ADENO Virus Test Device

IVD *For In-Vitro diagnostic and professional use only*

Store at (2-30 ºC) CE

INTENDED USE

The Adenovirus Device is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigens in human feces specimens to aid in the diagnosis of Adenovirus infection.

INTRODUCTION

Adenovirus is a major cause 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 diarrhea 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.

PRINCIPLE OF THE TEST

The Adenovirus Device is a qualitative lateral flow immunoassay for the detection of Adenovirus antigen in human feces 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-Adenovirus 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 a coloured line. A green coloured line 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.

MATERIALS PROVIDED

- Test Device.
- Package Insert.
- Stool collection tubes containing sample buffer.

MATERIALS REQUIRED BUT NO PROVIDED

- Specimen collection container
- Disposable gloves
- Timer

STORAGE AND STABILITY

- The tests are packaged in the sealed pouch at room temperature or refrigerated 2-30°C.
- The test cassette is stable through the expiration date printed on the sealed pouch. Do not uses beyond the expiration date.
- Do not freeze

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- 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 should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- The test must be carried out within 2 hours of opening the sealed bag.

SPECIMEN COLLECTION AND PREPARATION

- Collect sufficient quantity of feces (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/36-46.4ºF) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at –20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

TEST PROCEDURE

A. To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample.

1. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (approx. 125 mg).
2. Close the vial with the buffer and stool sample.
3. Shake the vial in order to assure good sample dispersion.

For liquid stool samples, aspirate the fecal specimen with a dropper and add 125 µL into the specimen collection vial with buffer.

B. Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the Adenovirus Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly **4 drops** into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

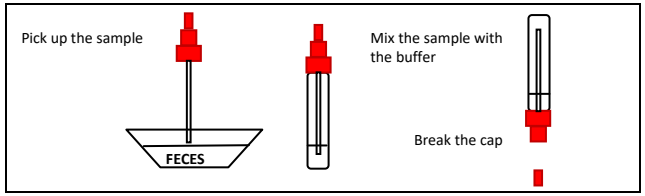
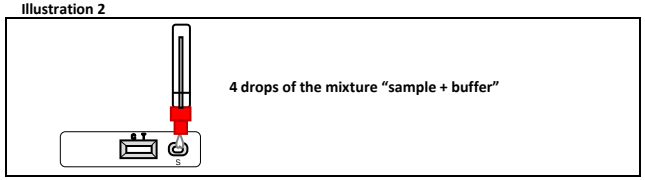


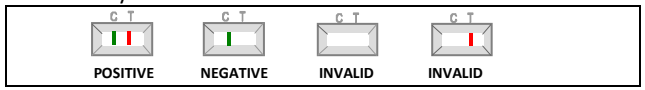
Illustration 2



INTERPRETATION OF RESULTS

(Please refer to the illustration below)

1. **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).
2. **NEGATIVE:** Only one green band appears across the control line region marked with the letter C (control line).
3. **INVALID:** A total absence of the control colored band (GREEN) regardless of the appearance or not of the result line red. 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 performance using a new test. If the problem persists, discontinue using the test kit and contact your local distributor.



NOTES ON THE INTERPRETATION OF RESULTS

- The intensity of the red coloured test line 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.

QUALITY CONTROL

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.

LIMITATIONS

1. Adenovirus Device will only indicate the presence of Adenovirus antigens in the specimen (qualitative detection) and should be used for the detection of Adenovirus antigens in feces specimens only. Neither the quantitative value nor the rate of increase in Adenovirus antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. 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.
5. This test provides a presumptive diagnosis of Adenovirus infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

PERFORMANCE

1. SENSITIVITY AND SPECIFICITY

The results obtained using the *Adenovirus* Device were confirmed using PCR.

Adenovirus Device was highly specific (>99%) and also highly sensitive (>99%).

2. CROSS-REACTIVITY

It was performed an evaluation to determine the cross reactivity of *Adenovirus* Device. There is not cross reactivity with common gastrointestinal pathogens occasionally present in feces.

Astrovirus	Escherichia coli	Salmonella
Campylobacter	Giardia lamblia	Shigella
Clostridium difficile	Helicobacter pylori	Staphylococcus aureus
Entamoeba hystolitica	Listeria monocytogenes	Yersinia
Cryptosporidium parvum	Norovirus	
Enterovirus	Rotavirus	

REFERENCES

- GUILLERMO BERNAOLA, WALTER LUQUE. et al., "Fisiopatología de las Infecciones por Adenovirus", Paediatrica Asociación de Médicos Residentes del Instituto de Salud del Niño Oct. 2001 - Mar. 2002 Volumen 4, Nº 2 Págs. 41 - 47.

ATLAS MEDICAL
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry