ROTAVIRUS CARD

Qualitative Determination
of Rotavirus in Stool

20 tests **REF 4057**

INTRODUCTION

Rotavirus is the major causes of infectious gastroenteritis in infants and children, also observed in adults. It is transmitted by fecal-oral contact. The main symptoms of viral gastroenteritis are watery diarrhoea and vomiting, sometimes with headache, fever and abdominal cramps. In general, symptoms begin 1 to 2 days following infection with Rotavirus that causes gastroenteritis and may last for 3 days.

PRINCIPLE

Rotavirus card is a sensitive and simple test for a fast and reliable detection of Rotavirus in stool.
During testing, sample is allowed to react with the red coloured conjugate monoclonal antibodies which are pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of positive result, the anti-Rotavirus antibodies present on the membrane will capture the coloured particles and a RED coloured line will be visible. This line is used to interpret the result.
The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN colored band always appear. The presence of this green band serves as: 1) verification that sufficient volume is added, 2) that proper flow is obtained, 3) as an internal control for the reagents.

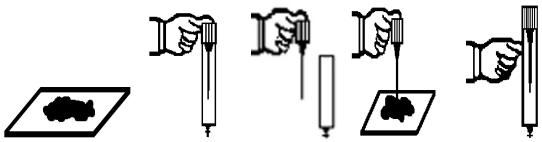
REAGENTS

Kit components:	REF 4057
Cards	**20**
***Collection vials**	**20**
(vials contain 2 ml of extraction solution)	
Labels	**40**
Instruction leaflet	**1**

STABILITY: if stored at room temperature (4-30°C) and in their original packages, cards an reagents are stable up to expiry date printed on the package. Do not freeze.

SAMPLE

1. Collect stool samples as soon as possible after the beginning of symptoms. Samples may be stored at 2-8°C for 1-2 days or freezed at -20°C. Do not freeze again.
2. Label each collection vials with patient's name
3. Unscrew the top of the sample collection device and dip the stick in the sample. Return the sample collection stick inside the collection device and screw it firmly. Shake well to facilitate sample dissolution. Repeat this operation twice, in order to collect an enough quantity of stool. If stool is liquid, put into the tube 100 µl of liquid. Shake well to facilitate sample dissolution.

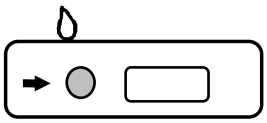


TEST PROCEDURE

1. Bring all reagents and specimens at room temperature (15-30°C).
2. Remove the card from its sealed bag just before using
3. Hold the cap with forefinger and thumb and break it, so it becomes a practical dropper. **WARNING**: to avoid accidental liquid overflow while breaking it, hold it upright with the fracture point above. During the operation wear proper personal protection means.

Squeeze the vial, pipette a few drops and discard them.

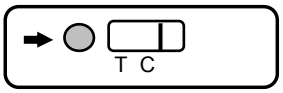
4. Place the vial above well on the card (➡) and pipette 6 buffer drops (150 µl) **slowly**



5. Read the result after 10 minutes.

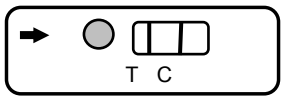
INTERPRETATION OF RESULTS

NEGATIVE RESULT



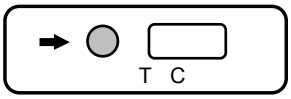
Only 1 **GREEN** band appears across the central window in the site marked with the letter C (control line).

POSITIVE RESULT



In addition to the GREEN control band, a distinguishable **RED** band also appears in the site marked with the letter T (test line).

INCONCLUSIVE RESULT



A total absence of the control colored band (GREEN) regardless the appearance or not of the test red line.

Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the tests with a new test. If the problem persists, contact your local distributor.

PERFORMANCE

The evaluation was conducted comparing results obtained using FAR Rotavirus Card to another commercial available Rotavirus card.
Sensitivity: 100% of concordance in sensibility.
Specificity: 98% of concordance in specificity.

LIMITATIONS AND NOTES

1. (*) Dangerous reagents are marked by an asterisk. Refer to MSDS.
2. The intensity of red band in the result line region (T) will vary depending on concentration of antigens present in the specimen. However, neither quantitative value nor rate of increase in antigens can be determined by this qualitative test.
3. The test must be carried out within 2 hours of opening the sealed bag.
4. This test provides a presumptive diagnosis for Rotavirus infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. All reagents and materials which come in touch with potentially infective samples must be treated with suitable disinfectants or with autoclave at 121°C for at least 1 hour.
6. After one week of infection, the number of viruses in faeces is decreasing, making sample less reactive. Stool samples should be collected within one week on the onset of symptoms.
7. Disposal of all waste material should be in accordance with law.

REFERENCE

1. Beards et al. J. Clin. Micr. Feb 1984, p. 248-254

IVD CE

Issue 03 - Mar 2015 RR/MS

Manufactured by: **FAR** srl
Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY
Phone +39 045 6700870 – Fax +39 045 7157763
website: http://www.fardiag.com e-mail: fardiag@fardiag.com