGE AND STABILITY:

1. The test must remain in the sealed pouch until use. DO NOT FREEZE. Keep away from sunlight. Do not use after the expiration date.
2. Once the package of the test cassette is opened, it must be used within 30 minutes.
3. The LOT and the expiration date were printed on the labeling.
4. Store as packaged in the sealed pouch at temperature (2 -30℃).

LIMITATIONS:

1. The test results of the product are for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory tests, treatment reactions, epidemiology and other information. Retest is recommended after a period of time for the suspicious specimens.
2. The test accuracy is affected by the specimen collection process, and improper specimen collection and storage process will affect the test results. High temperature and direct sunlight must be avoided.
3. This reagent can be used to carry out qualitative detection only for the SARS-CoV-2 antigen, influenza A virus antigen and influenza B virus antigen in specimens.
4. The negative result cannot exclude the possibility of SARS-CoV-2, influenza A virus and influenza B virus infection due to the limitation of antigen detection reagent methodology, and the antigen in the specimen may be below the detection limit. Therefore, other detection results and comprehensive clinical judgment must be combined to make an accurate diagnosis.
5. If SARS-CoV-2 antigen and / or influenza A virus and / or influenza B virus are positive, the result cannot rule out the presence of other co-infection pathogens.
6. The minor changes of SARS-CoV-2, and / or influenza A virus and / or influenza B virus amino acids in the target region may result in the failure of monoclonal antibody detection or the decrease of detection sensitivity.
7. Please use the swab provided in the kit when collecting swab specimens.
8. Proper specimen collection, storage and transportation are critical to the performance of the test.

PRODUCT PERFORMANCE INDEX:

1. Sensitivity and Specificity: SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit was compared with a leading commercial reagent (PCR); the results show that SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit has outstanding sensitivity and specificity.

Note:

* Confirmed cases were the patients diagnosed according to the treatment plan and PCR result.
* Confirmed excluded cases were identified by negative PCR results.

For Nasopharyngeal Swab:

SARS-CoV-2 Tests:

Reagents		PCR		Total
		Positive	Negative	
SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test	Positive	115	1	116
	Negative	1	106	107
Total		116	107	223

Results analysis:

Sensitivity=99.14 % (95% CI: 95.28%~99.85%)

Specificity=99.07 % (95% CI: 94.89%~99.83%)

Accuracy: 99.10% (95% CI: 96.79%~99.75%)

FluA Tests:

Reagents		PCR		Total
		Positive	Negative	
SARS-CoV-2 & Influenza A/ BAntigen Combo Rapid Test	Positive	109	3	112
	Negative	7	112	119
Total		116	115	231

Results analysis:

Sensitivity=93.97% (95% CI: 88.07%~97.05%)

Specificity=97.39 % (95% CI: 92.61%~99. 11%)

Accuracy: 95.67% (95% CI: 92.22%~97.63%)

Flu B Tests:

Reagents		PCR		Total
		Positive	Negative	
SARS-CoV-2 & Influenza A/ B Antigen Combo Rapid Test	Positive	116	4	120
	Negative	11	109	120
Total		127	113	240

Results analysis

Sensitivity=91.34 % (95% CI: 85. 15%~95.09%)

Specificity=96.46 % (95% CI: 91.25%~98.62%)

Accuracy:93.75% (95% CI: 89.95%~96. 18%)

For Oropharyngeal Swab:

SARS-CoV-2 Tests:

Reagents		PCR		Total
		Positive	Negative	
SARS-CoV-2 & Influenza A/ B Antigen Combo Rapid Test	Positive	108	1	109
	Negative	1	111	112
Total		109	112	221

Results analysis:

Sensitivity=99.08 % (95% CI:94.99%~99.84%)

Specificity=99. 11 % (95% CI: 95. 12%~99.84%)

Accuracy: 99. 10% (95% CI: 96.76 %~99.75%)

FluA Tests:

Reagents		PCR		Total
		Positive	Negative	
SARS-CoV-2 & Influenza A/ B Antigen Combo Rapid Test	Positive	111	3	114
	Negative	9	110	119
Total		120	113	233

Results analysis:

Sensitivity=92.50 % (95% CI: 86.36%~96.00%)

Specificity=97.35 % (95% CI: 92.48 %~99.09%)

Accuracy:94.85% (95% CI: 91.21%~97.03%)

FluB Tests:

Reagents		PCR		Total
		Positive	Negative	
SARS-CoV-2 & Influenza A/ B Antigen Combo Rapid Test	Positive	102	4	106
	Negative	10	104	114
Total		112	108	220

Results analysis:

Sensitivity=91.07 % (95% CI: 84.34%~95.08%)
Specificity=96.30 % (95% CI: 90.86%~98.55%)
Accuracy: 93.64% (95% CI: 89.60%~96. 17%)

2. Cross-reactivity: The SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit do not cross with the following common respiratory pathogens.

Virus/Bacteria/Parasite*	Cross-Reactivity (Yes/No)
SARS-CoV	NO
HCoV-NL63	NO
HCoV-229E	NO
HCoV-HKU1	NO
MERS-CoV	NO
Acinetobacter calcoaceticus	NO
Bacteroides fragilis	NO
Bordetella pertussis	NO
Branhamella catarrhalis	NO
Candidaalbicans	NO

3. Interference material/interference: following potential interfering substances have no effect on SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit. The final test concentration of the interfering substance is recorded in the following table.

Name of substance	Concentration
Whole blood	2%(v/v)
mucin	0.5%(v/v)
CVS nasal drops(phenylephrine)	10% (v/v)
Afrin (Oxymetazoline)	12% (v/v)
Nasal gel (Oxymetazoline)	12%(v/v)
Phenolic spray for sorethroat	15% (v/v)
tobramycin	5μg/ml
Mupirocin	8mg/ml
CVS nasal spray(Cromolyn)	15 % (v/v)
three OTC mouthwashes	25 % (v/v)

SYMBOLS MEANING:

Symbol	Introductions	Symbol	Introductions
LOT	Batch Code		Do not re-use
	Caution		Manufacturer
CE	CE Mark		Use-by date
	Keep dry		Date of manufacture
30°C 2°C	Temperature limit	IVD	In vitro diagnostic medical device
EC REP	Authorized representative in the European Community/ European Union		Do not use if package is damaged and consult instructions for use
	Keep away from sunlight		Indicates the need for the user to consult the instructions for use

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EC REP

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