IVD

Ver. 6.0 of September 2018

Please read this package insert carefully before use.

Capilia™ RSV Neo

INTENDED USE

To detect Respiratory Syncytial ("RS") virus antigens in nasal swabs or nasal aspirates (to assist in the diagnosis of RS virus infectious disease).

SUMMARY AND EXPLANATION OF THE TEST

RS virus is a virus that causes respiratory tract infections. It is a major cause of lower respiratory tract infections and hospital visits during infancy and childhood.

The symptoms are usually mild, and are often indistinguishable from those of a common cold. However, for some children, RS virus can cause bronchiolitis, leading to severe respiratory illness requiring hospitalization and, in rare cases, causing death.

Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents.

There are no antiviral drugs to treat RS virus infections, so treatment is largely directed at the symptoms.

Because the RS virus is highly contagious, rapid diagnosis and prompt treatment can have a positive effect on public health.

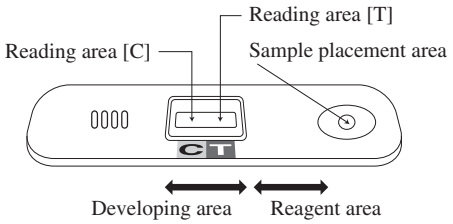
Capilia RSV Neo can provide rapid and accurate detection of RS virus antigens from symptomatic patients. No special instruments or equipment are required.

PRINCIPLE OF THE TEST

Measurement using this product is based on an immunochromatography assay using a monoclonal antibody that recognizes RS virus antigens.

This product consists of a test plate with a carrier strip composing of a sample placement area, a reagent area including a colloidal platinum-gold labeled anti-RS virus monoclonal antibody (mouse) (hereinafter referred to as "colloidal platinum-gold labeled anti-RS virus antibody"), a reading area [T] that fixes the anti-RS monoclonal antibody (mouse) (hereinafter referred to as "anti-RS antibody"), and a reading area [C] that fixes an anti-mouse immunoglobulin polyclonal antibody (rabbit) (hereinafter referred to as "anti-mouse immunoglobulin antibody").

Names of each area of the test plate



When a sample is placed on the sample placement area of the test plate, the colloidal platinum-gold labeled anti-RS virus antibody dissolves and forms an immune complex with the RS virus antigens in the sample. This immune complex migrates through the developing area by capillary action, is captured by the anti-RS virus antibody fixed in the developing area, and forms a black line of colloidal platinum-gold in the reading area [T]. The black line visually displys the existence of RS virus antigen in the sample.

Regardless of the existence of RS virus antigens in the sample, excess colloidal platinum-gold labeled anti-RS virus antibodies further migrates through the developing area, are captured by the anti-mouse immunogloblin antibody fixed in the developing area, and form a black line of colloidal platinum-gold in the reading area [C]. This means the colloidal platinum-gold labeled anti-RS virus antibodies have immigrated normally.

REAGENTS AND MATERIALS PROVIDED

REF CARS0970 Capilia RSV Neo (20 Tests)

Test plates

・Components

Colloidal platinum-gold labeled anti-RS virus monoclonal antibody (mouse)

Anti-RS virus monoclonal antibody (mouse)

Extraction Buffer (to be used equally with the four products.) Note

・Components

Buffer, detergent, sodium azide (0.09%)

Note The extraction buffer is able to be used equally with the four products below:

- Capilia Flu Neo (rapid test for detecting Influenza virus antigen)
- Capilia Adeno Neo (rapid test for detecting Adenovirus antigen)
- Capilia RSV Neo (rapid test for detecting RS virus antigen)
- Capilia hMPV (rapid test for detecting human metapneumovirus antigen)

Specimen	Flu	Adeno	RSV	hMPV
Nasal swab	○	○	○	○
Nasal aspirate	○	○	○	○
Nasal discharge/Nasal mucus	○	×	×	×
Pharyngeal swab	○	○	×	○
Keratoconjunctivitis swab	×	○	×	×

Nozzles

REF CARS0971 Capilia RSV Neo Test Plate (10 Tests)

Test plates

・Components

Colloidal platinum-gold labeled anti-RS virus monoclonal antibody (mouse)

Anti-RS virus monoclonal antibody (mouse)

MATERIALS REQUIRED BUT NOT PROVIDED

Timer, micropipette, pipette tips suction machine, suction trap, sterile swabs (as listed here)

Recommended Swab

The following swabs are recommended for use with the kit.

For Nasal Swab

①FLOQSwabs ™ (Cat No. 534CS01, Copan Italia S.p.A, Italy)

②Sterilized Swab P156A 10 pcs (Cat No. 4124, HEIWA MEDIC. CO., LTD, Japan)

To collect nasal aspirate, any of the above swabs may be used.

Acceptable Swab

The following swabs are acceptable for use with the kit.

・Tip material

Rayon, flocked nylon and polyester

・Standard tip size

For nasal swab

Plain dry swab:maximum diameter 3 mm, length 12 mm

Flocked swab:maximum diameter 3 mm, length 15 mm

・Shaft material

Paper, plastic (PS, nylon), aluminum

Unacceptable Swab

Do not use calcium alginate swabs.

WARNING AND PRECAUTIONS

1. Precautions when handling (including hazard control)

1) Handle all the specimens as if they contain infectious agents.
2) In consideration of the risk of infection, wear protective clothes such as a mask and gloves and handle the specimens and samples carefully during the test.
3) If the extraction buffer gets into your eyes, immediately flush with a large quantity of water for 15 minutes or more. If you still feel some abnormality, see a doctor for treatment.
4) If the extraction buffer comes into contact with your hands or clothes, wash your hands and/or clothes with soap and a large quantity of water.

2. Precautions when using

1) This product is a rapid test for detecting RS virus antigen.
   A definite diagnosis should be made by an attending physician, in combination with the clinical symptoms, the result of RT-PCR and other test results.
2) This product should be used in accordance with the procedure stated in the package insert.
3) In order to prevent deterioration, this product should be stored at temperatures between 2°C and 30°C. Avoid high temperatures and direct sunlight.
4) If this product has been refrigerated, it must be removed from the refrigerator at least 30 minutes before use to be acclimatized to room temprature.
5) **The aluminum pouch containing a test plate should not be opened until the test plate is about to be used.**
6) The sample placement area and the reading area of the test plate should not be touched with the hands.
7) A precipitate may be seen in the extraction buffer, but the product can be used as it is, because the precipitate has been shown not to affect test results.
8) Do not use a swab if it is broken, bent or stained.
9) For nasal sampling, do not keep forcibly insert the swab, when the distance to the site is clearly shorter than usual. In particular, there is the possibility of resistance being imposed on the stick when the sample is collected from an infant or a patient with a narrow nasal cavity. In such a case, do not swab hard, exerting force on the stick. Moreover, do not rotate the stick forcibly.
10) For nasal sampling, any mass of mucus on the tip of the swab should be gently removed with gauze. Do not wipe the tip too hard. Mucosal epidermal cells should remain on the tip for testing.
11) Do not use any products beyond the expiration date.

3. Precautions for disposal

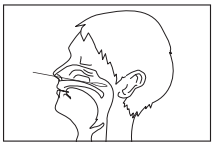
1) Because used test plates, swabs, tubes and nozzles after use, remaining samples, etc. may cause infections, they should be autoclaved (121°C, 20 min) or soaked in 0.1% sodium hypochlorite for more than one hour. When reagents, remaining reagents or their accessories are disposed of, they should be treated in accordance with the laws and regulations concerning medical waste disposal and water pollution control.
2) In the extraction buffer, 0.09% of sodium azide is included as a preservative. When solutions containing sodium azide continue to be discarded over a long period of time, explosive metallic azide may be produced if a drain is made of metal. Therefore, they should be discarded with a large quantity of water.

STORAGE CONDITIONS

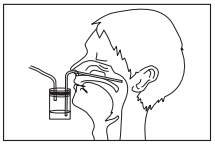
Storage : Store at 2°C to 30°C **DO NOT FREEZE.**
Keep away from direct sunlight.
Do not use test plate or extraction buffer after expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Methods of specimen collection



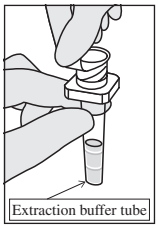
1) Sampling of nasal swab
Firmly insert a nasal swab into the nasal cavity and collect mucosal epithelium by swabbing the nasal turbinate several times.



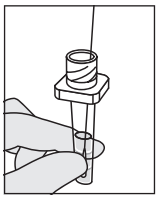
2) Sampling of nasal aspirate
Firmly insert one tube of a suction trap into the suction pump, and the other tube into a nasal cavity through an external nostril. Collect the nasal discharge aspirate in the suction trap by operating the suction pump. Soak the swab in the nasal aspirate collected by the trap, and let the swab absorb the nasal aspirate well. When nasal aspirate is taken using a micropipette or other instruments, dilute the nasal aspirate twofold with physiological saline and sample 200 μL of this dilution.

