RSV Rapid Test

Cat. No.:DTS729
Pkg.Size:

Intended use

CD RSV is a rapid immunochromatographic test for use in the qualitative screening of human nasopharyngeal samples for detection of the presence of respiratory syncytial virus (RSV) antigen.

General Description

Respiratory syncytial virus (RSV) is the most important cause of pneumonia and bronchiolitis in infants and small children. RSV causes a range of respiratory illness, the most common being a cold with profuse rhinorrhea. Of infants infected for the first time, 25-40% develop some lower respiratory tract disease. Between 1 and 2% of infected infants require hospitalization. Because of its high infectivity and because hospital staff as well as patients are susceptible, RSV has emerged as the most frequent cause of nosocomial infections on pediatric wards. RSV belongs to the family Paramyxoviridae and the genus Pneumovirus. It is morphologically similar to other paramyxoviruses with the exception that the diameter of its helical nucleocapsid is smaller, 13 to 14 nm rather than 18 nm. RSV is an antigenically heterogeneous species, with strain differences, which are due primarily to differences in one of the two antigenically active surface components. These differences between strains are probably of little or no practical importance from a diagnostic point of view, since available reagents, including monoclonal antibodies, react equally with all clinical isolates.

Principle Of The Test

The CD RSV test strip contains a unique monoclonal antibody that is conjugated to colloidal gold particles. A polyclonal antibody is immobilized in the test area of the strip. If the nasopharyngeal sample contains RSV antigens, these will form antigen-antibody complexes with the gold particles. As these complexes migrate along the test strip to the immobilized capture antibody, a pink/purple line is formed indicating a positive test. The remaining conjugate migrates to a second antibody on the control area of the test strip forming a pink/purple band. This indicates proper performance of the test.

Reagents And Materials Provided

1. 25 CD RSV dipstick tests in aluminum pouches with desiccant
2. 25 Dilution tubes
3. 2 White plastic dropper bottles, each containing 7.5 ml dilution buffer
4. 1 Plastic test holder with lid
5. 1 Instruction sheet

Storage

Kits should be stored at 4 - 30°C. Do not freeze. When stored correctly the product can be kept until the expiry date stamped on the box label.

Specimen Collection And Preparation

nasopharyngeal aspirates or washes

1. Label a sample dilution tube.

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2. Dispense 6 drops (0.25 ml) dilution buffer into the tube.
3. Add 0.25 ml of nasopharyngeal sample to the tube.
4. Thoroughly mix contents of tube (vortex mixer is recommended).

throat or nasopharyngeal swabs

1. Collect specimens using standard swab methods. Swabs with rayon or Dacron tips and plastic shafts may be used. Do not use swabs with cotton or calcium alginate tips, with wooden shafts or impregnated with charcoal or transport media containing agar or gelatin. If immediate testing is not possible, the patient samples should be placed in a dry plastic tube and stored refrigerated at 2-8°C.
2. Label a sample dilution tube.
3. Dispense 12 drops (0.5 ml) dilution buffer into the tube.
4. Swirl swab to thoroughly mix contents of tube.
5. Allow to stand for 15 minutes before removing swab and performing the assay.

Assay Procedure

1. Remove a CD RSV test strip from the pouch.
2. Label the test with a patient name or ID number. Insert the dipstick test vertically (with the blue arrows pointing downwards) into the sample tube with test fluid.
3. Remove dipstick from sample tube when fluid reaches the middle of the test area of the dipstick.
4. Place the dipstick test horizontally on a flat surface.

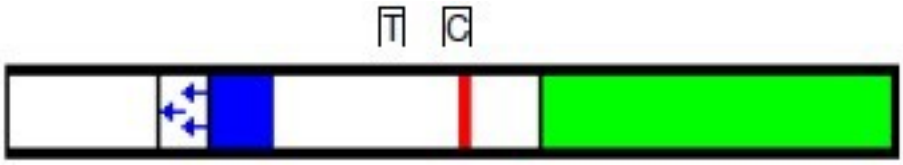
Quality Control

Each test strip contains a built in procedural control. Correct device performance is confirmed when a colored line appears in the control area of the strip. Good laboratory practice requires running a known positive control sample when a new lot of strips is used. If a positive result is not obtained, test results are not valid and the kit should not be used.

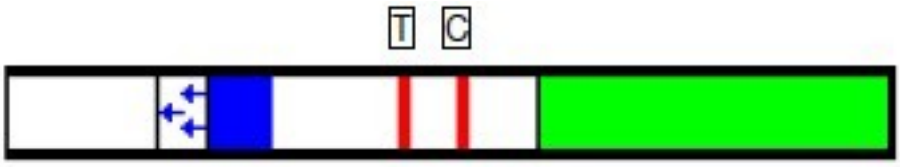
Interpretation of Results

Results should be read 15 - 20 minutes after removal from the test fluid (strongly positive results may appear earlier).

Negative: only one pink/purple band appears in the Control zone. No band is visible in the Test zone.



Positive: in addition to the Control band a clearly distinguishable pink/purple band also appears in the Test zone.



Inconclusive: If no control band is visible (with or without a visible band in the test zone) the test is inconclusive. The test should be repeated using a new device.

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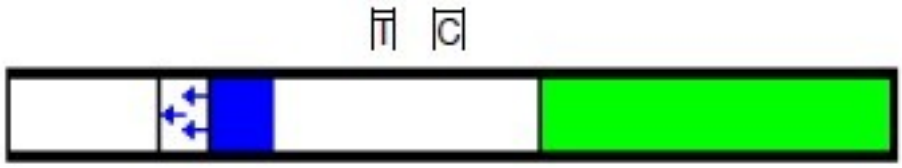

Specific Performance Characteristics

Clinical Comparison

A group of 75 nasopharyngeal samples from infants and young children were tested in the microbiology laboratory of a major urban hospital. Each sample was assayed by CD RSV, Coris (Belgium) RSV Respi-Strip, Binax (USA) Now RSV Test Kit, and Becton Dickinson (USA) Directigen RSV. Forty of the samples were negative by all assays and 33 were positive. Two samples were positive by CD RSV and negative by the other tests. As no “gold standard” was applied, it is not known whether these two samples were actually positive or negative.

Reproducibility

Ten negative nasopharyngeal samples and 10 samples of low to high positive responses were analyzed for the presence of RSV antigen on 10 consecutive days. No change in intensity of result color was detected upon repeated testing of the same sample.

Cross reactivity

Samples known to contain parainfluenza virus, rhinovirus, adenovirus, or rotavirus were tested and found negative by the CD RSV assay.

Limit of detection

Tests performed on dilutions prepared from a sample of RSV from tissue culture gave a detection limit equal to 0.44 µg/ml of viral protein (Long strain).

Precautions

1. Do not use kit or components beyond expiration date.
2. All components in the kit are for in-vitro diagnostic use only, not for internal or external use in humans or animals.
3. Infectious agents may be present in test specimens. Therefore all specimens should be regarded and handled as potential biohazards. Never pipette by mouth and avoid contact with open wounds.
4. Do not mix reagents from kits of different lots.
5. Incubation times or temperatures other than those specified may give erroneous results.

Limitations

1. Samples obtained after the acute phase of the disease may not contain enough virus particles to be detected by CD RSV.
2. A positive result by CD RSV indicates the presence of RSV antigen but does not rule out the presence of other pathogenic microorganisms.
3. Do not use samples containing preservatives or detergents.

REFERENCES

1. Hall, CB. 2000. Nosocomial respiratory syncytial virus infections: The “cold war” has not ended. Clin. Inf. Diseases 31:590-596.
2. Domachowske, JB and Rosenberg, HF. 1999. Respiratory syncytial virus infection: Immune response, immunopathogenisis, and treatment. Clin. Microbiol. Reviews 12:298-309.
3. Talis, A and McIntosh, K. 1991 Respiratory Syncytial Virus in Manual of Clinical Microbiology, Fifth ed., Am. Soc. Microbiol. pp 883-6.

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