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For information Use only- Not to be used for
performing the assay. Refer to the insert
accompanying the kit

40/41 Adeno–Strip, 40/41 Adeno-CIT, 40/41 Adeno Uni-Strip
In vitro rapid diagnostic test for Adenovirus gastro-enteritis (serotypes 40/41).



FOR IN VITRO USE

FOR PROFESSIONAL USE ONLY

References: C-1003, 25 tests per kit.

C-1203, 20 tests individually packed

C-1503, 10 tests individually packed, sampling devices

I. INTRODUCTION

Diarrhoea and gastro-enteritis in human beings can be caused by viruses (Rotavirus, Adenovirus, Astrovirus, Norwalk virus, etc), bacteria such as Salmonella and *E. coli*, and protozoa such as Cryptosporidium and Giardia. Viruses cause 45% of the diarrhoea in children under 1 year of age and 40% of the diarrhoea in children under 4.

The prevalence of Adenovirus is 4-12%. This makes it the second leading cause of viral enteritis in children under two years of age. Infection occurs via the faecal-oral route, but can result from the inhalation of aerosols as well. The incubation period lasts from 5 to 8 days and the symptoms of the stomach and intestinal inflammation are watery diarrhoea, vomiting, fever, and abdominal cramps.

The Adenoviruses are divided into six subgroups labelled A to F. Subgroup F is the most frequently involved in paediatric gastro-enteritis. The 40/41 Adeno-Strip detects subgroup F.

II. PRINCIPLE OF THE TEST

This test is ready to use and is based on the use of a homogeneous membrane system technology with colloidal gold particles. The faecal sample must be diluted in the dilution buffer that is supplied with the test. A nitrocellulose membrane is sensitized with antibody to Adenovirus.

The test's specificity is ensured by a monoclonal antibody directed against specific proteins of human Adenovirus 40/41 that is coupled to the colloidal gold. This conjugate is insolubilized on a polyester membrane.

When the strip is dipped into the liquid phase of the faecal suspension, the resolubilized conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-Adenovirus monoclonal antibody adsorbed to the nitrocellulose. If the sample contains Adenovirus 40/41, the conjugate-Adenovirus 40/41 complex remains bound to the anti-Adenovirus monoclonal antibody. The result – in the form of a red line that develops on the strip – is visible within ten minutes. The solution continues to migrate to encounter a control reagent (an anti-chicken IgY antibody) that binds a control conjugate, thereby producing a second dark red line and confirming that the test is working properly.

III. REAGENTS AND MATERIALS

Each kit contains 40/41 Adeno- strips, dilution buffer and optional components (for C-1503):

1. 40/41 Adeno- strips

Each strip is sensitized with a mouse monoclonal anti-Adenovirus antibody directed against the Hexon antigens of Adenovirus and a goat anti-chicken IgY polyserum. The purified reagents are adsorbed to the nitrocellulose.

The anti-Adenovirus conjugate is produced with mouse monoclonal antibody directed against the group F antigens (serotypes 40/41). This antibody is purified and coupled to colloidal gold particles.

These strips come in a bottle or a pouch with a desiccant.

2. Dilution buffer (15 ml)

Saline solution buffered to pH 7.5 with Tris and containing EDTA, NaN₃ (<0.1%), a detergent, and charged proteins.

3. Instruction for use (1)

4. Required materials (supplied with C-1503):

- 3 or 5 ml test tubes
- inoculating loops for taking the faecal samples
- cardboard rack

Materials to be ordered separately

-40/41 Adenovirus Control Test (Ref.: C-1083)

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- The 40/41 Adeno-Strips are *for in vitro* diagnostic only.
- Avoid touching the nitrocellulose with your fingers.
- Wear gloves when handling the samples.
- Dispose of gloves, swabs, test tubes, and sensitized strips in accordance with GLP.
- Never use reagents from another kit.
- If strips are stored in container, the container must be recapped/resealed as soon as the necessary number of strips for the operation has been removed, since the strips are sensitive to humidity. Make sure that the desiccant is present.
- If strips are stored in individual pouches, pouch must be opened with care to avoid damaging the strip.
- Two green lines indicate the antibody adsorption sites. They disappear in the course of the test.
- Discard the buffer solution if it is contaminated with bacteria or mould.
- The reagents' quality cannot be guaranteed beyond their shelf-life dates or if the reagents are stored under inappropriate conditions.

To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line placed under the green arrow.

V. STORAGE

An unopened 40/41 Adeno-Strip kit may be kept at between 4 and 37°C and used until the shelf-life date on the packaging. The strips remain stable for 15 weeks (in the closed container) after the bottle is opened if they are kept at between 4 and 37°C and in a dry environment. The 40/41 Adeno-Strips and the buffer must not be frozen.

