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**REF 31 111**

# VIKIA® Rota-Adeno

IVD

*Rapid test for the qualitative dual detection of rotavirus and adenovirus in human stools.*

## SUMMARY AND EXPLANATION

The "Rota-Adeno" test device is a rapid test, based on the immunochromatography technique (ICT), for the dual detection of rotaviruses and adenoviruses in a single stool extract.

Rotaviruses and adenoviruses are respectively the first and second most common agents responsible for acute gastroenteritis, mainly in young children (1). Viral diarrhea, which is often seasonal, evolves into an epidemic. During the acute stage of the illness, large quantities of virus are excreted and are responsible for spreading the epidemic.
Rotavirus and adenovirus cell culture is difficult, which is why immunological techniques are used. Rapid diagnosis of the infectious agent enables inadequate antibiotic treatment to be avoided and the infected patient to be rapidly isolated.

## PRINCIPLE

VIKIA Rota-Adeno is a qualitative test based on the association of monoclonal antibodies specific to rotavirus and adenovrius respectively. This test uses immunological reactions performed on a test strip by migration (ICT or lateral flow format).

The test consists of a plastic device (see the illustration on page 2) containing:

1. A chromatographic membrane to which are fixed:
   - in the test region, an anti-rotavirus monoclonal antibody (test region "R") and an anti-adenovirus monoclonal antibody (test region "A"),
   - in the control region, an anti-mouse IgG polyclonal antibody (control region "C").
2. A test strip impregnated with a conjugate consisting of a mixture of monoclonal anti-rotavirus antibody coupled to blue dyed polystyrene microspheres and monoclonal anti-adenovirus antibody coupled to red dyed polystyrene microspheres.

The sample is added to the sample well and migrates by capillarity along the membrane.
If the sample contains rotaviruses, they form an antigen-antibody complex with the antibodies specific to this virus present on the blue dyed polystyrene microspheres.
If the sample contains adenoviruses, they form an antigen-antibody complex with the antibodies specific to this virus present on the red dyed polystyrene microspheres.
The antigen-antibody complexes migrate along the membrane and bind to the anti-rotavirus and/or anti-adenovirus antibodies, forming complexes revealed by a blue and/or red line in the "R" or "A" test line regions of the membrane
Absence of this/these colored line(s) suggests a negative result.
To serve as a procedural control, a colored line will always appear in the control line region "C" if the test has been performed correctly.

## CONTENT OF THE KIT (20 TESTS) :

| | | |
|---|---|---|
| 20 sealed pouches | R1 | Each pouch contains:<br>- A ready-to-use test device (sheep anti-mouse IgG polyclonal antibody + anti-rotavirus and anti-adenovirus mouse monoclonal antibodies + polystyrene microspheres sensitized with anti-rotavirus and anti-adenovirus mouse monoclonal antibodies + 0.9 g/l sodium azide).<br>- A disposable specimen dropper. |
| 20 vials of fecal specimen dilution buffer | R2 | Ready-to-use.<br>Phosphate buffer (pH 7.2) + 0.9 g/l sodium azide. |
| 1 Package insert | | |

## MATERIAL REQUIRED BUT NOT PROVIDED

- A recipient for specimen collection.
- Timer.
- Centrifuge and pipette to dispense 80 µl if required.

## WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **For professional use only.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Do not use reagents past the expiration date indicated on the packaging.
- The test device should be stored in the sealed pouch containing the desiccant until use.
- The test device is a disposable; it should not be reused.
- All specimens should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "NCCLS M29-A, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline* - December 1997". For additional information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 93-8395, 3rd Edition (May 1993)", or the current regulations in the country of use.

- Do not interchange or mix reagents from different lots.
- Kit reagents contain sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.

## STORAGE CONDITIONS AND STABILITY

- Store the kit at 4-30°C.
- **DO NOT FREEZE.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the packaging. Do not use beyond the expiration date.
- The test device should remain in the pouch until use.

## SPECIMEN COLLECTION AND PREPARATION

### Specimen collection

- Viral detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of rotavirus and adenovirus in the stools of patients with gastroenteritis occurs 3-5 days (2) and 3-13 days (3) respectively after the symptoms have appeared. If the samples are collected long after the onset of diarrheic symptoms, the quantity of antigen may not be sufficient to obtain a positive reaction or the antigens detected may not be linked to the diarrheic episode.
- The stool samples must be collected in clean, dry, waterproof recipients containing no detergents, preservatives or transport media.
- Collect a sufficient quantity of stools (1-2 ml or 1-2 g) to obtain a representative sample.
- Transfer the samples to the laboratory within 6 hours following collection.
  The samples should then be stored at 2-8°C.
  The test must be performed within 72 hours following collection. If specimens cannot be tested within 72 hours, they should be frozen at -25 ± 6°C.

