

BIOCARD™ ROTASTICK

BIOCARD™ ROTASTICK is a sensitive and rapid stick test for the detection of rotavirus from faecal samples

INTRODUCTION

Rotaviruses are non-enveloped RNA viruses that replicate in the intestine. Rotaviruses have a segmented genome and carry two surface proteins that are significant for classification and for the host immune response. Rotaviruses have a wide spectrum of different types and subtypes and multiple types and subtypes circulate in communities at the same time. Rotaviruses are relatively large enteric viruses (70 nm). Seven rotavirus antigenic groups (A to G) are known. Groups A, B and C are associated with illness in humans and groups D and G with illness in animals only. Rotavirus causes approx. 150 million episodes of gastroenteritis annually, of which 2 million require hospitalization. Rotavirus causes approx. 350 000 –600 000 deaths annually.

TEST PRINCIPLE

Biocard™ Rotastick is a rapid one step qualitative immunoassay based on the immunochromatographic sandwich principle. The method employs a unique combination of highly specific anti rotavirus antibody-dye conjugate (gold) and anti rotavirus solid phase antibody to selectively identify rotavirus antigen with high degree of sensitivity.

TEST COMPONENTS

Biocard™ Rotastick,
Cat. no. 3-006-410

- 10 Disposable test sticks
- 10 Test tubes
- 10 Sterile sampling swabs
- 0,5 ml Positive Control
- 5 ml Biocard™ Rota Buffer
- Instructions for use

Biocard™ Rotastick,
Cat. no. 3-006-420

- 20 Disposable test sticks
- 20 Test tubes
- 20 Sterile sampling swabs
- 0,5 ml Positive Control
- 10 ml Biocard™ Rota Buffer
- Instructions for use

Materials needed but not provided

- specimen container
- timer

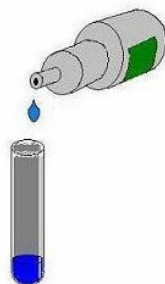
TEST PROCEDURE

1. Collection of the specimen

Faecal specimens should be collected in the acute phase of infection, when large amounts of virus are excreted. The chance of identifying a pathogen diminishes as time after acute illness passes. Rotavirus antigens are very resistant to destruction in the specimen and do not lose their activity during a few days of storage. For longer storage, it is recommended to deep freeze the specimens as such or diluted 1:10 in PBS buffer.

2. Handling of samples prior testing

Place a test tube in a workstation. Add 6 - 8 drops of Biocard™ Rota Buffer (approximately 225 µl) into the test tube.



Faecal specimens are collected using a cotton swab from the anus or from a diaper. The swab with a small amount of sample (approximately 25 µg) is put in the test tube. Please take care that not too much sample is caught on the inside of tube. The dilution should be approx. 1:10. The faecal sample is suspended in the buffer by rotating the swab.



Remove the swab from the tube. The test tube should stand at room temperature for 3 minutes to allow coarse particles to sediment. Samples can be stored for seven days refrigerated before the testing procedure.

3. Testing procedure

Take a stick from aluminium foil pouch and place it standing in the test tube with the filter end in the sample. The stick should not be submerged in the sample deeper than the length of the max line indicates.



Let the stick remain standing in the sample for 5 minutes.

4. Interpretation of the results

A positive result is indicated by the appearance of two red lines in the white central area of the stick. This can happen with clear positive samples already in 2 minutes and with weak positive samples in 5 minutes.



A negative result is indicated by the appearance of one red line, the control line, only. This is also an indication of proper performance of the test.



If the control line is not visible the test is inconclusive, whether or not the test line is visible. A new test must be performed.

STORAGE

Test packages can be stored at ambient temperature (+2 ... +27 °C), until expiry date. Biocard™ Rota Positive Control should be kept in refrigerator (+2 ... +8 °C).

CONTROLS

The proper performance of Biocard™ Rotastick can be checked by means of Biocard™ Rotastick Positive Control or with a known faecal specimen. The Positive control shall not be diluted further as it is ready for testing. The Biocard™ Rota Buffer used as a negative control shall produce a negative result. When known frozen specimens are used as controls, they shall always be diluted with Biocard™ Rota Buffer.

SENSITIVITY AND SPECIFICITY

Biocard™ Rotastick test was compared to EM technique known as the golden standard method for Rota virus detection.

EM TECHNIQUE At Helsinki University

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BIOCARD™ Rotastick	- 38	3
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Based on the test results it can be concluded that Biocard™ Rotastick showed sensitivity of 90 % and specificity of 100 % when compared to the golden standard method, EM technique.

Biocard™ Rotastick Test gave a distinct negative test result when tested with faecal specimens containing Adeno, Parvo and Astrovirus.

WARNINGS AND LIMITATIONS

Follow the instructions for use carefully; a failure to do so may result in false test results. Biocard™ Rotastick test may only be used for in-vitro qualitative detection of rotavirus antigen from faecal specimen according to the instructions for use.

A diagnosis should not be made solely according to the Biocard™ Rotastick –test result. The result should be used in conjunction with additional diagnostic information available for the physician.

Do not use the test if the foil pouch is damaged. Do not use expired tests or reagents. Only use the reagents that came with the kit. Use each test strip only once.

The test should be performed in accordance with generally accepted virological principles of handling and containment of potentially hazardous samples. All samples are potential pathogens. Used materials and samples should be disposed of with appropriate caution.

Sodium Azide has been added 0,09 % to the reagents as a preservative. Avoid contact with skin and mucous membranes.

Positive control contains materials derived from animals. Handle with appropriate care.

REFERENCES

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