# RSV+ADENO-RESPI-DIPSTICK

**For *in Vitro* diagnostic use**

**In vitro immunochromatographic test for the detection of RSV and Adenovirus Respiratory antigens in nasopharyngeal secretions (swabs, washings or aspirates)**

## I INTENDED USE

The RSV+Adeno Respi Dipstick test is a rapid immunochromatographic assay for the qualitative detection of RSV and Adenovirus antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) to aid in the diagnosis of Respiratory Syncytial Virus and Adenovirus infection. For professional *in Vitro* diagnostic use only.

## II. INTRODUCTION

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

## III. PRINCIPLE OF THE TEST

The RSV+Adeno Respi Dipstick is a qualitative immunoassay for the detection of RSV and Adenovirus Respiratory antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against RSV and Adenovirus antigens on the test line region. During testing, the sample reacts with the particles coated with anti-RSV antibodies and anti-Adenovirus antibodies which were 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 (RSV or Adenovirus) or two (RSV and Adenovirus) coloured test 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.

## IV. REAGENTS AND MATERIALS

Each kit contains:

**1. RSV + Adeno-Respi-Dipstick (25 strips):** These dipsticks (strips ) come in a bottle with a desiccant.

**2. Diluent (14,0 mL):** Saline dilution buffered to pH 7.5, containing $NaN_3$ (<0,1%), a detergent, and charged proteins.

**3. Instruction for use (1)**

**Required materials (not supplied)**

3 or 5 mL test tubes; Specimen collection container; Disposable gloves and container; Testing tubes; Plastic pipettes.

## V. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- The RSV+Adeno Respi Dipstick test is for in vitro diagnosis only.
- Avoid touching the nitrocellulose with your fingers.
- Wear gloves when handling the samples.
- Disposable gloves, swabs, test tubes, and sensitized strips in accordance with GLP.
- Never use reagents from another lot.
- The tube containing the sensitized strips must be recapped as soon as the necessary number of strips for the operation has been removed, since the strips are sensitive to humidity. Make sure that the desiccant is present.
- Discard the dilution buffer if it is contaminated with bacteria or mould.
- The reagents' quality cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.

## VI. STORAGE

An unopened kit may be kept at between 2 and 30°C and used until the shelf-life date on the packaging.
The strips remain stable for 15 weeks after the tube is opened if they are kept between 2 and 30°C and in a dry environment. The kit must not be frozen.

## VII. SAMPLES

Specimens to be tested should be obtained and handled by standard methods for the collection of nasopharyngeal secretions (NPS), washes, aspirates or swabs. The use of transport media has not been validated on the kit.
The NPS specimens must be tested as soon early they are collected (testing sensitivity decrease over time). If necessary, they may be stored at 2-8°C for up to 24 hours or -20°C for longer periods of time that cannot exceed 1 month. Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

**1. Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):**

- Instill 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.

**2. 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.

## VIII. PROCEDURE

If the kit was kept at 4°C, let all the reagents warm up to room temperature before proceeding with the test.
Write the specimen number on the test tube (one test tube per sample).

**Specimen Preparation Procedure**

Performance claims of samples types other than NPS have not been established. We recommend the use of fresh NPS for optimal test performance.

**1. Nasopharyngeal wash or aspirate samples:**

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 (3 drops or 150uL) and mix.

**2. Nasopharyngeal swab:**

Use a separate testing tube or vial for each sample (swab). Add the Diluent (10 drops or 500uL) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much liquid possible from the swab and mix.
Place the marked test tubes in a rack

-. Mix in order to homogenized the sample above prepared (see Samples paragraph)
-. Leave the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Start the timer. Read the result at 10 minutes after dispensing the sample.

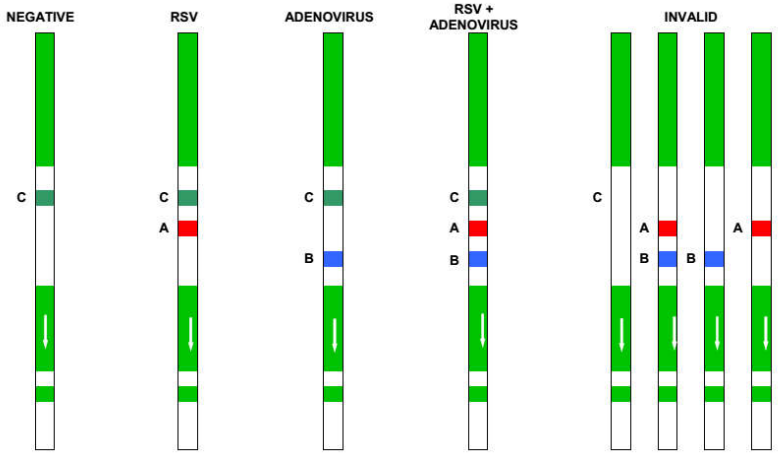
To avoid diluting the latex conjugate in the solution, take care not to immerse the strip above the line placed under the arrows.

