Rapid-VIDITEST
RSV Blister

One step RSV Blister test for the detection of Respiratory Syncytial Virus from nasal specimens.

Instruction manual

Producer: VIDIA spol. s r.o., Nad Safinou II 365, Vestec, 252 42 Jesenice, Czech Republic,
Tel.: +420 2 61 090 565, www.vidia.cz

INTENDED USE
The Rapid-VIDITEST RSV Blister test is a one step coloured chromatographic immunoassay for the qualitative detection of RSV antigens. It can be used directly with nasal swabs or nasal wash or nasal aspirate specimens.

INTRODUCTION
Respiratory Syncytial Virus (RSV) is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age. Illness begins most frequently with fever, runny nose, cough, and sometimes wheezing. Severe lower respiratory tract disease may occur at any age, especially among the elderly or among those with compromised cardiac, pulmonary, or immune systems. RSV is spread from respiratory secretions through close contact with infected persons or contact with contaminated surfaces or objects.

PRINCIPLE OF THE TEST
The Rapid-VIDITEST RSV Blister test is a qualitative immunochromatographic assay for the determination of RSV antigens. The membrane is pre-coated with mouse monoclonal antibodies, on the test band region, to recognize these antigens. During testing, the sample is allowed to react with the coloured conjugate (anti-RSV mouse monoclonal antibodies-red microspheres) which was pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured particles. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERIALS PROVIDED
- Rapid-VIDITEST RSV Blister tests
- Reagent B (sample diluent)
- Testing tubes
- Sterile swabs
- Disposable pipettes
- Instructions for use
MATERIALS REQUIRED BUT NO PROVIDED
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION

Nasal swab specimen:
Collect specimen with a sterile swab from one nostril. Insert the swab approximately 3 cm into the nostril rotating against the nasal wall. Process the swab as soon as possible after collecting the specimen.

Nasal Wash or Aspirate specimen:
For Adult: Place the irrigator up to the nose. Let the sterile saline water run into the nose (2.5 mL). It will run out the opposite side. Tilt and twist the irrigator side to side and up and down directing the water flow into all portions of the nasal cavity. Collect the wash in a clean specimen container, tilt the head forward and allow the water with mucus to run out of the nostril into the specimen container. Repeat the mucus collection for the other nostril and collect it into the same container.

For children: use an aspiration bulb or bulb syringe to instil the saline water into one nostril leaning the children head. Aspirate the mix of mucus-saline water into the bulb and transfer it into a clean container. Repeat for the other nostril and transfer the fluid into the same specimen container.

Samples should be process as soon as possible after collection. The samples can be stored in the refrigerator (2-4 ºC) for 8 hours prior to testing.

TEST PROCEDURE
Allow the tests, swabs and controls to reach to room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay. Only bring to room temperature the number of tests required to assay before opening it.

- Procedure A using nasal swab samples:
1. Add 15 drops (1) Reagent B and immediately put the swab into the tube.
2. Mix the solution by rotating the swab forcefully against the side of the tube at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution (2). Extract as much liquid as possible from the swab, squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
3. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
   3.a. Don’t remove the test from the blister cavity and use it as soon as possible. Place the test on a flat surface. Use a separate pipette and device for each sample or control. Dispense exactly 5-6 drops or 200 µL on the white end of the test (3a). Read the result at 10 minutes.
   3.b. Place the test vertically with the white end submerged into the sample taking care of not surpassing the limit of immersion indicated with the arrows (3b). Read the result at 10 minutes.
Procedure B using nasal wash or aspirate samples:

1. Add 6 drops (1) of the nasal wash or aspirate samples with a pipette and 3 drops (2) of Reagent B in a testing tube.
2. Mix the solution with the pipette at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution (3).
3. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
   3.a. Don’t remove the test from the blister cavity and use it as soon as possible. Place the test on a flat surface. Use a separate pipette and device for each sample or control. Dispense exactly 5-6 drops or 200 µL on the white end of the test (3a). Read the result at 10 minutes.
   3.b. Place the test vertically with the white end submerged into the sample taking care of not surpassing the limit of immersion indicated with the arrows (3b). Read the result at 10 minutes.
INTERPRETATION OF RESULTS (Please refer to the illustration below)

NEGATIVE: Only one GREEN band (control line) appears in the white central zone of the test (control region).

POSITIVE: In addition to the GREEN control band, a distinguishable RED band (result line) also appears in the white central zone of the test (result region).

INVALID: A total absence of the control coloured band (GREEN) regardless of the appearance or not of the result line (RED). 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 performance using 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 band in the result line region will vary depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL
A green line appearing in the control region is the internal procedural control, included in the test. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS
1. The test must be carried out within 2 hours of opening the sealed pack.
2. This test provides a presumptive diagnosis for RSV infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated. It is recommended that negative test results be confirmed by cell culture.
3. The Rapid-VIDITEST RSV Blister test should be used only with nasal swabs, nasal wash and nasal aspirate samples. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper nasal specimens must be obtained.

4. A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test.

5. In case the tests did not run due to thick mucus, dispense a drop of sample diluent until seeing the liquid running through the reaction zone.

STORAGE AND STABILITY
Store as packaged in the blister at 2-30ºC. The test is stable through the expiration date printed on each blister. The test must remain in the closed pack until use. Do not freeze.

PRECAUTIONS
- Rapid-VIDITEST RSV Blister is intended for professional in vitro diagnostic use.
- Do not use after expiration date.
- Do not use test devices if the blister has been damaged during storage.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. A new swab must be used for each sample to avoid contamination errors.
- The tests should be discarded in a proper biohazard container after testing.

PERFORMANCE
Sensitivity
Different virus culture 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 a 95% of concordance in sensitivity with another commercial rapid test.

Specificity
The use of mouse monoclonal antibodies in the elaboration of Rapid-VIDITEST RSV Blister test assures high degree of specificity for the detection of this virus, compared with another commercial rapid test.

REFERENCES

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

<table>
<thead>
<tr>
<th>IVD</th>
<th>In vitro diagnostic device</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>Use by</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>