

Adenovirus Rapid Test Card

Immunochromatographic rapid test card for qualitative detection of adenovirus antigen in feces

INTRODUCTION

Human gastroenteritis is a multifactorial disease. It can be caused by various pathogens agents : viruses (Adenovirus or Rotavirus), bacteria (Salmonella) or protozoan microorganisms such as *Cryptosporidium parvum*.

Diagnosis of the ethiological agent of diarrhea can only be performed in laboratory since no relevant clinical signs allow to differentiate amongst different microorganisms. Moreover classical techniques involving cell culture, electron microscopy, floatation and staining techniques allow to identify these agents, it is well known that these ways of identification are time consuming and sometimes not sensitive enough.

ELISA technology has rapidly replaced these techniques giving rise to simplicity, rapidity, sensitivity and specificity. Unfortunately this procedure is time and money consuming and not suitable for physicians or for one shot analysis. Moreover, in emergency case, the only possibility to diagnose Adenovirus is to perform a latex test which is less sensitive than ELISA, needs faecal material manipulation and more or less skill to be interpreted.

SUMMARY AND PRINCIPLE OF THE TEST

The test uses new homogenous immunochromatographic system with gold particules. It is a ready to use test which only needs a faecal sample dilution with the supplied ready to use dilution buffer. Specificity is ensured by using a monoclonal antibody conjugated with gold particules and directed against specific human genus-specific Adenovirus antigens. The immunochromatographic stick is coated with a monoclonal immunoreagent specific for genus-specific Adenovirus hexon antigens. Liquid sample and gold conjugate both migrate by capillarity and reach the first specific anti-Adenovirus monoclonal reagent. If Adenovirus is present in the sample, it is blocked and immunoreaction appears as a red-pink line. As sample still migrates, it reaches the second non specific anti-mouse IgG which gives rise to a second red-pink line. This rear line indicates that the chromatography has been developed without hindrance. It appears also with negative samples.

REAGENTS AND MATERIALS

Cassette	50
Extraction Buffer	2X15ml
Instruction for use	1

PRECAUTION FOR USERS

- For in-vitro diagnostic use only.
- Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
- Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
- Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
- Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week, making the diagnosis more difficult. The samples can be stored in the refrigerator for 1 to 2 days. For longer storage they must be kept frozen at -20°C. In this case, the sample should be totally thawed, and brought to room temperature and homogenised before testing.

STORAGE OF TEST KIT

The Adenovirus Rapid Test can be stored at any temperature between 4-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

ASSAY PROCEDURES

- Allow all reagents to reach room temperature before use.
- Place 0.5-1ml of extraction buffer in a properly marked testing tube.
- Add a sample portion of approximately 5-6 mm size (25-100mg), with a swab, a wooden applicator or a bacteriology loop. Press the applicator to the tube and rotating it at the same time. For liquid or semi-solid stools add 100 microliters of stool using an appropriate pipette.
- Vortex or stir to release the virus into diluent.
- Add 3-4 drops to the sample well of the test device.

- Incubate the test at room temperature and read the test after **5-15 minutes**.

INTERPRETATION OF RESULTS



Negative: One pink line appears in control line, showing the test has been carried out correctly. There will be no line in test region

Positive: In addition to a pink colored control line, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. The test should be repeated using a new strip.

LIMITATIONS OF THE ASSAY

- The test should be used only for the detection of adenovirus antigen in faecal samples.
- The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result
- More than 200 samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques (ELISA) was excellent. However, interferences in the performance of the tests should not be excluded.
- No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible rotavirus infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.

PERFORMANCE:

Asia Lyon Adenovirus ELISA	Positive Negative	Adeno Test	
		Positive	Negative
		38	2
		6	340

Specificity: $340/(340+6) = 98.3\%$

Sensitivity: $38/(38+2) = 95\%$

Inter-series and intra-series accuracy: 100 %

Interference: Cross reactivity has been evaluated and found to be negative compared to positive specimens of *Cryptosporidium Parvum*, rotavirus.

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