For professional in vitro diagnostic use only.

**INTENDED USE**

Vitassay Rotavirus+Adenovirus is a rapid, immunochromatographic, one step assay for the simultaneous qualitative detection of rotavirus and adenovirus in human stool samples.

Simple, non-invasive and highly sensitive immunoassay to make a presumptive diagnosis of rotavirus and/or adenovirus infection.

**INTRODUCTION**

Viral pathogens are the most common cause of gastroenteritis in developed countries. Human rotavirus and adenovirus infections are major causes of acute outbreaks and sporadic cases of gastroenteritis, occurring primarily among children less than 2 years of age. Patient hospitalization is often required, with enormous infection control implications.

**PRINCIPLE**

Vitassay Rotavirus+Adenovirus is a qualitative immunochromatographic assay for the detection of rotavirus and adenovirus in human stool samples.

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

**Strip B:** The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against adenovirus.

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

The presence of these **green** lines (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 contamination errors. Device for single use.
- 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+Adenovirus. 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 (2-30°C/35.6-86°F).

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**

- 25 tests/kit
- Vitassay Rotavirus+Adenovirus
- Instructions for use.
- 25 vials with diluent for the sample dilution.

**MATERIAL REQUIRED BUT NOT PROVIDED**

- Specimen collection container.
- Disposable gloves.
- Timer.

**SPECIMEN COLLECTION**

Collect 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 (2-8°C/35.6-46.4°F) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20°C (-4°F). 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 (approx. 125mg). 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 125 µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.

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

**PROCEDURE**

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

1. Shake the vial with the sample vigorously to obtain a good sample dilution.

2. Remove the Vitassay Rotavirus+Adenovirus 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 A – rotavirus (figure 5) and 4 drops, using the same vial, in the circular window marked with the letter B – adenovirus (figure 6).

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.

### INTERPRETATION OF THE RESULTS

<table>
<thead>
<tr>
<th>RESULTS</th>
<th>Strip A Rotavirus</th>
<th>Strip B Adenovirus</th>
<th>INTERPRETATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
<td>There is rotavirus and adenovirus presence. Infection caused by rotavirus and adenovirus.</td>
</tr>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>Negative</td>
<td>There is rotavirus presence. Infection caused by adenovirus.</td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>Negative</td>
<td>Invalid result, we recommend repeating the assay using the sample with another test. Note: Wrong procedural techniques or deterioration of the sample.</td>
</tr>
</tbody>
</table>

**ANY OTHER RESULTS**

Valid result. No infection caused by rotavirus and/or adenovirus.

Invalid result due to solid particles in the sample. Stir the sample and read the results again.

Note: Wrong procedural techniques or deterioration of the sample.
Acute gastroenteritis is a worldwide health problem. It has also been reported as an important factor for childhood morbidity and mortality worldwide. Almost 1.76 million children under age 5 die annually from gastroenteritis in both developed and developing countries.

Group A rotaviruses (HRV) are the major cause of pediatric acute gastroenteritis worldwide, followed, to a lesser extent, by enteric adenoviruses types 40 and 41 and various viral agents. Globally, an estimated 702,000 children die each year from rotavirus diarrhea, the vast majority of whom are in developing countries. Children under 5 years of age are particularly prone, and infection is predominant among those aged 6-24 months.

**EXPECTED VALUES**

Acute gastroenteritis is a worldwide health problem. It has also been reported as an important factor for childhood morbidity and mortality worldwide. Almost 1.76 million children under age 5 die annually from gastroenteritis in both developed and developing countries.

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**PERFORMANCE CHARACTERISTICS**

**Clinical sensitivity and specificity**

An evaluation was performed using Vitassay Rotavirus+Adenovirus and other commercial test (Ridascreen®Rotavirus ELISA Test, r-Biopharm).

Results were as follows:

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitassay Rotavirus + Adenovirus rotavirus</td>
<td>18</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>44</td>
<td>62</td>
</tr>
</tbody>
</table>

And evaluation was performed using Vitassay Rotavirus+Adenovirus and PCR.

Results were as follows:

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCR</td>
<td>7</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>52</td>
<td>59</td>
</tr>
</tbody>
</table>

The results showed that Vitassay Rotavirus+Adenovirus has a high sensitivity and specificity to detect rotavirus and adenovirus.

**REFERENCES**


**SYMBOLS FOR IVD COMPONENTS AND REAGENTS**

- **IVD**: in vitro diagnostic device
- **LOT**: batch code
- **DIL**: sample diluent
- **REF**: catalogue number
- **Temp**: temperature limitation
- **Man**: Manufacturer
- **Use by**: use by date
- **Keep dry**: keep dry