## IX. INTERPRETING THE RESULTS

**POSITIVE**
In the case two lines appears across the central window, in the Result Line Region (red test line) and in the control line region (green control line). The sample is **positive to RSV**
In the case two lines appears across the central window, in the Result Line Region (blue test line) and in the control line region (green control line). The sample is **positive to Adenovirus.**
In the case three lines appears across the central window, in the Result Line Region (red and blue test line) and in the control line region (green control line). The sample is **positive to RSV-Adenovirus**.

**NEGATIVE**
In the case only one line appears in the control line region (green control line).

**INVALID**
A total absence of the green control coloured band regardless the appearance or not of the red and blue test lines. 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.




## X. PERFORMANCE

**A. ExpectedValues:** 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. Everyone is at risk of adenovirus infection, but patients with weak immune systems or with underlying respiratory or cardiac disease are most at risk for severe complications from any respiratory infection, including adenovirus infections.

**B. Sensitivity- Specificity (Correlation):** Different virus extract dilutions were tested directly in the sample diluent or spiked in a negative nasopharyngeal specimen in accordance with the kit instructions.
The detection of RSV and/or Adenovirus Respiratory with RSV+Adeno Respi Dipstick showed >95% of sensitivity for RSV compared with other commercial rapid test, NOW® RSV, Binax and >99% of sensitivity compared with Adenovirus Respi CorisBioConcept and with Patho®Adenovirus (Remel). Some clinical nasopharyngeal specimens were collected by an Hospital and used for the performance comparison studies with commercially available immunofluorescence PathoDx®Adenovirus (Remel) and Adenovirus Respi rapid test (CorisBioConcept).

| RSV+Adeno Respi Dipstick Mascia Brunelli | PathoDx®Adenovirus Test | | | Adenovirus Respi Test | | |
|---|---|---|---|---|---|---|
| | + | - | Total | + | - | Total |
| + | 20 | 0 | 20 | 20 | 0 | 20 |
| - | 0 | 5 | 5 | 0 | 5 | 5 |
| Total | 20 | 5 | 25 | 20 | 5 | 25 |

The use of mouse monoclonal antibodies in the elaboration of RSV+Adeno Respi Dipstick assures high degree of specificity for the detection of RSV and Adenovirus antigens.

**C. Riproducibility:** To verify the accuracy intra lot a positive sample of RSV and Adenovirus and Diluent (as negative sample) were tested ten replicates using the same dipstick lot in the same experimental condition. All the results were accurated.
To verify the between lot variation same positive samples (positive for RSV, Adenovirus and Diluent) were tested using three different production lots. All the results were accurated.

**D. Interference:** It was performed an evaluation to determine the cross reactivity of RSV+Adeno Respi Dipstick. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples: HSV, Parainfluenza, Enterovirus, Rhinovirus, Nocardia asteroides, Streptococcus pneumoniae, Moraxella catarrhalis, Staphylococcus aureus, Streptococcus pyogenes, Aspergillus niger, Legionella pneumophila, Candida albicans, Haemophilus influenzae, Influenza A&B.

## XI. LIMITS OF THE KIT

1. RSV+Adeno Respi Dipstick will only indicate the presence of RSV/Adenovirus in the specimen (qualitative detection) and should be used for the detection of RSV and Adenovirus Respiratory antigens in nasopharyngeal specimens only (from swab, aspirate or wash). Neither the quantitative value nor the rate of increase in 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/Adenovirus respiratory infection.
3. This test provides a presumptive diagnosis of RSV/Adenovirus respiratory infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

## XII. BIBLIOGRAPHIC REFERENCES

- Church, D. L., Davies, H. D. et al. (2002). "Clinical and economic evaluation of rapid influenza A virus testing in nursing 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.
- KENNETH E. IRMEN AND JAMES J. KELLEHER. Use of Monoclonal Antibodies for Rapid Diagnosis of Respiratory Viruses in a Community Hospital. Clinical and Diagnostic Laboratory Immunology, May 2000, p. 396–403 Vol. 7, No. 3., Dusseldorf, Germany

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| IVD | In Vitro Diagnostic Medical Device | | Temperature limitation | LOT | Batch code (EXXX) | | Manufacturer | | Keep dry | NON STERILE | Non-sterile |
| | Consult Instructions for use | | Use by (year/month) | REF | Catalogue number | | Do not reuse | | Fragile, handle with care | | Keep away from heat |

**CONTENT (25 tests)** **Ref. VC1019**

| | |
|---|---|
| Dipstick | 25 Strips |
| Diluent | 1 x 14,0 mL |
| Instruction for use | 1 item |

**EDMA (EDMS) Code 1570909000** CE IVD