With a collected specimen, prepare the sample according to the procedure specified in the following "Sample preparation" section and perform the test as quickly as possible.

2. Sample preparation

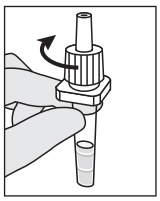


Remove the aluminum sealing cap from the extraction buffer tube, while taking care not to spill the liquid.



Soak the swab that collected the specimen in the extraction buffer, and stir well.
Then, pinch the tip of the swab firmly with the soft wall of the extraction buffer tube with your fingers and squeeze out the swab. Use this squeezed-out liquid as the sample.
When using a nasal aspirate specimen diluted twofold with physiological saline, add 200 μL of the specimen to the extraction buffer in the tube, and mix well. Use this mixture as the sample.

TEST PROCEDURE



1) Firmly attach the nozzle (with a filter) provided in the kit to the top of the extraction buffer tube.
2) Hold the middle of the tube with the fingers and dispense **3 drops of the sample (80−120 μL)** onto the sample placement area of the test plate. Hold the tube perpendicularly and take care not to let the tip of the nozzle touch the sample placement area.
3) Observe the reading area of the test plate after **3 to 5 minutes** and interpret the result according to the "READING TEST RESULTS."

READING TEST RESULTS

1. Reading the result

Allow the samples to react according to the procedure and read the black lines that appear in the reading area.

Positive

When black lines are seen at both [T] and [C] in the reading area (two lines), the result is read as positive. When a very faint black line is seen in the reading area [T], the result is also interpreted as positive.

Negative

When no black line is seen at [T] in the reading area but a black line is seen only at [C] in the reading area (one line), the result is read as negative.
When a black line at [C] in the reading area is faint but visually recognizable, chromatographic development has occurred normally.

Retesting

When no black line is seen at [C] in the reading area, there may be some problem with the test procedure or the reagent quality. The test should be performed again, using another test plate.

A line that appears anywhere within the sections of the reading area, which are separated by color, is considered valid.

(Note)

1. When black lines are seen at both [T] and [C] in the reading area 3 to 5 minutes after dispensing the sample, the result is read as positive. No black line at [T] in the reading area even 5 minutes after dispensing the sample indicates a negative result.
2. Do not use the test plate for reading a result beyond the judgment time as the result may change due to drying, etc.
   If the amount of antigen in the sample is very low and close to the detection limit of this product, a black line may appear at [T] in the reading area after 5 minutes or more of the judgment time, due to the feature of immunochromatography. In addition, due to a non-specific reaction caused by specimen-derived components, a black line may appear at [T] in the reading area after 5 minutes or more of the judgment time in rare cases.
   A definite diagnosis should be made comprehensively, not only based on the test result of this product but also taking other test results and clinical symptoms into account.

3. A black line may not appear at [C] in the reading area due to problems with the test procedure or the reagent quality. In this case, the test should be performed again, using another test plate. If the same result is obtained in the re-test, try the test once more using the sample diluted twofold with saline as the black line may not appear at [C] in the reading area due to a factor in the specimen.
4. If the amount of antigen is very high, a very thick line may be seen at [T] in the reading area and no black line may be seen at [C] in the reading area. In that case, dilute the sample with more extraction buffer and perform the test again.
   Example) Method for dilution of sample : Dispense 3 drops of the sample to a new extraction buffer tube, mix throughly and use the solution as the test sample.
5. The line is valid even if there is unevenness in depth and there are breaks in the line.

LIMITATINS

1. This product is a rapid test for detecting RS virus antigen.
   A definite diagnosis should be made by an attending physician, in combination with the clinical symptoms, the result of RT-PCR and other test results.
2. The test plate should be used immediately after opening the packaging.
   When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
3. This product should be used for *in vitro* diagnosis only and should not be used for any other purposes.
4. Please use this product following the operational method described in this package insert. We cannot guarantee results obtained from any other operations and for any other purposes that are not described in the package insert.
5. The extraction buffer contains sodium azide, etc. If the solution comes into contact with eyes or mouth or adheres to the skin by mistake, take emergency measures such as thorough washing with water and seek medical treatment if necessary.

PERFORMANCE CHARACTERISTICS

1. Clinical data

The result of the clinical performance evaluation in Japan (Comparison with RT-PCR.)

