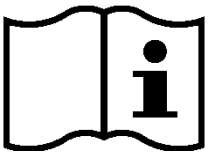

Useŕs Manual

Rota Virus Antigen One-Step

For the detection of Rota Virus antigen in faeces samples

REF AS1003-AG01

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Please use only the valid version of the package insert provided with the kit.

1. Table of Contents

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2. Introduction

Rota viruses have been diagnosed as causing diarrhoea in nearly every mammalian species. Rota viruses are important causes of severe gastroenteritis in many new-born animals, especially in intensively reared farm animals. Rota viral gastroenteritis may result in mortality for populations at risk such as infants, the elderly and immunocompromised patients. In temperate climates, Rota virus infections occur mainly in the winter months.
It is one of the factors in “Neonatal disease complex”, 27% of death cases were caused by Rota virus (Animal Pharm, April 1997). Infected animals exceed enormous numbers of Rota viral particles, and usually are detectable up to 1 week after infection or for more than 30 days in immunocompromised patients, thus contaminating the environment. The risk of getting a herd outbreak of neonatal diarrhoea is particularly high during the parturition season because of rapid spread of the virus.
Rota virus is transmitted by the faecal-oral route; clinical as well as subclinical infections are common. Symptoms are diarrhoea, vomiting, dehydration and apathy.
Since Rota virus is resistant to many disinfectants and is not inactivated by either extreme temperature nor pH, the source of infections may persist on a farm for many months. A built-up of contamination can also depend on shedding of Rota virus by subclinical infected adult animals. Rota virus can also cross species barriers. Human Rota virus can infect animals and visa-versa, with canine- and feline-like viruses found in humans. Given these circumstances there is a high need for a rapid and simple test to diagnose Rota virus infection.

3. Intended use of the test kit

This One-Step test is intended to use as practical/routine screening test that can be done in a few minutes. This test kit is designed to detect Rota virus antigen by use of a rapid immunochromatic assay.

4. Principle of the test kit

The Rota antigen One-Step test is based on a chromatographic principle in which a monoclonal antibody reacts with epitopes of the Rota virus. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in the test zone “T”. Rota virus in the faeces sample that is applied to the test strip at the sample zone “S”, will bind to the colloidal gold particles which then migrate to zone “T”. A colour change in zone “T” indicates a positive test. Labelled colloidal gold particles are also immobilized on the test strip in the control zone “C”, to indicate that the test is working properly.

5. Contents

- 6 x Pouches, each containing 1 test strip, 1 pipette and 1 cotton swab
- 6 x Buffer vials
- 1 x Protocol

6. Handling and storage of specimens

The One-Step should be stored at room temperature (±21°C). An unopened package can be used until the expiry date. An unopened package must be used immediately. If the conditions are no longer fulfilled the test can no longer be used. Avoid freezing and heating as this will contribute to destruction of the test. Samples may be used fresh or may be kept frozen below -20°C before use.

7. Sample material

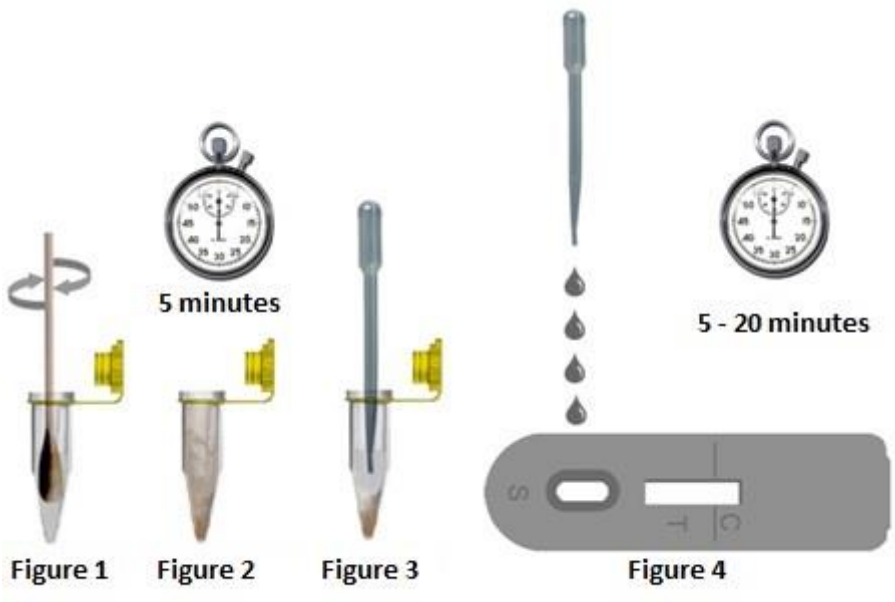
It is advised to test fresh samples. It is advised to test samples as concentrated as possible.

