clonatest®

RSV CASSETTE CE

RSV

A rapid test for the qualitative detection of *RSV* antigens from human nasopharyngeal specimens.

ONE STEP

COD CT45100
20 Test
For professional *in vitro* diagnostic use only

SUMMARY

Linear RSV Cassette is a qualitative lateral flow immunoassay for the detection of *RSV* antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against *RSV* antigens on the test line region.

During testing, the sample reacts with the particle coated with anti-*RSV* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate one coloured lines. A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PACKAGING CONTENTS

REF	CT 45100	20 RSV cassettes 1 Diluent B (sample diluent) 1 RSV Positive Control 20 Testing tubes 20 Sterile swabs

STORAGE AND STABILITY

Store at 2-30ºC.

The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Nasopharyngeal swab method:

- Bend shaft to follow curve of nasopharynx
- Insert swab through nostril to posterior nasopharynx.
- Rotate swab a few times to obtain infected cells
- For an optimal sample, repeat procedure using other nostril

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):

- Instil several drops of solution saline into each nostril
- Place catheter through nostril to posterior nasopharynx
- Apply gentle suction. Using rotating motion, slowly withdraw catheter
- For an optimal sample, repeat procedure using other nostril

Send specimen to lab immediately (testing sensitivity decrease over time). Cool specimen to 2º-4ºC (36º-40ºF) during storage and transport.

MATERIALS REQUIRED

- Disposable gloves
- Timer.

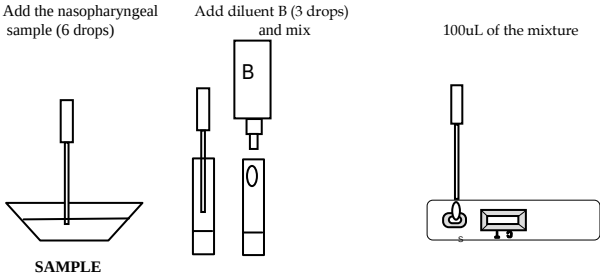
PROCEDURE

Allow the tests, samples and buffer to reach to room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

To process the collected nasopharyngeal wash or aspirate samples (see illustration 1):

Use a separate pipette and testing tube for each sample. Add the nasopharyngeal wash or aspirate sample (6 drops or 300uL) in a testing tube or vial. Add the diluent B (3 drops or 150uL) and mix. Remove the RSV Device from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense exactly 100uL into the specimen well (S). Start the timer. Read the result at 10 minutes after dispensing the sample.

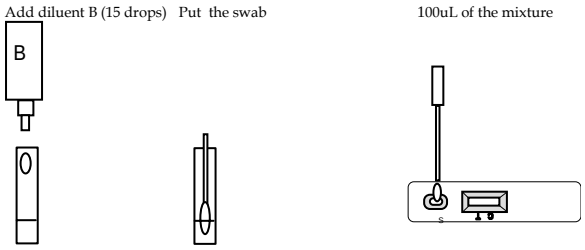
Illustration 1 Nasopharyngeal aspirate or wash



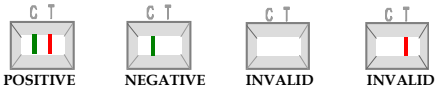
To process the collected nasopharyngeal swab (see illustration 2):

Use a separate testing tube or vial for each sample (swab). Add the diluent B (15 drops or 500uL) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much liquid possible from the swab. Remove the *RSV* Device from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense exactly 100uL into the specimen well (S). Start the timer. Read the result at 10 minutes after dispensing the sample.

Illustration 2 Nasopharyngeal swab



INTERPRETATION OF RESULTS



POSITIVE: Two lines appears across the central window in the result line region (**red** test line marked with the letter T) and in the control line region (**green** control line marked with the letter C).

NEGATIVE: Only one **green** band appears across the control line region marked with the letter C (control line).

INVALID: A total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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QUALITY CONTROL

Internal procedural controls are included in the test. A GREEN line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

It is recommended that a positive control and a negative control be evaluated to verify proper test performance when a new shipment of test devices are received.

CLINICAL SIGNIFICANCE

RSV is generally considered the most frequent cause of pneumonia, bronchiolitis, and tracheobronchitis among infants and young children, it is now known to be the etiologic cause in 14-27% of cases of pneumonia in the elderly during the winter season.

Although a wide variety of viral agents are capable of causing lower respiratory tract infections in children and adults, influenza A & B; respiratory syncytial virus (RSV); parainfluenza viruses 1, 2, and 3; and adenovirus are the most common. Of these, influenza A & B and RSV are the most important causes of medically attended acute respiratory illness. In addition to sharing a similar seasonal prevalence, it is important to remain cognizant that influenza A & B and RSV share overlapping clinical features and infection potential for certain high-risk patient groups (e.g., extremes of age, underlying cardiopulmonary disease and immunosuppression).

ANALYTICAL PERFORMANCE

SENSITIVITY AND SPECIFICITY

Different virus extract dilutions were tested directly in the sample diluent or spiked in a negative nasal specimen in accordance with the kit instructions.
The detection of RSV showed >95% of sensitivity compared with another commercial rapid test and showed >99% of specificity compared with the commercial rapid test.

CROSS-REACTIVITY

It was performed an evaluation to determine the cross reactivity of *RSV* Device. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:

- Influenza A&B
- Adenovirus

NOTES

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

LIMITATIONS

1. RSV Cassette will only indicate the presence of *RSV* in the specimen (qualitative detection) and should be used for the detection of *RSV* antigens in nasopharyngeal specimens only (from swab, aspirate or wash). Neither the quantitative value nor the rate of increase in RSV antigens concentration can be determined by this test.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *RSV* infection.
3. This test provides a presumptive diagnosis of *RSV* infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

REFERENCES

1. BARENFANGER et al., "Clinical and Financial Benefits of Rapid Detection of Respiratory Viruses: an Outcomes Study". Journal of Clinical Microbiology. August 2000, Vol 38 No 8, p. 2824-2828.

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