Kind of samples	Sensitivity (%)	Specificity (%)	Accuracy (%)	Total number
Nasal swab	86.1 (68/79)	100 (103/103)	94 (171/182)	182
Nasal aspirate	82.1 (69/84)	100 (87/87)	91.2 (156/171)	171

2. Sensitivity (Detection limit)

The minimum detection limit of this reagent is as follows.

Subtype	RS Virus Strain	Minimum detection limit
A	Long	2.14×10^3 $TCID_{50}$/mL
	A-2	3.95×10^3 $TCID_{50}$/mL
B	9320	1.34×10^3 $TCID_{50}$/mL
	Wash/18537/'62	2.68×10^2 $TCID_{50}$/mL
	WV/14617/'85	3.00×10^3 $TCID_{50}$/mL

3. Reactivity

This product is confirmed to have reactivity with the following RS virus subtypes A and B.

RS virus Subtype A (Long)
Subtype A (A-2)
Subtype B (9320)
Subtype B (Wash/18537/'62)
Subtype B (WV/14617/'85)

4. Cross reactivity

No cross-reactivity was found with the following bacteria, fungi and viruses.

1) Bacteria and fungi

Acinetobacter baumannii
Aspergillus niger
Bordetella pertussis
Burkholderia cepacia
Candida albicans
Candida glabrate
Enterococcus faecalis
Enterococcus gallinarum
Escherichia coli
Haemophilus aphrophilus
Haemophilus parainfluenzae
Kingella kingae
Legionella anisa
Legionella bozemanii
Legionella dumoffii
Legionella gormanii
Legionella jordanis
Legionella micdadei
Legionella longbeachae
Legionella pneumophila SG-1
Legionella pneumophila SG-2
Legionella pneumophila SG-3
Legionella pneumophila SG-4
Legionella pneumophila SG-5
Legionella pneumophila SG-6
Legionella pneumophila SG-7
Legionella pneumophila SG-8
Legionella pneumophila SG-9
Legionella pneumophila SG-10
Legionella pneumophila SG-11
Legionella pneumophila SG-12
Legionella pneumophila SG-13
Legionella pneumophila SG-14
Legionella pneumophila SG-15
Legionella pneumophila SG-16
Mycobacterium fortuitum
Mycobacterium kansasii
Mycobacterium marinum
Proteus mirabilis
Proteus vulgaris
Pseudmonas aeruginosa
Serratia marcescens
Staphylococcus epidermidis
Streptococcus Group A
Streptococcus Group B
Streptococcus Group C
Streptococcus Group F
Streptococcus Group G
Streptococcus mitis
Streptococcus mutans
Streptococcus pyogenes (Group A)
Streptococcus pneumoniae Type1
Streptococcus pneumoniae Type3
Streptococcus pneumoniae Type5
Streptococcus pneumoniae Type19F

2) Viruses

Adenovirus Type 1
Adenovirus Type 2
Adenovirus Type 3
Adenovirus Type 4
Adenovirus Type 6
Adenovirus Type 11
Adenovirus Type 19
Adenovirus Type 37
Influenza virus A (H1N1)
Influenza virus A (H3N2)
Influenza virus B

INTERFERING SUBSTANCES

The following substances were found to have no effect on the results at the concentrations indicated.

Hemoglobin (0.25%), Naphazoline nitrate nasal drops 0.05% (25%), Flunase nasal solution 50 µg 56 metered sprays (6.25%), Acetylsalicylic acid (20 mg/mL), Acetaminophen (10 mg/mL), Ibuprofen (20 mg/mL), Oxymetazoline hydrochloride (0.1 mg/mL), Clarithromycin (2.5 mg/mL), Diphenhydramine hydrochloride (2.5 mg/mL), Cefixime (2.5 mg/mL), Dextromethorphan hydrobromide hydrate (2.5 mg/mL), (R) - (−) - Phenylephrine hydrochloride (1 mg/mL), Chlorpheniramine maleate (5 mg/mL)

REFERENCES

TAKEUCHI Y et al. Evaluation of New RSV Rapid Test Kit Using Immunochromatography. *J. J. A. Inf. D.* 2010;84:309-312.

INQUIRES

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GLOSSARY OF SYMBOLS

CE	CE Marking (European directive 98/79/EC on *in vitro* diagnostic medical devices)	EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device		Do not reuse
2℃ 30℃	Temperature limitation		Manufacturer/Manufactured by
	Use by YYYY-MM		Consult instructions for use
LOT	Batch code		Caution, consult accompanying documents
REF	Catalog number		Keep away from sunlight
Σ n	Contents sufficient for <n> tests		Fragile, handle with care
	Open here		