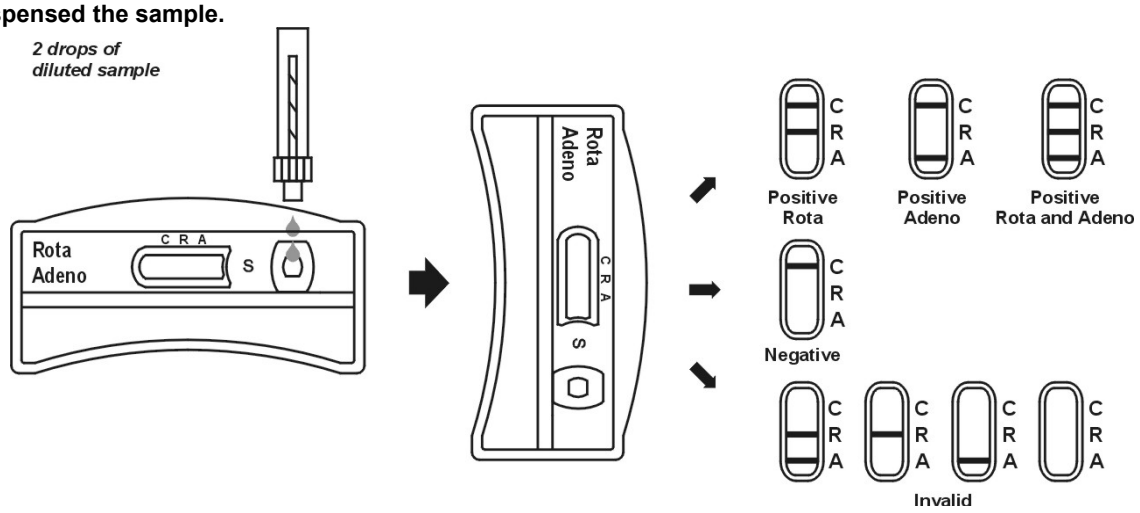
  **Bring the necessary reagents to room temperature before use.**

### Specimen preparation

1. Allow the stool sample to come to room temperature (15-30°C) before performing the test.
2. Unscrew the cap on the R2 vial and remove the applicator stick required to collect the specimen.
3. Collect approximately 50 mg of stools (equivalent to 1/4 of a pea) using the applicator stick in the R2 vial. Insert the sample into the R2 vial containing the dilution buffer.
   If stools are liquid, collect the specimen using the specimen dropper and dispense 2 drops (approximately 50 µl) into the R2 vial containing the dilution buffer.
4. Screw the cap back onto the R2 vial.
5. Shake vigorously to homogenize.

## INSTRUCTIONS FOR USE

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean, level surface.
3. Break off the tip of the R2 vial containing the diluted sample.
4. Turn the R2 vial upside down and hold it vertically. Transfer 2 drops of diluted sample (approximately 80 µl) to the sample well (S) of the test device and then start the timer. Avoid trapping air bubbles in the sample well (S). See illustration below.
5. Wait for the control line "C" to appear and possibly lines "R and/or "A". **Read the results 10 minutes after having dispensed the sample.**




**Note: low viral loads may be detected between 10 and 15 minutes. Do not take into account the appearance of new lines after 15 minutes.**

If the sample does not migrate (presence of particles …), centrifuge the diluted sample contained in the R2 vial. Collect 80µl of the supernatant, dispense into the sample well S. Start the timer and continue from step 5 onwards in the above instructions for use.

## INTERPRETATION OF RESULTS

(Refer to the illustration on page 2)

**POSITIVE: Two or three distinct lines appear**: one in the control region (C), one or two in the test region, blue in R and/or red in A.

If a blue line appears in the test region R: the sample is positive for rotavirus.

If a red line appears in the test region A: the sample is positive for adenovirus.

If both lines appear, blue in test region R and red in test region A: the sample is positive for rotavirus and adenovirus.

**NEGATIVE: One colored line appears in the control region (C).** No line appears in the A or R test region.

**INVALID: The control line fails to appear**; insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device.

If the problem persists, discontinue using the kit and contact your local distributor.

**NOTE :** The intensity of the blue and/or red color in the "R" and/or "A" test line region(s) may vary depending on the concentration of rotavirus and/or adenovirus present in the sample. However, the concentration of virus in the specimen cannot be determined by this qualitative test.

Interpretation of test results should be made taking into consideration the patient's history, and the results of any other tests performed.

## QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) confirms sufficient specimen volume and correct procedural technique. If the control line does not appear, the test is invalid.

### Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

## LIMITATIONS OF THE METHOD

- **DO NOT INTERPRET THE RESULT AFTER 15 MINUTES.**
- False negative results may occur if the number of viral particles is too low.
- False positive and or uninterpretable results may be observed if the quantity of stools is too large.
- A positive result does not rule out the presence of another pathogenic microorganism in the stools.
- The results must be interpreted taking into account clinical data.
- VIKIA Rota-Adeno has not been tested on meconium. Therefore, it is not recommended to use this type of specimen.

## PERFORMANCE

A multi-center evaluation was conducted using 435 stool samples collected from children and young adults with symptoms of diarrhea and/or gastroenteritis. VIKIA Rota-Adeno was evaluated in comparison with another immunochromatography technique (ICT) available on the market.
The results that were discrepant between the two immunochromatography tests were resolved using an EIA and/or a PCR technique.
The results given below for the VIKIA test were obtained with a reading after 10 minutes.

### Sensitivity

Rotavirus detection: 103 positive stools (100 frozen collection stools and 3 stool samples collected in routine)

| n = 103 | | VIKIA Rota-Adeno | |
|---|---|---|---|
| | | Positive | Negative |
| Other test ICT | Positive | 99 | 0 |
| | Negative | 4 | 0 |

- Relative sensitivity of the VIKIA test compared to the other ICT test:

100% [96.3 - 100]% out of 103 positive stools

- Agreement: 96.1%

Four specimens that were not detected with the comparative technique, were confirmed to be positive using an EIA and/or a PCR technique.

Adenovirus detection: 42 positive stools (36 frozen collection stools and 6 stool samples collected in routine).

| n = 42 | | VIKIA Rota-Adeno | |
|---|---|---|---|
| | | Positive | Negative |
| Other ICT test | Positive | 41 | 1* |
| | Negative | 0 | 0 |

* this sample became positive after 10-15 minutes.

- Relative sensitivity of the VIKIA test compared to the other ICT test:

97.6% (87.4 - 99.6)% out of 42 positive stools

- Agreement: 97.6%

**Specificity**: 290 negative stool samples collected in routine

| | | **VIKIA Rota-Adeno** | | | |
|---|---|---|---|---|---|
| n = 290 | | Rotavirus detection | | Adenovirus detection | |
| | | Positive | Negative | Positive | Negative |
| Other ICT test | Positive | 0 | 8 | 0 | 5 |
| | Negative | 0 | 282 | 0 | 285 |

- Relative specificity: rotavirus and adenovirus: 100% [98.6 - 100]% out of 290 negative stools
- Agreement:
  - Rotavirus detection: 97.2%
  - Adenovirus detection: 98.3%

The specimens which were found positive with the comparative technique, were confirmed to be negative using a EIA and/or PCR technique.

**CROSS REACTIVITY**

No cross-reactivity was observed with the following bacteria and viruses which may be present in stools:

*Staphylococcus aureus methicillin S 2067* (n=1)

*Staphylococcus aureus methicillin R 325* (n=1)

*Staphylococcus methicillin S 9486* (n=1)

*Enterobacter agglomerans A131* (n=1)

*Campylobacter jejuni 49* (n=1)

*Campylobacter fetus 33293* (n=1)

*Candida albicans 2173* (n=1)

*Klebsiella pneumoniae 331* (n=1)

*Vibrio cholerae 1825* (n=1)

*Vibrio parahaemolyticus 1728* (n=1)

*Escherichia coli 1190* (n=1)

*Escherichia coli PM 2123* (n=1)

*Shigella sonnei 938* (n=1)

*Alcaligenes faecalis 420* (n=1)

*Yersina enterocolitica 1907* (n=1)

*Pseudomonas aeruginosa 1156* (n=1)

*Salmonella enteridis 1M195* (n=1)

*Streptococcus gr. D 50* (n=1)

*Streptococcus gr. D 1050* (n=1)

*Enterovirus* (n=4)

*Hepatitis A virus* (n=2)

*Virus Aichi* (n=1)

*Astrovirus* (n=5)

*Coronavirus* (n=4)

## WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

## LITERATURE REFERENCES


1. WILHELMI I, ROMAN E, SANCHEZ-FAUQUIER A – Viruses causing gastroenteritis - Clin Microbiol Infect. – April. 2003, vol.9, p.247-262.
2. FLEWETT T.H. and Woode G.N.(1978) – The Rotaviruses Archives of Virology, 57 : 1-23.
3. WADELL G. (1990) – Adenoviruses. In Principles and Practice of Clinical Virology. (eds A.J. Zuckerman et al) John Wiley and Sons Ltd, p267-287.


## INDEX OF SYMBOLS

| Symbol | Meaning |
|---|---|
| REF | Catalogue number |
| | In vitro diagnostic medical device |
|  | Manufactured by |
|  | Temperature limitation |
|  | Use by |
| LOT | Batch code |
|  | Consult instructions for use |
|  | Contains sufficient for <n> tests |
|  | Do not re-use |

## WARRANTY

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