CE IVD

FRENOVO

FLU A+B ANTIGEN RAPID TEST

Instructions For Use

PRODUCT NAME

FLU A+B ANTIGEN RAPID TEST

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasal swab or throat swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

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. The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus. Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2-23%. However, RT-PCR is expensive, complex and must be performed in specialized laboratories. The kit qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasal swab or throat swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasal swab, throat swab.

The kit is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab, throat swab. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Extraction Tubes (with Caps): 20 pieces extraction tubes (with 220ul buffer) in zipper bag.
3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction Solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate swab, tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix extraction solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 15 minutes incubation time following the addition of extracted solution. Do not read results beyond 20 minutes.

STORAGE INSTRUCTIONS

1. The kit and extraction solution should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SPECIMEN COLLECTION

Nasopharyngeal swab sample

Insert a sterilized swab into a nasal cavity securely from a nostril and collect mucoepidermis wiping turbinate several times.

Pharyngeal swab sample

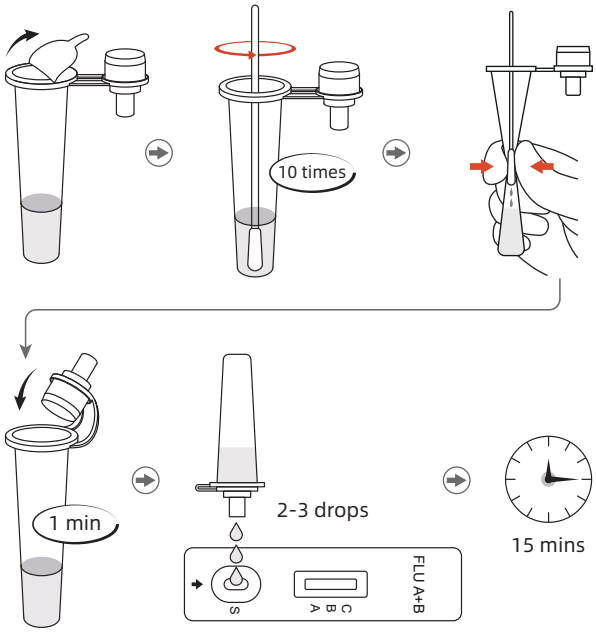
Insert a sterilized swab into pharynx and collect mucoeoidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.

The clinical samples should be tested immediately after collection, otherwise the samples must be sealed in individual dry container but no longer than 8 hours under room temperature. It is recommended to collect sample from Nasopharyngeal for more accurate results.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction tube on the work station and tear open the aluminum foil. Put the swab specimen into the extraction tube, rotate the swab for about 10 times, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
3. Install the dropper cap on the extraction tube and leave for 1 minute, then put 2 to 3 drops into the specimen hole of the test card, start the timer.
4. Read the results at 15 minutes, and the results after 20 minutes are no longer valid.



INTERPRETATION OF RESULTS

POSITIVE Influenza A: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

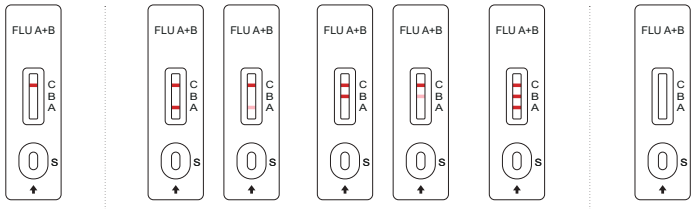
POSITIVE Influenza B: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: Three distinct colored lines appear. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

NOTE: The intensity of the color in the test line regions (A or B) will vary based on the amount of Flu A or B antigen present in the sample. So any shade of color in the test regions (A or B) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line regions (A or B).

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasal swab or throat swab specimens. Neither the quantitative value nor the rate of increase in Influenza A and/or B virus concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of Influenza A and/or B virus in the specimen from both viable and non-viable Influenza A and B strains.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the nasal/throat swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for influenza A and/or B does not preclude an underlying co-infection
9. with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Nasal swab specimen		FLU A		
Method		PCR		Total Results
FLU A+B	Results	Positive	Negative	
	Positive	95	5	100
	Negative	2	95	97
Total Results		97	100	197
Clinical sensitivity		95/97=97.94 % (95%CI* 92.75% to 99.75%)		
Clinical specificity		95/100=95.00 % (95%CI* 88.72% to 98.36%)		
Accuracy		(95+95)/(95+2+5+92)=96.47 % (95%CI* 92.82% to 98.56%)		

Nasal swab specimen		FLU B		
Method		PCR		Total Results
FRENOVO FLU A+B	Results	Positive	Negative	
	Positive	87	7	94
	Negative	3	93	96
Total Results		90	100	190
Clinical sensitivity		87/90=96.67 % (95%CI* 90.57% to 99.31%)		
Clinical specificity		93/100=93.00 % (95%CI* 86.11% to 97.14%)		
Accuracy		(87+93)/(87+3+7+93)=94.74 % (95%CI* 90.53% to 97.45%)		

Throat swab specimen		FLU A		
Method		PCR		Total Results
FRENOVO FLU A+B	Results	Positive	Negative	
	Positive	72	6	78
	Negative	3	94	97
Total Results		97	100	175
Clinical sensitivity		72/75=96.00 % (95%CI* 88.75% to 99.17%)		
Clinical specificity		94/100=94.00 % (95%CI* 87.40% to 97.77%)		
Accuracy		(72+94)/(72+3+6+94)=94.86 % (95%CI* 90.46% to 97.62%)		

