

Respiratory Syncytial Virus Dipstick

Immunochromatographic rapid test card for qualitative detection of RSV antigen in nasopharyngeal secretions

INTRODUCTION

RSV, Respiratory Syncytial Virus, is the major cause of respiratory illness in all ages. It represents the most frequent cause of serious respiratory tract infections in infants and children younger than 4 years of age but is also responsible for severe problems in elderly and immunocompromised patients giving rise to high death rates. Pneumonia and bronchiolitis are the two most frequent severe infections prevalent in infants aged 2 to 6 months. Infection of older children and adult may be mild, usually self-limiting, causing nasal stuffiness and discharge not distinguishable from a common cold.

Each year, up to 50 % of infants are infected. RSV 125,000 hospitalisations in the US. Those children who require hospitalisation are newborns and those who suffer from asthma, lung disorders or heart problems. Moreover, RSV bronchiolitis in the first year of life is one of the most important risk factors for the subsequent development of asthma.

It is a highly contagious disease through contact with respiratory secretions. It is also a common cause of nosocomial infections whose prevalence increases during community outbreaks through casual contacts. RSV affects both the upper and lower respiratory tracts, but pneumonia and bronchiolitis are the most prevalent lower respiratory illnesses. Bronchiolitis could be recognized by cough, wheeze, onset of dyspnea, increase of respiratory rate up to 40 breaths per minute and bluish discoloration of the skin around the mouth. Findings of crackles and respiratory distress are common symptoms of pneumonia.

PRINCIPLE OF THE TEST

The RSV test is a dipstick immunoassay that allows the capture and visual detection of RSV antigen (viral fusion protein). The patient specimen is placed in the extraction buffer, enhancing the exposure of the viral fusion protein antigen. After extraction, the Test Strip is placed in the extraction buffer where the RSV fusion proteins in the specimen will react with the reagents in the Test Strip.

This dipstick can detect RSV either in nasopharyngeal secretions or in culture supernatant after several days in order to reach a better sensitivity. When the strip is dipped into the extraction solution of NPS (nasopharyngeal secretions) or culture extracted solution, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample material come into contact with the anti-RSV antibody that it is adsorbed onto the nitrocellulose strip. If the sample contains RSV, the conjugate-RSV complex will remain bound to the anti-RSV antibody adsorbed onto the nitrocellulose. The result is visible within 15 minutes in the form of a red line that develops on the strip. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.

REAGENTS AND MATERIALS

Device	25
Sample Diluent	15ml
Instruction for use	1

PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

STORAGE OF TEST KIT

The RSV Dipstick can be stored at any temperature between 4-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked within 3 months.

SPECIMEN COLLECTION, PREPARATION AND TEST PROCEDURE

Specimens to be tested should be obtained and handled by standard methods for the collection of NPS, washes or swabs.

Please use Copan Diagnostics Inc. Flocked Swab to collect the samples. Cat No. 519CS01 or 502CS01. This swab can have a higher sensitivity.

The NPS and washes specimens must be tested as soon as possible after they are collected. If necessary, they may be stored at 2-8°C for up to 24 hours or at -20°C for longer periods of time. If swabs are not stored in a transport medium or with a gel or a sponge matrix, they should be tested immediately.

Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

We recommend the use of fresh NPS for optimal test performance.

1. Liquid nasopharyngeal washings and/or aspirates. If the sample to be tested is liquid, mix 0,25 mL with 0,25 mL or 8 droplets of the extraction buffer to reach a sample extraction ratio of 1/2.
2. Swabs. Swabs can be stored either in a tube containing a transport medium either in a device with a gel or a sponge matrix. Alternatively, swabs can be used to perform the test immediately after collection ("dry swab" procedure).
 - a- If the swab is stored in a liquid transport medium, it should be wiped out in the medium by pressing its matrix on the tube's wall and the resulting solution should be processed as in point 1.
 - b- If the swab is stored in a non-liquid matrix, and that the lab has saline water or distilled water, it should be placed in a tube containing at least 0,5 mL of a saline solution or distilled water, agitated and the liquid expressed by pressing the swab on the tube wall. Process as in Step 1.
 - c- Dry swab procedure: When there is no dilution medium available, the dry swab should be dipped directly after sampling in 15 droplet or 500 µL of extraction buffer, twisted and wiped out by pressing the swab on the tube wall. The RSV Respi-Strip will be dipped directly in this solution. Only MicroRheologics swabs can be used. Care should be taken not to press the swab against any surface before expressing the sample, as this could lead to sample leakage and reduced sensitivity.
3. Stir thoroughly to homogenize the solution
4. Immerse the sensitized strip in the direction indicated by the arrows.
5. Let react for 15 minutes. Results must be read on wet strips after 15 minutes incubation

INTERPRETATION OF RESULTS

Negative: One pink line appears in control line, showing the test has been carried out correctly. There will be no line in test region

Positive: In addition to a pink colored control line, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. The test should be repeated using a new strip.

LIMITATIONS OF THE ASSAY

1. The test should be used only for the detection of RSV antigen in NPS samples.
2. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result
3. More than 200 samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques (ELISA) was excellent. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible RSV infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.

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