The One Step Rotavirus Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of rotavirus in human feces specimens, providing results in 10 minutes. The test utilizes antibody specific for rotavirus to selectively detect rotavirus from human feces specimens.

**PRINCIPLE**

The One Step Rotavirus Test Device (Feces) is a qualitative, lateral flow immunoassay for the detection of rotavirus in human feces specimen. In this test, the membrane is pre-coated with anti-rotavirus antibody on the test line region of the specimen reacts with the specimen coated with anti-rotavirus antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-rotavirus antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To see a positive control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS**

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.
- The test device should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch 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 tested.
- The test is used to detect rotavirus by local regulations.
- Humidity and temperature can 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. This test must remain in the sealed pouch containing desiccant until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- Viral 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 diarrheal 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 specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.

**INTERPRETATION OF RESULTS**

(Positive to the illustration above)

**Relative Sensitivity**: >99.9% (97.3% - 100.0%).

**Relative Specificity**: 97.9% (83.6% - 99.5%).

**Precision**

Intra-Assay: Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

Inter-Assay: Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

**Cross-Reactivity**

Cross reactivity with following organisms has been studied at 1.0 x 10^13 organism/ml. The following organisms have been found negative when tested with the One Step Rotavirus Test Device (Feces).

**BIBLIOGRAPHY**