Human Adenovirus Resp. Rapid test

Cat.No: DTSXY-Z8
Lot. No. (See product label)

Size

20T

Intended use

The Adenovirus Resp. Rapid test is one step test for the qualitative detection of Adenovirus antigens from human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate).

General Description

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. Symptoms of respiratory illness caused by adenovirus infection range from the common cold syndrome to pneumonia, croup, and bronchitis.

Principle Of The Test

The Adenovirus Resp. Rapid test Card is a qualitative lateral flow immunoassay for the detection of Adenovirus antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against Adenovirus antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Adenovirus 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 a coloured line. A green coloured line 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.

Reagents And Materials Provided

1. Rapid
2. Adeno Resp. Card tests (Plastic pipettes included)
3. Instructions for use
4. Diluent (sample diluent)
5. Swabs
6. Testing tubes or vials
7. Adenovirus Respiratory Control swabs

Materials Required But Not Supplied

1. Specimen collection container
2. Disposable gloves
3. Shaker or vortex
4. Timer

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Specimen Collection And Preparation

Nasopharyngeal swab method:
1. Bend shaft to follow curve of nasopharynx.
2. Insert swab through nostril to posterior nasopharynx.
3. Rotate swab a few times to obtain infected cells.
4. For an optimal sample, repeat procedure using other nostril.

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):
1. Instil several drops of solution saline into each nostril.
2. Place catheter through nostril to posterior nasopharynx.
3. Apply gentle suction. Using rotating motion, slowly withdraw catheter.
4. For an optimal sample, repeat procedure using other nostril.

Send specimen to lab immediately (testing sensitivity decrease over time). Cool specimen to 2-8°C during storage and transport for 8 hours prior to testing.

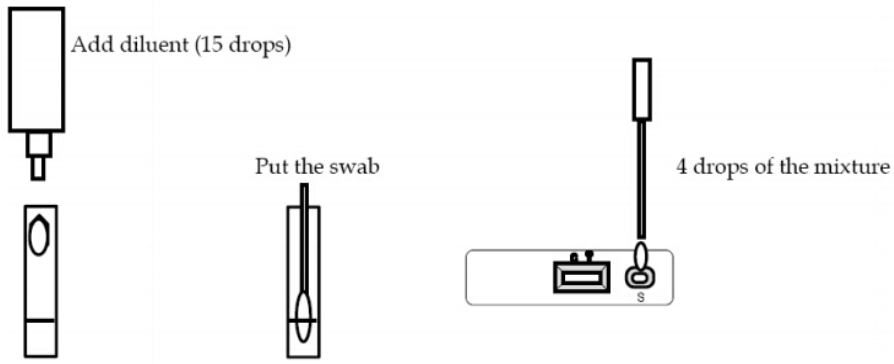
Reconstitution And Storage

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Assay Procedure

Allow the tests, samples and buffer to reach room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.To process the collected nasopharyngeal swab:

Use a separate testing tube or vial for each sample (swab). Add the diluent (15 drops) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much liquid possible from the swab. Remove the test. Card test from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer. Read the result at 10 minutes after dispensing the sample.



To process the collected nasopharyngeal wash or aspirate samples:

Use a separate pipette and testing tube for each sample. Add the nasopharyngeal wash or aspirate sample (6 drops) in a testing tube or vial. Add the diluent (9 drops) and mix with shaker. Remove the test. Card test from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer. Read the result at 10 minutes after dispensing the sample.

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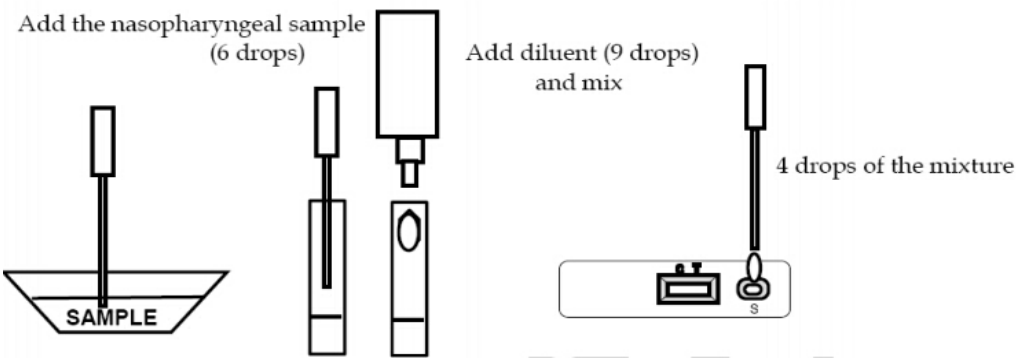
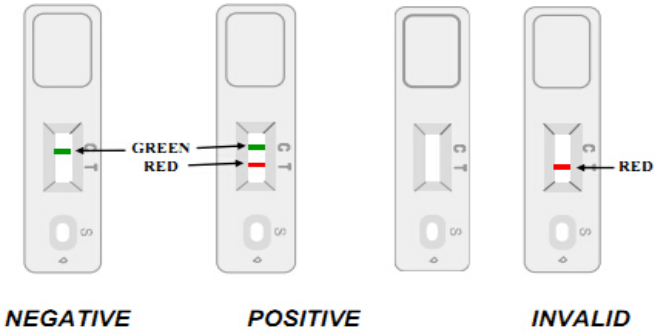


Quality Control

Internal procedural controls are included in the test:
A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

Interpretation Of Results



NEGATIVE: Only one **GREEN** line appears across the control line region marked with the letter C (control line).
POSITIVE: Two lines appear across the central window, a **RED** test line marked with the letter T and a **GREEN** control line marked with the letter C.
INVALID: Total absence of the GREEN control coloured line 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 your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:
The intensity of the red coloured test line 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.

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Performance Characteristics

Sensitivity and specifity:
The Rapid test was highly specific (>99%) and also sensitive (>99%) compared with the results of an immunochromatographic test (CorisBioConcept) and an inmunofluorescence test (Remel).

Cross-Reactivity:
It was performed an evaluation to determine the cross reactivity of Adenovirus Respiratory test. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:
1. Respiratory syncytial virus
2. Influenza type A
3. Influenza type B

Precautions

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

Limitations

1. The Rapid test will only indicate the presence of Adenovirus in the specimen (qualitative detection) and should be used for the detection of Adenovirus antigens in nasopharyngeal specimens only (from swab, aspirate or wash). Neither the quantitative value nor the rate of increase in Adenovirus 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 Adenovirus respiratory infection.
3. This test provides a presumptive diagnosis of Adenovirus respiratory 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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