ADENOVIRUS CARD

For** in Vitro **diagnostic use only

Rapid test in card format for detecting Adenovirus in human stool specimen

I. INTRODUCTION AND INTENDED USE

Adenovirus are major causes of infectious gastroenteritis in infants and young children, also observed in adults. It is transmitted by fecal-oral contact. The main symptoms of viral gastroenteritis are watery diarrhoea and vomiting. The affected person may also have headache, fever, and abdominal cramps ("stomach ache"). In general, the symptoms begin 1 to 2 days following infection with Adenovirus that causes gastroenteritis and may last for 5-8 days.
Adenovirus Card is a screening immunochromatographic assay to detect Adenovirus antigen in stool samples. Detect Adenovirus hexon antigen (capsid), common in the types implicated in gastroenteritis (including serotypes **40** and **41**).

II. PRINCIPLE OF THE TEST

Adenovirus Card is a non-invasive lateral flow assay, rapid, precise and easy to perform. Is a qualitative immunochromatographic assay for the determination of Adenovirus in faeces samples. The membrane is pre-coated with monoclonal antibodies, on the test band region, against Adenovirus antigens.
During testing, the sample is allowed to react with the coloured conjugate (anti-Adenovirus monoclonal antibodies-blue 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 conjugate (BLUE band). 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.

III. REAGENTS AND MATERIALS

each kit contain materials for 25 tests:

1. **Card for immunochromatographic reaction, (25)**.
2. **Extraction buffer (25):** 25 vial containing 1 mL of ipotonic solution.
3. **Instruction for use (1)**

Required materials (not supplied)

Specimen collection container
Disposable gloves
Plastic pipettes
Timer or clock.

AUXILIARY REAGENTS (Not supplied with this kit)

Positive and Negative control (Mascia Brunelli REF. UD80015)

IV. PRECAUTIONS

- For *in* vitro and professional use only
- Do not use after expiration date.
- Stool specimen can be potentially infectious. Safety measures for handling as well as storing the collected specimen must be fixed by the operators.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

V. STORAGE

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). 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. SAMPLES AND PREPARATION

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing. Specimens may be frozen and thawed twice.

Liquid or Semi-Solid Stools

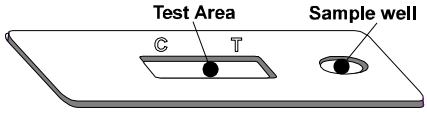
Using a separate pipette for each stool, draw stool of the sample itself. Dispense 6-7 drops of each stool into a separate extraction tube. Mix carefully, then vortex 15 seconds.
Care should be taken when pipetting semi-solid stool. The addition of less than indicated of stool may cause a false-negative test. The addition of more than indicated of stool may cause invalid results due to restricted sample flow.

Formed / Solid Stools

Unscrew the top of the extraction tube. Collect the stool sample with the tip of the collection device by dipping in three different places of the same stool specimen.. Verify to transfer a small portion (approximately 6 mm diameter) of stool. Put the collection device back into the plastic test tube. Shake the extraction tube in order to get an homogeneous solution. Wait at least 3 minutes. Repeat the operations just to obtain a dark yellow-brown solution, if necessary.
The transfer of too little stool, or failure to mix and suspend the stool in extraction tube completely may result in a false-negative test results. Care should be taken to transfer no less and no more than the amount indicated. The sample should be thoroughly mixed with a vortex before testing. The addition of excessive amount of stool may cause invalid results due to restricted sample flow.

VII. PROCEDURE

1. Remove the test card from the protective pouch. Identify the plastic cassette with the patients data.
2. Gently shake the test tube containing the sample under investigation.
3. Brake the tip of the test tube and squeeze 5--6 drops (150 µL) of the extracted mixture into the sample well "S" of the card.
4. Read the result 10 minutes after the sample addition.



VIII. INTERPRETING THE RESULTS

Positive
In addition to the control GREEN band, a clearly distinguishable RED band appears in the test region "T". The intensity of the band colour in the test region is proportionally to the antigen concentration in the sample.
Negative
In the reading window only one GREEN band appears in the control region "C". This is the control line assuring the correctness of test performing.
Invalid
No band appears in the control region. The test is to be considered as in conclusive and it is recommended to repeat the test.

Positive Negative Invalid

IX. CHARACTERISTICS

Expected values: Adenoviruses cause diarrhea mostly in young children, but older children and adults can also be affected. Adenovirus infections occur throughout the year.
Sensitivity and specificity: The sensitivity of test has been determined on 35 positive stool samples and specificity on 30 negative stool samples, agreement of 99%
Cross-reactivity: No cross-reactions have been found with bacteria normally present in the gastro-intestinal tract and those ones generally infecting the same area such as Rotavirus , Enterovirus and Astrovirus.

X. LIMITS OF THE TEST

- **Adenovirus Card will only indicate the presence of Adenovirus in the specimen (qualitative detection) and should be used for the detection of Adenovirus antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in Adenovirus antigens concentration can be determined by this test.**
- **As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but must be confirmed by further analysis.**
- **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 Adenovirus infection.**
- **The components of this I.v.D. were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.**

XI REFERENCES: *see Italian version*

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacture r		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 **REF. VC194020**
Membrane Test 25 items
Extraction Buffer tube 25 items x 1.0 mL
Instructions for use 1 item

EDMA Code 15 70 90 90 00 CE IVD