ADENO RESPI CARD

For in *Vitro* diagnostic use only

In vitro diagnostic rapid test for the detection of Respiratory Adenovirus in nasopharyngeal secretion or sample culture

I. INTRODUCTION AND INTENDED USE

The Adenovirus is responsable for disorders of respiratory cable and eyes and have been calculated to cause 5-10% of respiratory viral infections. These viruses cause a wide types of disorders: pharyngitis, pneumonia, conjunctivitis, hemorrhagic from cystitis and diarrhea. Among the 47 serotypes, only serotypes 40 and 41 were clearly associated with gastric problems but not respiratory.
The Adenovirus infect children at an early age causing colds and cough, while pharyngitis and conjuntivitis are more common in adolescents and young adults. These viruses are known as the cause of infections of the upper and lower respiratory tract as a result of certain conditions of stress. Some infections such as pneumonia have been identified in immunosuppressed patients.
All serotypes are endemic and some can cause respiratory problems, sometimes involving the eyes. Of the 47 serotypes, types 2, 3, 5 and 7 are the most common.
The virus is transmitted through direct contact or aerosol resulting in humoral and cellular reply immediately. Usually the disease has a positive course with the exception of immunocompromised patients for whom it can be lethal.
Adeno Respi Card Mascia Brunelli è a immunochromatographic rapid test for a qualitative detection of Adenovirus antigens in nasopharyngeal secretions, to aid for diagnosis of Adenovirus infection.

II. PRINCIPLE OF THE TEST

The Adeno Respi Card Mascia Brunelli is a qualitative lateral flow immunoassay for the detection of *Adenovirus* antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against Adenovirus antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Adeno antibodies which was pre-dried on the test strip. The mixture moves 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 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. Adeno Respi card (25 devices): the devices are in a sealed pouch containing a dissecant.
2. Extraction buffer-Diluent (1 x 12,5 mL): Saline dilution buffered, containing NaN3 (<0,1%), a detergent, and charged proteins.
3. Instruction for use (1)

Required materials (not supplied)

Test tubes 3 or 5 mL - Specimen collection container - Disposable gloves – Sterile swabs – Plastic dropper.

IV. SPECIAL PRECAUTIONS

- The kit is for professional use and for in vitro diagnosis only.
- Do not use after expiration date. Do not use the test if pouch is damaged.
- The test should remain in the sealed pouch until use.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- 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 AND STABILITY

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

VI. SPECIMENS COLLECTION

Specimens to be tested should be obtained and handled by standard methods. 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.

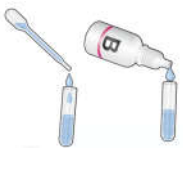
Send specimen to lab immediately (testing sensitivity decrease over time). Cool specimen to 2º-4ºC (36º-40ºF) during storage and transport.

VII. PROCEDURES

Preparations

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.



(1)

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)

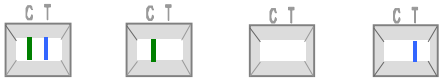

(3)

VIII. INTERPRETING THE RESULTS

POSITIVE: In addition to the GREEN control band across the central window in the site marked with the letter C (control line), a blue band (test line) also appears in the site marked with the letter T (result region). The sample is positive for Adenovirus.

NEGATIVE: Only one GREEN control band appears across the central window in the site marked with the letter C (control line).

INVALID: A total absence of the control coloured band. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely the reasons for control line failure. Review the procedure and repeat the tests using a new test.



Positive Negative Invalid

The intensity of the blue coloured band in the result line region 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. Correlation, Sensitivity-Specificity

An evaluation was conducted comparing the results obtained using the Adeno Respi Card to a commercial immunochromatographic test and a commercial available Immunofluorescence test. Follow the results:

IFI test: PathoDx®Adenovirus IC test: Adenovirus Respi Adeno-Respi-Card MB	**Positive**	**Negative**	**Total**
Positive	20	0	20
Negative	0	5	5
Total	20	5	25

Sensitivity = >99% against immunofluorescence and immunochromatographic test
Specificity = >99%
PPV = Positive Predictive Value = >99%
PNV = Negative Predictive Value = >99%

B. Accuracy

Whithin-run: A positive coltural sample of Adenovirus has been tested 10 times with the same batch of Adeno Respi Card. The extraction buffer has been tested 10 times with a positive colture of Adenovirus. The results are correct for all cases, 100%.
All 10 tests performed with positive sample show two colored lines. All 10 tests performed with extraction buffer show negative result, only one colored line appear.
Between-run: A positive colture of Adenovirus has been tested 3 times with different batches of Adeno Respi Card. The extraction buffer has been tested 3 times with a positive coltural sample of Adenovirus. The results are correct for all cases, 100%.
All the batches showed positive results with positive coltural sample and negative results with the extraction buffer used like sample.

C. Interference

- It was performed an evaluation to determine the cross reactivity with the follows pathogens. There is not cross reactivity with follows pathogens: RSV, Influenza A&B.

- X. LIMITS OF THE KIT

The results obtained with this kit must be interpreted together with other clinical information and laboratory findings available to the physician.
A positive result does not preclude the possibility of infections by other pathogens.
This test provides a presumptive diagnosis of Adenovirus respiratory infections during the acute phase of infections. NPS samples collect after acute phases of infection may contain titles of antigens below the threshold of sensitivity of the reagent. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

XI. REFERENCES

1. Comparison of a Rapid Immunochromatographic Diagnostic Test with Viral Culture to Detect Adenovirus in Respiratory Specimens. Van Beers D., Chaker S., De Foor M., Viehoff R. Posters/Journal of Clinical Virology 27 (2003), p. 33.
2. Adeno Respi-Strip, an Immunochromatographic Test for the Detection of Respiratory Adenovirus. Renuart I., Mertens P., Leclipteux Th. European Biotech Crossroads, October 15-16, 2002 – Lille-Grand Palais-France.
3. Comparison of Adeno Respi-Strip with Another Rapid Adenovirus Test. Mertens P. Confidential – For Internal Use Only

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)

Adeno Respi Card
Extraction Buffer-Diluent
Instruction for use

COD. VC1014

25 Devices (Card)
1 x 12,5 mL
1item

EDMA (EDMS) CODE 1570909000 CE IVD