Nasal swab specimen		FLU B		
Method		PCR		Total Results
FRENOVO FLU A+B	Results	Positive	Negative	
	Positive	58	9	67
	Negative	3	91	94
Total Results		61	100	161
Clinical sensitivity		58/61=95.08 % (95%CI* 86.29% to 98.97%)		
Clinical specificity		91/100=91.00 % (95%CI* 83.60% to 95.80%)		
Accuracy		(58+91)/(58+3+91+9)=92.55 % (95%CI* 87.34% to 96.09%)		

Clinical sensitivity = (95+87+72+58)/(97+90+75+61)=96.59 % (95%CI* 93.99% to 98.29%)
Clinical specificity = (95+93+94+91)/(100+100+100+100)=93.25 % (95%CI* 90.23% to 95.50%)
Accuracy: (95+87+72+58+95+93+94+91)/ (97+90+75+61+100+100+100+100) =94.74% (95%CI* 92.86% to 96.25%)

Minimum detection limit

The minimum detection limit of FLU A for The kit is 1700 $TCID_{50}$/ml.
The minimum detection limit of FLU B for The kit is 2100 $TCID_{50}$/ml.
$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Reactivity with Human Influenza Strain

The kit was tested with the following human influenza strains and all tests presented positive results:

Influenza A Virus	Influenza B Virus
A/NWS/33 10(H1N1)	Bright
A/Hong Kong/8/68(H3N2)	B/R5
A/Port Chalmers/1/73(H3N2)	B/Russia/69
A/WS/33(H1N1)	B/Lee/40
A/New Jersey/8/76(HswN1)	B/Hong Kong/5/72
A/Mal/302/54(H1N1)	

Specificity Testing with Various Viral Strains

The kit was tested with the following human various strains and all tests presented negative results:

Description	Test Level
Human adenovirus C	5.62 x 10^5 $TCID_{50}$/ml
Human adenovirus B	1.58 x 10^4 $TCID_{50}$/ml
Adenovirus type 10	3.16 x 10^3 $TCID_{50}$/ml
Adenovirus type 18	1.58 x 10^4 $TCID_{50}$/ml
Human coronavirus OC43	2.45 x 10^6 LD_{50}/ml
Coxsackievirus A9	2.65 x 10^4 LD_{50}/ml
	1.58 x 10^5 $TCID_{50}$/ml
Coxsackievirus B5	1.58 x 10^7 $TCID_{50}$/ml
Human herpesvirus 5	1.58 x 10^4 $TCID_{50}$/mll
Echovirus 2	3.16 x 10^5 $TCID_{50}$/ml
Echovirus 3	1 x $10^4$$TCID_{50}$/ml
Echovirus 6	3.16 x 10^6 $TCID_{50}$/ml
Herpes simplex virus 1	1.58 x 10^6 $TCID_{50}$/ml
Human herpesvirus 2	2.81 x 10^5 $TCID_{50}$/ml
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58 x $10^6$$TCID_{50}$/ml
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml
Measles	1.58 x $10^4$$TCID_{50}$/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml
Sendai virus	8.89 x 10^7 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x $10^7$$TCID_{50}$/ml
Parainfluenza virus 3	1.58 x 10^6 $TCID_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml
Human respiratory syncytial virus	1.58 x 10^5 $TCID_{50}$/ml
Rubella	2.81 x $10^5$$TCID_{50}$/ml
Varicella-Zoster	1.58 x $10^3$$TCID_{50}$/ml

Interference Substances

The following potential interfering substances have been tested using FRENOVO COIVD-19 antigen rapid test and no interference was observed:

Substance	Concentration
Whole Blood	1%
Mucin	100 μg/ml
phlegmatic temperament	500μg/ml
Sodium cromoglicate	12μg/ml
Oxymetazoline hydrochloride	60μg/ml
Phenylephrine hydrochloride	200μg/ml
N-acetylp-aminophenol	250μg/ml
Aspirin	30μg/ml
Ibuprofen	200μg/ml
Morpholine hydrochloride	200μg/ml
Cefalexin	3μg/ml
Gentamicin	3μg/ml
kanamycin	3μg/ml
Tetracycline	3μg/ml
Chloramphenicol	3μg/ml
Erythrocin	3μg/ml
vancomycin	3μg/ml
Nalidixic acid	3μg/ml
Hydrocortisone	3μg/ml
Insulin	3μg/ml

Cross Reaction

The following organisms were tested at 1.0x10 8 org/ml and has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Arcanobacterium	Pseudomonas aeruginosa
Candida albicans	Staphylococcus aureus subspaureus
Corynebacterium	Staphylococcus epidermidis
Enterococcus faecalis	Staphylococcus saprophylicus
Enterococcus faecium	Streptococcus agalactiae
Escherichia coli	Streptococcus bovis
Haemophilus	Streptococcus dysgalatiae / subsp.dysgalatiae
Moraxella catarrhalis	Streptococcus oralis formerly Streptococcus
Neisseria gonorrhoeae	Streptococcus pneumoniae
Neisseria lactamica	Streptococcus pygenes
Nesseria subllava	Streptococcus salivarius
Proleus vulgaris	Streptococcus sp group F.type 2

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

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