

# Rotavirus Rapid Test Stick

Immunochromatographic rapid test strip for qualitative detection of rotavirus antigen in feces

## INTRODUCTION

Rotaviruses are the main cause of acute gastroenteritis, especially in children under the age of two years. Rotaviruses have been identified in almost 50% of the faeces of children with gastroenteritis, responsible for 600,000-800,000 death annually. Rotavirus infections occur frequently during the winter months. Gastroenteritis from enteric viruses can be mortal in risk populations such as children, the elderly or immunosuppressed individuals. Characteristic symptoms include vomiting, hydrodiarrhoea for between 3 and 8 days, high temperature and stomach pains. Rotaviruses transferred via the faecal-oral route are eliminated in large quantities into the intestine, so that hospital-borne infections from rotaviruses are regarded very seriously, particularly in baby stations and paediatric clinics, and are difficult to control. Early and reliable detection so that rotaviruses can be recognised and further infections avoided is therefore very important.

## PRINCIPLE OF THE TEST

The Rotavirus Rapid Test Strip employs red gold-conjugated monoclonal antibodies against antigen VP6 of group A of rotavirus, and solid-phase specific rotavirus antibodies. In this test the specimen is first treated with an extraction solution to extract rotavirus antigens from the feces. Following extraction, the only step required is to add the extract to the reaction device. As the sample flows through the test membrane, the colored particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the colored particles. Red color lines will be visible, depending upon the virus content of the sample. These lines, after 5-15 minutes of incubation at room temperature, are used to interpret the result.

## REAGENTS AND MATERIALS

Device	25
Sample Diluent	15ml
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.

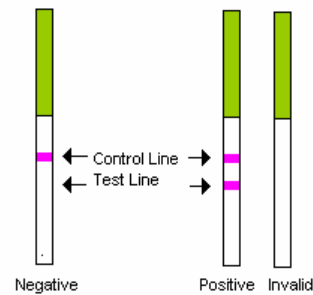
## STORAGE OF TEST KIT

The Rotavirus Rapid Test Device 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 opened within 3 months.

## ASSAY PROCEDURES

- Place 0.5ml of extraction buffer in a properly marked testing tube.
- Add a sample portion of approximately 5-6 mm size (25-50mg), 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.
- Stir to homogenize the sample to release the virus into diluent.
- Take the strip from its sealed tube and dip it into the tube with the arrow pointing to the bottom.
- 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 rotavirus 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 800 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

		Rota Stick	
		Positive	Negative
Dako ELISA	Positive	205	5
	Negative	4	603

**Specificity:** 603/(603+4)= 99.3 %

**Sensitivity:** 205/(205+5)=97.6 %

**Inter-series and intra-series accuracy:** 100 %

**Interference:** Cross reactivity has been evaluated and found to be negative compared to positive specimens of *E.coli*, *Cryptosporidium Parvum*, Adenovirus , Adeno 40/41.

## Literature:

- CUKOR G., and BLACKLOW N. R., "Human Viral Gastroenteritis", *Microbiological Reviews*, Vol.48 No 2, June 1984, pp. 157-179
- ESTES, M. K. and COHEN, J.; "Rotavirus Gene Structure and Function", *Microbiological Reviews*, Vol. 53 No 4, Dec. 1989, pp. 410-449

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