VI. SAMPLES

The stool specimens must be tested as soon after they are collected as possible. If necessary, they may be kept at 2-8°C for 1 week or -20°C for longer periods of time. Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

VII. PROCEDURE

Preparations:

If the 40/41 Adeno-Strip was kept at 4°C, let all the reagents warm up to room temperature before proceeding with the test. Write the patient's name or specimen number on the test tube (foresee one test tube per sample). Place the marked test tubes in a rack.

Procedure:

1. Add 0.5 ml or 15 drops of the dilution buffer solution to each tube.
2. Dip the inoculating loop containing the stool sample into the tube. The dilution ratio must be at most 4% w/v. For liquid samples, take 2 loops of 10 µL, for solid samples, take 1 loop.
3. Stir to homogenize the solution and let stand for 1-2 minutes.
4. Discard the inoculating loop and immerse the sensitized strip in the direction indicated by the green arrow.
5. Let react for 10 minutes. Results must be read on wet strips after 10 minutes incubation.

VIII. INTERPRETING THE RESULTS

The results are to be interpreted as follows:

1 upper line = negative
2 lines = positive
0 line = invalid*

The absence of the control line, which is the upper line, makes the result invalid. In this case, the sample must be retested.

The intensity of the test line may vary according to the quantity of antigens found in the sample. Any signal, even weak, on the test line must be regarded as a positive result. Nevertheless, the test is qualitative and cannot predict the quantity of antigens present in the sample. The clinical presentation and other test results must be taken into consideration to establish diagnosis. During the drying process, a very faint shadow may appear at the test line. It should not be regarded as a positive result.

To store the results, let the strip dry after removing the absorbent material at its base.

IX. QUALITY CONTROL

In accordance with Good Laboratory Practices, we recommend checking the test's performance regularly in line with the laboratory's requirements. To do this, the 40/41 Adenovirus Control Test (C-1083), in which the strip is immersed, may be used. Refer to the C-1083 package insert.

X. PERFORMANCES

A. Sensitivity - Specificity (Correlation):

The kit was validated by comparing the 40/41 Adeno-Strip kit's results with those of an ELISA test.

The 40/41 Adeno-Strip kit's sensitivity and specificity were tested on 153 stool samples. The following results were obtained:

ELISA 40/41 Adeno-Strip	Positive	Negative	Total
Positive	9	1	10
Negative	0	143	143
Total	9	144	153

Sensitivity = 100 % (9/9)
 Specificity = 99.30 % (143/144)
 Reliability (Concordance) = 99.35 % (152/153)
 (N = 153)

B. Accuracy:

To check the intra-lot accuracy, same positive sample and a buffer solution have been processed 15 times on sticks of the same production lot in the same experimental conditions. All observed results were correct as expected.

To check the inter-lot accuracy, some samples (positive and buffer) were processed on six different production lots. All results were correct as expected.

C. Limit of detection:

The 40/41 Adeno-Strip's limit of detection is the dilution detection threshold below which it no longer detects Adenovirus 40/41. This limit was determined by comparing it with ELISA on four stool specimens positive for Adenovirus 40 and 41. The results showed that the 40/41 Adeno-Strip kit's limit of detection for two of the specimens tested was identical to that of the ELISA technique. It was below that of the ELISA technique for one of the stool specimens and above that of the ELISA technique for the last stool specimen. It should be pointed out that the 40/41 Adeno-Strip test is not sensitive to the background noise problems that plaque ELISA.

D. Interference:

Cross reactivity with samples positive for the following pathogens was tested and found to be negative:

- *Cryptosporidium parvum* (n = 9)
- *Campylobacter jejuni* (n = 10)
- *Giardia lamblia* (n = 10)
- Rotavirus (n = 25)
- *E. coli* O157: H7 (n = 2)
- *Salmonella typhimurium* (n = 1)
- *Salmonella enteritidis* (n = 1)
- *Yersinia enterocolitica* (n = 3)
- *Helicobacter pylori* (n = 1)
- *Aeromonas hydrophila* (n = 1)

XI. LIMITS OF THE KIT

40/41 Adeno-Strip kit results must be compared with all other available clinical and laboratory information.

A positive test does not rule out the possibility that other pathogens may be present.

The 40/41 Adeno-Strip is an acute-phase screening test. Stool specimens that are collected after this phase may contain antigen titres below the reagent's sensitivity threshold.

XII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem, or if performances do not correspond with those indicated in this package insert:

1. Record the lot No of the kit in question
2. If necessary, store the problematic sample in the freezer as soon as possible
3. Contact Coris BioConcept or your local distributor

XIII. BIBLIOGRAPHIC REFERENCES

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



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Reference: IFU 5703

Package insert last updated October 2007

REF	Catalogue number		Manufactured by
IVD	In vitro diagnostic medical device		Temperature limitation
	Contains sufficient for <n> tests	DIL SPE	Diluent specimen
	Consult instructions for use		Do not reuse
	Keep for the dry		Use by
DIL AS	Diluent assay	CONT NaN3	Contains Sodium azide

