ADENOVIRUS CARD PLUS

For in *Vitro* diagnostic use only

Rapid test on format card for the detection of Adenovirus in human stool specimen, including positive and negative controls

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 Plus 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**). The kit also contain negative and positive controls.

II. PRINCIPLE OF THE TEST

Adenovirus Card Plus 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:
25 cards for the immunochromatographic reaction. Once opened, the test must be carried out within 2 hours.
25 vials containing 1,0 mL of Extraction solution.
6 Plastic droppers
Positive Control: N.1 vial with dropper containing non-infectious components, sodium azide (NaN_3) as preservative (1 x 0.5 mL).
Negative Control: use Extraction buffer-Diluent
Store the kit at temperature between 2-30ºC. Do not freeze.

Required materials (not supplied)
Specimen collection container
Disposable gloves
Timer or clock.

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

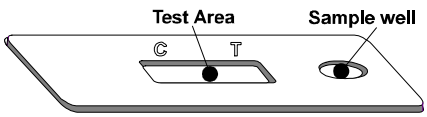
Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC) for 1-2 days prior to testing. For longer storage the specimen must be kept 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 FOR STOOL SAMPLES

1. Allow the reagents to reach to room temperature prior to testing. Remove the test card from the protective pouch. Identify 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.

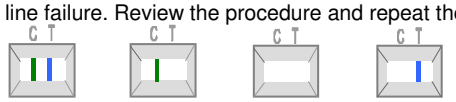


VII. PROCEDURE FOR CONTROLS
For the Positive and Negative Control use the same procedure (from step 3 onwards)

VIII. INTERPRETING THE RESULTS
Positive Test: 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 Test: Only one GREEN control band appears across the central window in the site marked with the letter C (control line). The sample is negative for Adenovirus.

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

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: An evaluation was conducted comparing the results obtained using the Adenovirus Card Plus to a commercial available ELISA assay. Adenovirus Card Plus was highly specific (95%) and also highly sensitive (>99%) compared with the results of that ELISA assay.
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 Plus 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
1. Comparison of immunochromatography with ELISA to detect Adenovirus in stools specimens. Th. Leclipteux D. Col, M. Venuti, F. Paulart, D. Van Beers, M. De Foor and R. Viehof. New Insights in Gastrointestinal Diseases, London, UK, May 1998
2. Set-up of a rapid immunochromatographic diagnostic test for Adenovirus detection. R. Viehoff, D. Van Beers, M. De Foors, D. Col, M. Venuti, F. Paulart and Th. Leclipteux. European Society for Clinical Virology. Progress in Clinical Virology IV, Hamburg, Germany, August 1998
3. Comparison of a immunochromatographic test for the simultaneous detection of Rotavirus and Adenovirus in stools. Depierreux Christophe, Coppe Philippe, Leclipteux, Thierry. Journées Francophones de Virologie. Paris, France, Avril 2000
4. Evaluation d'un Test Immunochromatographique pour la Détection Simultanée du Rotavirus et de l'Adenovirus dans les Matières Fécales. Depierreux Christophe, Leclipteux, Thierry. Virologie, mars-avril 2000, Vol. 4, N°2, p.137 (A20)
5. Evaluatie van de Immunochromatografische Isolatie van Rota- an Adenovirus. C. Tessa, M. Van Ranst Thesis, UZ Gasthuisberg Leuven, 2000
6. Study of Infectious Intestinal Disease in England – Microbiological Findings. D.S. Tompkins et al. Commun. Dis. Public Health 1999: 2108-113

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. VC194020P**
Card for immunochromatographic reaction	25 items
Vials with extraction solution	25 x 1,0 mL
Plastic droppers	6 items
Positive Control	1 x 0.5 mL
Instruction for use	1 item

EDMA (EDMS) Code 1570909000 CE IVD