FRENOVO

RSV Antigen Rapid Test Kit

Instructions For Use

PRODUCT NAME

RSV Antigen Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

This product is used for in vitro qualitative detection of the antigen of Respiratory Syncytial Virus (RSV) in human nasal swabs or throat swab specimens. It is intended to aid in the rapid diagnosis of RSV viral infections.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Respiratory syncytial virus is a member of the Paramyxoviridae family and is the most significant respiratory pathogen for infants and children. Infection usually causes mild to moderate severe upper respiratory illness that may lead to life threatening pneumonia or bronchiolitis. RSV infections are seasonal and are most prominent from December to March in the northern hemisphere. The virus is spherical in shape with a lipoprotein envelope synthesized from the plasma membrane of the infected host cell. The virus is spread rapidly through droplets dispersed in the air or secretions from the respiratory tract of infected individuals.

The kit is a qualitative, lateral flow immunoassay for the detection of RSV virus antigen in nasal swab, throat swab.The assay is conducted by adding specimen to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Extraction Tubes (with Caps): 25 pieces filled 220 ul extraction solution.
3. Instructions For Use: 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 Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit test is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit test is for professional use only.
2. The Instructions For Use instructions must be followed to ensure optimum test performance.
3. The kit test 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 test 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

1.Nasopharyngeal swab sample

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

2.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.

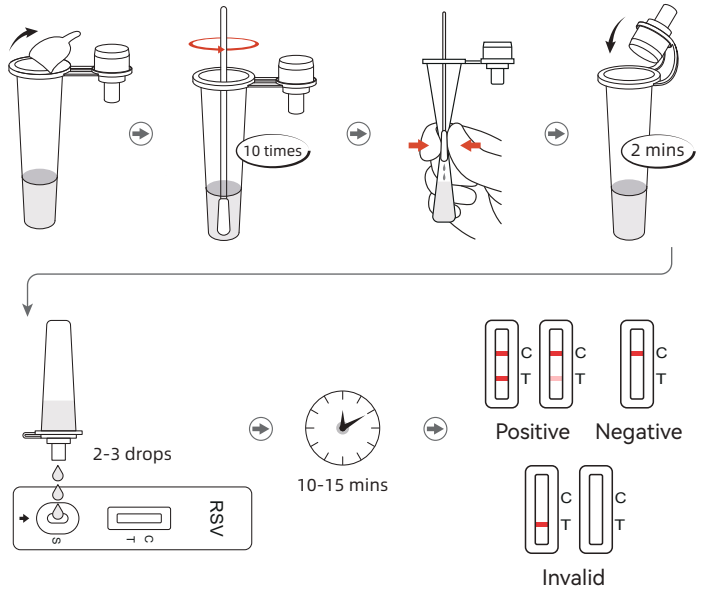
The clinical samples should be tested immediately after collection, otherwise the samples must be sealed in individual dry container but no longer than 8 hours under room temperature. It is recommended to collect sample from nasopharyngeal for more accurate results.

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.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 each test, start the timer.
4. Read the results at 10 minutes, and the results after 15 minutes are no longer valid.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that RSV virus antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the RSV virus antigen has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line, and the test shall be conducted again.

LIMITATIONS

1. The kit test is for professional in vitro diagnostic use only. The test should be used for the detection of RSV virus in nasal swab or throat swab specimens. Neither the quantitative value nor the rate of increase in RSV virus concentration can be determined by this qualitative test.
2. The kit test will only indicate the presence of RSV virus in the specimen or not.
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 RSV 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 results may occur 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 RSV virus does not preclude an underlying co-infection 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 test and PCR. The results indicated that The kit test has a high sensitivity and specificity as summarized below:

Nasal swabs		PCR		Total Results
FRENOVO RSV rapid test kit	Results	Positive	Negative	
	Positive	103	1	104
	Negative	2	125	127
Total Results		105	126	231

Throat swab		PCR		Total Results
FRENOVO RSV rapid test kit	Results	Positive	Negative	
	Positive	95	4	99
	Negative	3	134	137
Total Results		98	138	236

Clinical sensitivity =97.54% (95%CI* 94.35% to 99.20%)
Clinical specificity =98.11 % (95%CI* 95.64% to 99.38%)
Accuracy: =97.86% (95%CI* 96.10% to 98.97%)

Interference Substances

The following potential interfering substances have been tested using The kit test and no interference was observed: whole blood (2%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Benforin (12mg/L); Benforin (120 mg/L); Beclomethasone (20 ug / L); Budesonide (40 ug/L); Benzocaine (40 ug/L), , tobramycin 140mg / L, Chlorpheniramine (5 mg/mL); Dexamethasone (20 ug/L); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Flunisolide (10 ug/L); Fluticasone (40 ug/L); Guaiacol glyceryl ether (20 mg/mL); Hydroxyazoline (4 ug/L); Mometasone (8 ug/L); Mupirocin (4 mg/L); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); Sodium chloride (100 mg/L); Sodium sulfate (1:160); Triamcinolone (1.2 mg/L); Phenylpropanolamine (20 mg/mL) and Zanamivir (4 mg/L).

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.
Bacterial Panel (107~109 org/mL):
Acinetobacter calcoaceticus, Bacteroides fragilis, Moraxelle catarrhalis, Chlamydia pneumoniae, Haemophilus influenzae, Neisseria gonorrhoeae, Neisseria meningitidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus sanguis, Streptococcus salivarius, Streptococcus (Gp.,B,C,G), Pertussis, Pseudomonas aeruginosa, Proteus vulgaris, Mycobacterium tuberculosis, Mycoplasma orale, Lactobacillus, Corynebacterium, Escherichia coli, Gonococcus.

Viral Panel (104–108 TCID50/mL):
Human coronavirus, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Human Coronavirus OC43, Human Coxsackievirus A9, Coxsackievirus B5, Cytomegalovirus, Enterovirus EV71, Measles, Mumps, Sendai virus, Parainfluenza virus (1,2,3), Human herpesvirus2.

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
	Biological risks		

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