

## Rota–Strip, Rota-CIT, Rota Uni-Strip

*In vitro Rapid Diagnostic Test for the detection of Rotavirus in faecal specimens.*

### **FOR *IN VITRO* USE**

### **FOR PROFESSIONAL USE ONLY**

**Reference : C-1001, 25 tests per kit**

**C-1501, 10 tests individually packed, sampling devices**

**C-1201, 20 tests individually packed**

### **I. INTRODUCTION**

Diarrhoea and gastro-enteritis in human beings can be caused by viruses (Rotavirus, Adenovirus, Astrovirus, Calicivirus, etc), bacteria such as Salmonella spp and E. coli, and protozoa such as Crypto-sporidium and Giardia. Viruses cause 45% of the diarrhoea in children under 1 year old and 40% of the diarrhoea in children under years.

Rotavirus is the leading cause of gastro-enteritis in children under five years with a worldwide prevalence of almost 40% leading to 600 000 death a year, mainly (85%) in developing countries (NEJM-2006). It is transmitted by faecal-oral contact. After an incubation period of about three days it triggers fever, vomiting, and diarrhoea that can persist for up to ten days. It remains a severe infection, even in the developed world. In the United States, 20 to 40 deaths from rotavirus infections occur each year. As it is highly contagious, it spreads very rapidly in paediatric populations, which are risk groups for these infections.

### **II. PRINCIPLE OF THE TEST**

This test is ready to use and is based on the 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 antibodies directed against Rotavirus. The test's specificity come from a mono-clonal antibody directed against Group A VP6 proteins of human Rotavirus that is conjugated to colloidal gold particles. This conjugate is dried onto a polyester membrane.

When the strip is dipped into the liquid phase of the faecal suspension, the conjugate is solubilized and migrates with the sample by passive diffusion. The conjugate and sample material come into contact with the monoclonal antibody anti-Rotavirus that is adsorbed to the nitrocellulose strip. If the sample contains Rotavirus, the conjugate-Rotavirus complex will remain bound to the monoclonal antibody anti-Rotavirus. 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 that binds a control conjugate, thereby producing a second red line.

### **III. REAGENTS AND MATERIALS**

Each kit contains Rota- strips, a dilution buffer and optional components (for C-1501):

#### **1. Rota -Strip strips**

Each strip is sensitized with a mouse monoclonal antibody directed against the VP6 Rotavirus antigen and a goat anti-chicken IgY polyserum.

The anti-Rotavirus conjugate is produced with a mouse monoclonal antibody directed against the human Rotavirus Group A VP6 antigens. This purified antibody is conjugated 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, NaN<sub>3</sub> (<0.1%), a detergent, and charged proteins.

#### **3. Instruction for use (1)**

#### **4. Required materials (supplied with C-1501 catalog number)**

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

### **IV. SPECIAL PRECAUTIONS.**

- All operations linked to the use of the test must be performed in accordance with the Good Laboratory Practices (GLP).
- The Rota-Strips are for in vitro diagnostic use 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 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 sachet 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 during 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 under the blue arrow.

### **V. STORAGE .**

An unopened Rota-Strip kit may be kept at between 4 and 30 °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 30°C and in a dry environment.

The Rota-Strips and the buffer must not be frozen.

Real-time long-term stability is under evaluation. Intermediate results are available at CORIS BioConcept.

### **VI. SAMPLES.**

The stool specimens must be tested as soon after they are collected as possible. If necessary, they may be stored at 2-8°C for 24 hours 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 Rota-Strip kit was kept at 4°C, let all the reagents in the unopened packaging warm up to room temperature before proceeding with the test.

Indicate 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. Plunge 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 blue arrow.
5. Let react 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. PERFORMANCE.**

#### **A. Sensitivity- Specificity (Correlation) :**

The kit was validated by a third party (France) by comparing the Rota-Strip's results with those of an ELISA test.

The Rota-Strip kit's sensitivity and specificity were tested on 214 stool samples. The following results were obtained:

Rota strip	Elisa	Positive	Negative	Total
Positive		104	0	104
Negative		2	108	110
Total		106	108	214

Sensitivity : 98.1 %      Positive Predictive value : 100%  
 Specificity : 100 %      Negative Predictive value : 98.1%  
 Reliability : 99.1%

### B. Accuracy

Intra-batch reproductibility tests were carried out by testing the same positive samples and the buffer alone using 15 strips from a single batch. All results were correct as expected.

To check the inter-lot accuracy, same samples were tested on 3 different production lots in the same sampling conditions as above. The results were correct in 100% of the cases.

### C. Interference

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

- *Cryptosporidium parvum*
- *Giardia lamblia*
- Adenovirus groupe A à F
- Adenovirus 40/41
- *E. coli* 0157 : H7
- *S. typhimurium*
- *S. enteritidis*
- *Escherichia coli* K99
- Coronavirus
- *Entamoeba histolytica*
- *Entamoeba dispar*

### X. LIMITS OF THE KIT

Rota-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 Rota-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.

### XI. TECHNICAL PROBLEMS / COMPLAINTS








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

- Note the lot No. of the kit in question.
- If necessary, store the problem sample in the freezer as soon as possible

Contact Coris BioConcept or your local distributor

### XII. BIBLIOGRAPHIC REFERENCES

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2. Detection of rotavirus in faecal specimens with a monoclonal antibody enzyme-linked immunosorbent assay : comparison with polyclonal antibody enzyme-immunoassays and a latex agglutination test. Sneyers et al. Comp. Immun. Microbiol. Infect. Dis., vol 12, n°4, pp 95-104, 1989
3. Comparison of Three Rapid Immunoassays for the Detection of Rotavirus Antigen in Stool Samples. I. Van der Donck et al. ESCV Winter Meeting 1999, Rotterdam, the Netherlands
4. Evaluacion de tres Metodos de Deteccion de Rotavirus en Heces. I. Wilhelmi et al. 6th Congreso Nacional de Virologia, Madrid, 26th Oct. 99
5. Evaluation d'un test immunochromatographique pour la détection simultanée du Rotavirus et de l'Adenovirus dans les matières fécales. Depierreux C. & Leclipteux T.

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 dry		Use by
DIL AS	Diluent assay	CONT NaN3	Contains Sodium azide

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6. Rotavirus

Umesh D. Parashar, Joseph S. Bresee and all, Centers for Disease Control and Prevention

, Atlanta, Georgia, USA

Emerging Infectious Diseases 4(4) :561-570, 1998. Centers for Disease Control

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