VITASSAY

# Rotavirus

Rapid test for the qualitative detection of rotavirus in human stool samples.

IUE-7355008 Ed00 May 2016

CE IVD EN

Vitassay

**For professional *in vitro* diagnostic use only.**

## INTENDED USE

**Vitassay Rotavirus** is a rapid one step immunochromatographic assay for the qualitative detection of rotavirus in human stool samples.

Simple, non-invasive and a highly sensitive screening assay to make a presumptive diagnosis of rotavirus infection.

## INTRODUCTION

Over the last years some viruses have been detected as the cause of diarrhea. Among the viral agents associated with these illnesses, rotavirus is the most important so that their detection is epidemiologically important.

Rotavirus infections of adults are usually subclinical but occasionally cause illness in parents of children with rotavirus diarrhea, immunocompromised patients (including those with HIV), the elderly, and travelers to developing countries. In temperate climates, rotavirus diarrhea occurs predominantly during the fall and winter; in tropical setting and in developing countries, seasonality is less marked.

## PRINCIPLE

**Vitassay Rotavirus** is a qualitative immunochromatographic assay for the detection of rotavirus in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against rotavirus.

During the process, the sample reacts with the antibodies against rotavirus, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

## PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Rotavirus**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF).

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

## MATERIALS

| MATERIAL PROVIDED | MATERIAL REQUIRED BUT NOT PROVIDED |
|---|---|
| ▪ **25** tests/kit **Vitassay Rotavirus**<br>▪ Instructions for use.<br>▪ **25** vials with diluent for the sample dilution. | ▪ Specimen collection container.<br>▪ Disposable gloves.<br>▪ Timer. |

## SPECIMEN COLLECTION

Collet sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

Samples can be stored in the refrigerator (2-8ºC/35.6-46.4ºF) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC (-4ºF). Samples must be brought to room temperature before testing.

## SPECIMEN PREPARATION

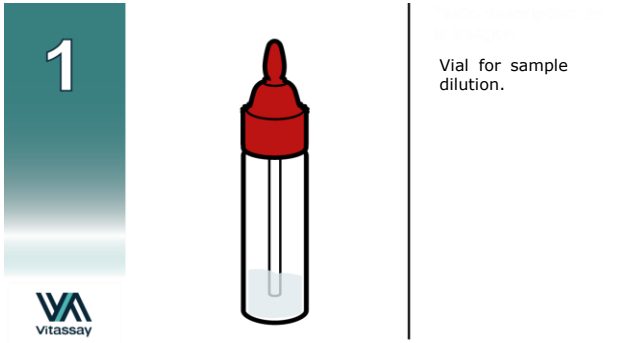
1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2), and add it into the vial with diluent for the sample dilution. For liquid stool, take 125µL of the



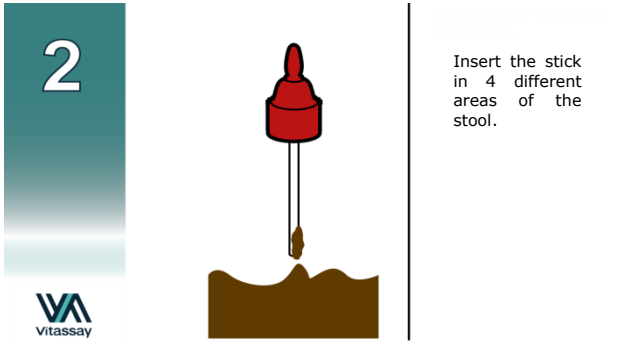
Vitassay
Parque Tecnológico WALQA
Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
www.vitassay.com

sample using a micropipette and transfer it into vial with diluent for the sample dilution.

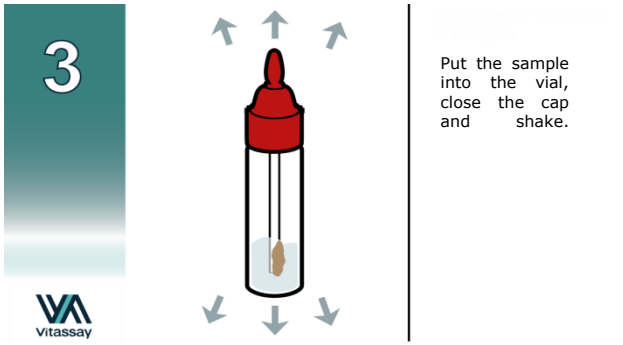
3. Close the vial with the diluent and stool sample. Shake vigorously the vial in order to assure good sample dispersion (figure 3).




Vial for sample dilution.




Insert the stick in 4 different areas of the stool.



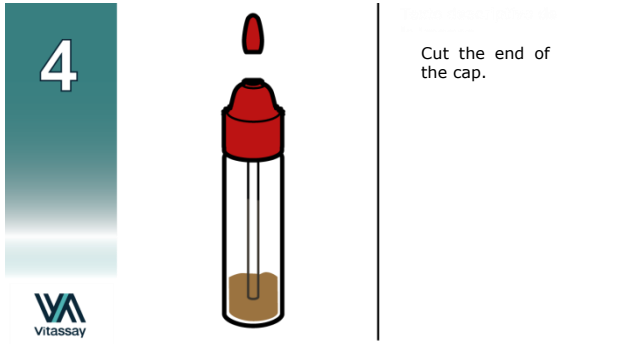

Put the sample into the vial, close the cap and shake.