8. Precautions

- Handle all biological materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth
- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different serials lots together.
- Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and sampling throughout this procedure are necessary to maintain precision and accuracy.
- Each test strip is ultimately used as an optical reference. Therefore, do not touch the surface of the test strip and protect it from damage and dirt.

9. Test protocol

1. Unpack the test strip, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Take an individual sample using the included swab.
3. The swab should be washed in the buffer vial containing the buffer (Figure 1).
4. Squeeze the swab to the wall of the buffer vial to leave much liquid as possible.
5. Let particles sink to the bottom for 5 minutes (Figure 2). After 5 minutes 2 layers should be visible. If necessary centrifuge the sample.
6. Add **4 drops** of the supernatant (upper liquid) of the buffer vial containing the sample, with the included pipette ***slowly*** to the sample zone "S" (Figure 4).
7. Read the result after 5 – 20 minutes (for the interpretation of the test result see chapter 10 and chapter 11).



10. Validation of the test

To validate an EVL One-Step a control line should always be visible at control zone "C". If no control line is visible the test should be considered invalid.
Results should be read in the given time. Results read after the given time should be considered invalid. Invalid tests should be repeated with a new test.

11. Interpretation of the test results

Positive:
Two lines are visible, in zone "T" and zone "C" (Figure A). The sample contains Rota virus antigen. Positive results may vary in optical density due to variations in viral concentrations in the sample.

Weak positive:
Two lines are visible, a weak line in zone "T" and a line in zone "C" (Figure B). The sample contains low concentrations Rota virus antigen.

Negative:
Only one line is visible in zone "C" (Figure C). The sample does not contain Rota virus antigen.

Not valid:
No line is visible in zone "C" (Figure D). Repeat the test procedure.

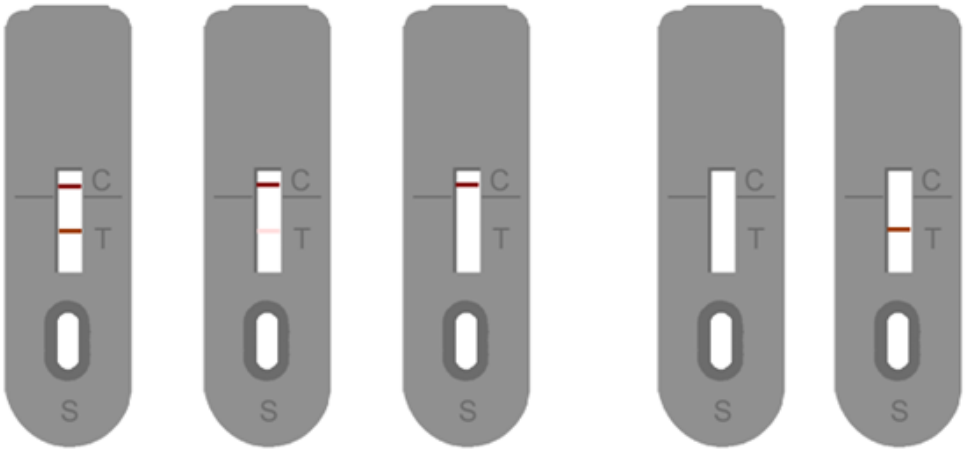


Figure A: Positive | Figure B: Weak positive | Figure C: Negative | Figure D: Not Valid

Important:
A positive result should be confirmed by PCR or virus isolation. Diseased bur negative tested patients should be retested within 2-3 weeks.

In rare circumstances extreme high concentrations of E. coli bacteria might give strange precipitation in the zone "T".

12. Symbols used with EVL ASSAYS

Symbol	English
	Consult instructions for use
	European Conformity
IVD	In vitro diagnostic device
RUO	For research use only
REF	Catalogue number
LOT	Lot/ No. / Batch code
	Contains sufficient for <n> tests
	Storage Temperature
	Expiration Date
	Legal Manufacturer
Distributed by	Distributor
Content	Content
Volume/No.	Volume / No.

The entire risk as to the performance of these products is assumed by the purchaser. EVL shall not be liable for indirect, special or consequential damages of any kind resulting from use of the products. In case of problems or questions contact EVL.