RSV RESPI CARD PLUS

For in *Vitro* diagnostic use

In vitro immunochromatographic test for the detection of RSV Respiratory antigens in nasopharyngeal secretions and swabs

I. INTENDED USE

The RSV Respi Card Plus test is a rapid chromatographic immunoassay for the qualitative detection of RSV antigens in human nasopharyngeal specimens to aid in the diagnosis of RSV infection. The test including a positive control.

II. SYNTHESIS AND PRINCIPLE OF THE TEST

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

III. REAGENTS AND MATERIALS

Each kit contains:
1. RSV Respi card (25 devices): the devices are in sealed pouch with dessicant.
2. Extraction buffer-Diluent (15 mL): Saline solution buffered, containing NaN_3 (<0,1%), a detergent and charged proteins. Use the diluent like negative control.
3. Positive control (1 x 0,5 mL): N.1 vial with dropper containing non-infectious components, sodium azide (NaN_3) as preservative
4. Instruction for use (1)
Required materials (not supplied)
3 or 5 mL test tubes - Specimen collection container- Disposable gloves - Sterile swabs - Plastic pipettes

IV. PRECAUTIONS

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

V. STORAGE

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

VI. SPECIMENS CIOLLECTION AND PREPARATION

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.
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.

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.

Send specimen to lab immediately (testing sensitivity decrease over time). Cool specimen to 2º-4ºC (36º-40ºF) during storage and transport.

VII. PROCEDURES

Allow the tests, samples and buffers to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pack until ready to perform the assay.
To process the collected nasopharyngeal wash or aspirate samples (see illustration 1):
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 (illustration 1). Remove the Adeno-respi card from its sealed pack and use it as soon as possible. Use a separate test card for each sample. Dispense exactly 4 drops of diluted sample in the sample well S (illustration 3). Start the timer. Read the result at 10 minutes after dispensing the sample.

To process the collected nasopharyngeal swab (see illustration 2):
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 (illustration 2). Remove the Adeno-respi card from its sealed pack and use it as soon as possible. Use a separate test card for each sample. Dispense 4 drops of sample in the sample well S (illustration 3). Start the timer. Read the result at 10 minutes after dispensing the sample.

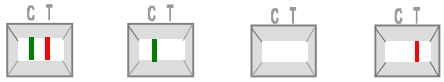
(2)

(1)

(3)

Procedure for the controls
1. Allows the reagent to reach to room temperature (15-30°C). Remove the RSV Card from its sealed pouch and labelled.
2. Dispense 3 drops (150 µL) of Positive or Negative control in the card's well (S).
3. Wait 10 minutes, than observe the comparison of coloured bands in area test, "T" and "C".

VIII. INTERPRETATION OF THE RESULTS



Positive Negative Invalid

POSITIVE:
Two lines appears across the central window in the result line region (red test line marked with the letter T) and in the control line region (green control line marked with the letter C). The sample is positive to RSV.
NEGATIVE:
Only one green band appears across the control line region marked with the letter C (control line).
INVALID:
A total absence of the green control coloured band 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 you local distributor.

The intensity of the red coloured band 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.
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.

IX. 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.
B. Sensitivity- Specificity (Correlation)
Different virus 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 95% of sensitivity compared with another commercial rapid test and showed >99% of specificity compared with the commercial rapid test. (BinaxNOW®, Alere). PPV >99% NPV 91%
C. Interference
It was performed an evaluation to determine the cross reactivity of RVS Respi Card. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:
- Adenovirus
- Influenza A&B

X. LIMITS OF THE KIT

1. RSV Respi Card will only indicate the presence of RSV in the specimen (qualitative detection) and should be used for the detection of RSV 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 infection.
3. This test provides a presumptive diagnosis of RSV infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician

XI. REFERENCES

1. ANN R. FALSEY and EDWARD E. WALSH. "Respiratory Syncytial Infection in Adults", Clinical Microbiology Reviews, July 2000, Vol. 13, No.3, p. 371-384
2. DIANE C. HALSTEAD, SANDRA TODD, and GALE FRITCH; "Evaluation of Five Methods for Respiratory Syncytial Virus Detection" Journal of Clinical Microbiology. May 1990, Vol 28 No 5, p. 1021-1025.

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. VC1015P**
RSV Respi Card	25 devices
Extraction buffer-Diluent	1 x 15 mL
Positive control	1 x 0,5 mL
Instruction for use	1 item

EDMA Code 15 70 90 90 00 CE IVD