

Rotavirus FIA Rapid Test Device

Catalogue No.: F12-RTV-001
(Human Faeces)

A rapid test for the qualitative detection of Rotavirus antigens in human faecal specimens with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Rotavirus FIA Rapid Test Device is intended for *in vitro* quantitative detection of Rotavirus antigens in human faecal specimens. This test is an aid to assist in the diagnosis of Rotavirus infections.

SUMMARY

Rotavirus has a genome of 11 double-stranded RNA segments surrounded by a triple-layered capsid consisting of a core, inner capsid, and an outer capsid layer. Rotaviruses are the major cause of severe diarrheal disease in children below five years worldwide.^{1,2} An estimated 215,000 children died from severe rotavirus-related gastroenteritis in 2013, with most of these deaths occurring in developing countries.³

Accurate and rapid diagnosis of rotavirus infection is important to determine appropriate treatment and to prevent the unnecessary use of antibiotics and spread of the infection.

PRINCIPLE

The Rotavirus FIA Rapid Test Device detects Rotavirus Antigen based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. The Rotavirus Antigen in the specimen will be combined with the Rotavirus antibody that has been conjugated with fluorescence microspheres and the combination will be captured by another Rotavirus antibody coated on the membrane. The more Rotavirus Antigen in the specimen, the more fluorescent microspheres will be captured on the membrane. The concentration of Rotavirus Antigen in the sample is positively related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Rotavirus Antigen in the sample can be calculated and reported by the Fluorescence Immunoassay Device (BR-FIA-2000).

REAGENTS

The test includes Rotavirus antibody-1 coated particles and Rotavirus antibody-2 coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda Rotavirus FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the

sealed pouch.

2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

Materials Provided:

- 25 x foil wrapped Rotavirus Rapid Test Device
- 25 x Specimen collection tubes with buffer solution
- 1 x ID card (Rotavirus)
- Package Insert

Materials required but not provided:

- Specimen Collection Containers
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

Collect sufficient quantity of faeces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present).

Specimen Storage and Shipping

Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 °C if not tested within 6 hours. For long term storage, specimens should be kept below -20 °C. If specimens are to be shipped, these should be packed in compliance with local regulations covering the transportation of etiological agents.

Preparation

Before performing the test, please bring the specimen to room temperature (15-30 °C). Frozen specimens must be completely thawed and mixed well prior to testing.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick Test* mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. To process faecal specimens:

For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the faecal specimen in **at least 3 different sites** to collect approximately **50 mg** of faeces (equivalent to 1/4 of a pea). Do not scoop the faecal specimen.

For Liquid Specimens:

Pipette **80 µL** of faeces into the specimen collection tube containing the buffer.

Tighten the cap onto the specimen collection tube and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Let the tube sit for 2 minutes.

4. Remove the test Device from the sealed foil pouch and place it on a clean, level surface. The Device should be used within one hour of opening.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and **discard 2 drops of the extracted specimen (approximately 80 µL)**, then transfer

2 full drops of the extracted specimen (approximately 80 µL) to the specimen well of the test device and then start the timer. Avoid trapping air bubbles in the specimen well.

- Test results should be read at 15 minutes with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The test result of the Rotavirus FIA Rapid Test Device is calculated by the Fluorescence Immunoassay Device (BR-FIA-2000) and displayed on the screen.

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value ≥ 1.00 are considered positive for Rotavirus.
- Test results of a Value < 1.00 are considered negative for Rotavirus.

The Reference Value is not a quantitative value or the rate of antigens to Rotavirus concentration. This is only a qualitative test.

QUALITY CONTROL

Each Rotavirus FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient specimen is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an "N/A" message on the Analyser. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS OF THE TEST

- The Rotavirus FIA Rapid Test Device should be used only with the Fluorescence Immunoassay Device (BR-FIA-2000).
- The test should preferably be performed on freshly collected samples. For stored specimens, please refer to specimen storage.
- The Rotavirus FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of Rotavirus Antigen.
- The test may yield low results due to Rotavirus Antigen epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of Rotavirus Antigen with time and temperature.
- Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test samples.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated. And it should not be used as the sole criteria for clinical result.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The kit was evaluated on 100 clinical samples confirmed by ELISA method. The results show that the relative sensitivity of the Rotavirus FIA Rapid Test Device is 98% and the relative specificity is 96%.

Method		ELISA		Total Results
Results		Positive	Negative	
Rotavirus FIA Rapid Test Device	Positive	49	2	51
	Negative	1	48	49
Total Results		50	50	100
Relative Sensitivity		98% (95%CI*: 89.4%~99.9%)		
Relative Specificity		96% (95%CI*: 86.3%~99.5%)		
Relative Accuracy		97% (95%CI*: 91.5%~99.4%)		

*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens of negative, low positive and high positive controls. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens of negative, low positive and high positive controls. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Cross reactivity with following organisms has been studied at 10 x 109

organisms/mL. The following organisms were found negative when tested with the Rotavirus FIA Rapid Test Device.

<i>Staphylococcus aureus</i>	<i>Neisseria gonorrhoea</i>	<i>Acinetobacter spp</i>
<i>Pseudomonas aeruginosa</i>	<i>Group B Streptococcus</i>	<i>Salmonella choleraesuis</i>
<i>Enterococcus faecalis</i>	<i>Proteus vulgaris</i>	<i>Gardnerella vaginalis</i>
<i>Group C Streptococcus</i>	<i>Enterococcus faecium</i>	<i>Acinetobacter calcoaceticus</i>
<i>Klebsiella pneumoniae</i>	<i>Proteus mirabilis</i>	<i>E.coli</i>
<i>Branhamella catarrhalis</i>	<i>Candida albicans</i>	<i>Chlamydia trachomatis</i>
<i>Hemophilus influenzae</i>	<i>Neisseria meningitides</i>	

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- Desselberger U. Rotaviruses. *Virus Res* 2014;190:75-96.
- Kim JS, Kim HS, Hyun J, Kim HS, Song W, Lee KM, et al. Analysis of rotavirus genotypes in Korea during 2013: an increase in the G2P[4] genotype after the introduction of rotavirus vaccines. *Vaccine* 2014;32: 6396-402.
- Tate JE, Burton AH, Boschi-Pinto C, Parashar UD, World Health Organization–Coordinated Global Rotavirus Surveillance Network. Global, regional, and national estimates of rotavirus mortality in children < 5 years of age, 2000-2013. *Clin Infect Dis* 2016;62:S96-S105

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test		<i>in vitro</i> diagnostic medical device
	Consult instructions for use		Batch code
	Storage temperature		Contains sufficient for <n> tests
	Catalogue number		Do not use if package is damaged

Thank you for purchasing Biopanda's Rotavirus FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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