2. The feces specimen must be collected in a clean, dry, waterproof container containing no detection of rotavirus in human feces specimens.

The Rotavirus Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of rotavirus in human feces specimens to aid in the diagnosis of rotavirus infection.

**Summary**

Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children. It is known that rotavirus activity is most prevalent in the winter months. Endemics as well as epidemics affecting thousands of people have been reported in temperate climates, rotavirus infections occurring mainly in the winter months. Rotavirus is transmitted by the oro-faecal route with an incubation period of 1-3 days.

In temperate climates, rotavirus infections occur mainly in the winter months. Endemics as well as epidemics affecting thousands of people have been reported. While rotavirus infections are most prevalent in the winter months, rotavirus infections are transmitted by the oro-faecal route with an incubation period of 1-3 days. Rotavirus is a highly contagious virus and can spread rapidly through close contact. It is important to monitor and track rotavirus infections to prevent outbreaks.

**Materials**

Materials Provided:
- Test cassette
- Sample collection tube with extraction buffer
- Buffer
- Droppers
- Centrifuge and pipette to dispense 80 μl or more

**Directions for Use**

1. Allow the test, specimen, buffer, and control to reach room temperature (15-30°C) prior to testing.
2. To collect fecal specimens:
   - Collect sufficient quantity of feces (1-2 mL) in a clean, dry specimen collection container to obtain enough virus particles. Best results will be obtained if the samples are collected within 6 hours after collection.
   - Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long-term storage, specimens should be kept below -20°C.
3. To process fecal specimens:
   - Use the tip (total 50 μl of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - Hold the dropper vertically, aspirate fecal samples, and then transfer 2 drops of the liquid specimen (approximately 50 μl) into the specimen collection tube containing the extraction buffer.
4. To perform the test:
   - Hold the container upright and unscrew the tip of the specimen collection tube. Insert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 μl) to the well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. To read results at 10 minutes after dispensing the specimen. Do not read results after 10 minutes.

**INTERPRETATION OF RESULTS**

**Positive:** Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

**Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T).

**Interfering Substances:** The test contains anti-rotavirus antibody coated particles and anti-rotavirus antibody coated on the membrane.

**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Test cassette should not be used if the package is damaged.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if tip of the cassette is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being handled.
- The used test should be discarded according to local regulations.
- Humidity and temperature may adversely affect results.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. Before opening the test, the test cassette should remain in the sealed pouch containing desiccant until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

1. Viable detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of rotavirus in the feces of patients with gastroenteritis occurs 3-5 days after onset of symptoms. If the specimens are collected long after the onset of diarrhea symptoms, the quantity of antigen may not be sufficient to obtain a positive reaction or the antigen detected may not be linked to the diarrhea episode.
2. The feces specimen must be collected in a clean, dry, waterproof container containing no detergents, preservatives or fixatives.
3. Bring the necessary reagents to room temperature before use.

**BIBLIOGRAPHY**


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**Index of Symbols**

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