## PROCEDURE

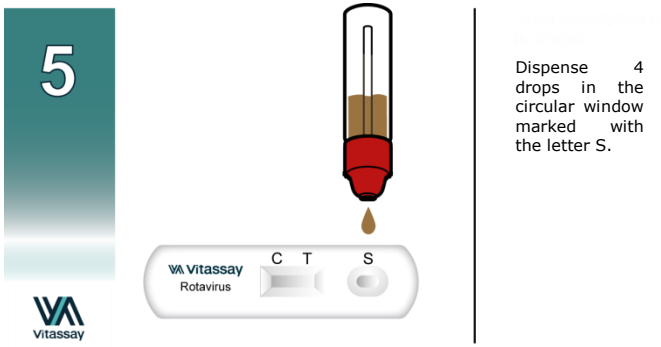
Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC / 59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample to obtain a good sample dilution.
2. Remove the **Vitassay Rotavirus** from its sealed bag just before using it.
3. Take the vial containing the diluted sample, cut the end of the cap (figure 4) and dispense 4 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.




Cut the end of the cap.




Dispense 4 drops in the circular window marked with the letter S.

## INTERPRETATION OF THE RESULTS

| | | |
|---|---|---|
| C T | **NEGATIVE**<br>Only one green line in the control zone **(C)**. | There is no Rotavirus presence. No infection caused by Rotavirus. |
| C T | **POSITIVE**<br>In addition to the **green** line (**control line C**), a red line appears (**test line T**). | There is Rotavirus presence. Viral infection caused by Rotavirus. |
| **ANY OTHER RESULTS** | | Invalid result, we recommend repeating the assay using the sample with another test. Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation still persist, discontinue using the test kit and contact your local distributor. |

**Notes:** The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

## QUALITY CONTROL

Internal procedural control is included in **Vitassay Rotavirus**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

## LIMITATIONS

- **Vitassay Rotavirus** must be carried out within 2 hours of opening the sealed bag.
- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
- The intensity of test line may vary depending on the concentration of antigens.
- The use of other samples different from human samples has not been established.
- The quality of **Vitassay Rotavirus** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of rotavirus in fecal samples. A positive result should be followed up with additional laboratory techniques (biochemical methods or microscopy) to confirm the results. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been



Vitassay
Parque Tecnológico WALQA
Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
www.vitassay.com

evaluated and must be based in the correlation of the results with further clinical observations.

- Negative results should not be considered as conclusive; it is possible that the concentration of antigens is lower than the detection limit value. If symptoms or situation still persist, a rotavirus determination should be carried out with another technique (for example microscopy).

## EXPECTED VALUES

Diarrheic illnesses are one of the most common causes of morbidity and mortality between infants in developing countries, causing three millions of deaths each year. Group A of human rotavirus is the most frequent cause of acute diarrhea.

Mortality due to rotavirus infection in developing countries is greater than in developed countries; the frequency of the infection in developing and developed countries is similar.

## PERFORMANCE CHARACTERISTICS

### Clinical sensitivity and specificity

An evaluation was performed comparing **Vitassay Rotavirus** and another commercial test (Ridascreen®*Rotavirus* ELISA Test, r-Biopharm) with fecal samples.

Results were as follows:

| | | **Ridascreen®*Rotavirus* ELISA Test** | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **Vitassay Rotavirus** | **Positive** | 18 | 1 | 19 |
| | **Negative** | 0 | 43 | 43 |
| | **Total** | 18 | 44 | 62 |

| **Vitassay Rotavirus vs Ridascreen®*Rotavirus* ELISA Test** | | | |
|---|---|---|---|
| **Sensitivity** | **Specificity** | **PPV** | **NPV** |
| >99% | 98% | >94% | >99% |

The results showed that **Vitassay Rotavirus** has a high sensitivity and specificity to detect Rotavirus.

### Cross reactivity

No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in feces:

| | | |
|---|---|---|
| *Adenovirus* | *Escherichia coli O157:H7* | *Salmonella typhi* |
| *Astrovirus* | *Giardia lambia* | *Shigella boydii* |
| *Campylobacter coli* | *Helicobacter pylori* | *Shigella dysenteriae* |
| *Campylobacter jejuni* | *Listeria monocytogenes* | *Shigella flexneri* |
| *Clostridium difficile* | *Norovirus* | *Shigella sonrei* |
| *Cryptosporidium parvum* | *Salmonella enteritidis* | *Staphylococcus aureus* |
| *Entamoeba hystolitica* | *Salmonella paratyphi* | *Yersinia enterocolitica* |
| *Enterovirus* | *Salmonella typhimurium* | |

## REFERENCES


1. GONZÁLEZ FERNÁNDEZ MARÍA DE LOS ANGELES; HIDALGO RODRÍGUEZ ROXANA; SILVA BLAY SILVA. "Rotavirus. Enfermedad emergente de transmisión digestiva". Rev Cubana Pediatra 2003; 75(1).

2. UMESH D. PARASHAR; JOSEPH S. BRESEE; JON R. GENTSCH; ROGER I. GLASS. "Rotavirus". Emergency Infectious Diseases 1998, Vol. 4, No. 4, pp. 561-570.

3. FELIPE MOTA-HERNÁNDEZ; CLAUDIA GUTIÉRREZ-CAMACHO; SOFÍA VILLA-CONTRERAS; JUAN CALVA-MERCADO; CARLOS F. ARIAS; LUIS PADILLA-NORIEGA; HÉCTOR GUISCAFRÉ-GALLARDO. "Pronóstico de la diarrea por rotavirus". Salud Pública de México 2001, Vol. 43, No. 6, pp. 524-528.


## SYMBOLS FOR IVD COMPONENTS AND REAGENTS

| | | | |
|---|---|---|---|
| IVD | *in vitro* diagnostic device | | Keep dry |
| | Consult instructions for use | | Temperature limitation |
| | Use by | | Manufacturer |
| LOT | Batch code | Σ n | Contains sufficient for <n> test |
| DIL | Sample diluent | REF | Catalogue number |

Vitassay




Vitassay

**Parque Tecnológico WALQA**
Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
www.vitassay.com