**Norovirus Rapid Test Cassette (Feces) Package Insert**

**A rapid, one step test for the qualitative detection of Norovirus in human feces.**

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

**[EXTENDED USE]**

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

**[SUMMARY]**

Norovirus (NoV) are a genetically diverse group of single stranded RNA, nonenveloped viruses belonging to the Caliciviridae family. For decades they were called “small round structured viruses” (SRSV) or “Norwalk-like viruses” until recently when their taxonomy was investigated using modern molecular techniques. Initially, about 30 different serotypes of SRSV were recognized, but more recently three genogroups have been identified with the genus Norovirus, Genogroup 1 and Genogroup 2 (with limited associated serotypes) and a third Genogroup 3 (NoV-GIII) associated with bovine and porcine infection. Norovirus are a major cause of gastroenteritis worldwide, often causing explosive outbreaks in institutions. They are highly contagious, with an incubation period of as few as ten particles being able to cause infection through ingesting contaminated food and water and by person-to-person spread. Transmission is predominantly faecal-oral but may be airborne due to aerosolisation of vomitus, which typically contains abundant infectious virus particles. Outbreaks associated with norovirus occur within 12 hours of exposure. The ability of Noroviruses to cause outbreaks in institutions has became a major public health issue. Outbreaks of norovirus infection can be associated with restaurants and institutions as diverse as private homes, hospitals and elite sports teams. Infections in infants, elderly or frail patients can be fatal if untreated.

The symptoms of Norovirus illness usually start with nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people additionally have a low fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the infected person may feel very sick. In most people the illness is self-limiting with symptoms usually lasting for about 1 or 2 days. In general, children experience more vomiting than adults.

**[PRINCIPLE]**

The Norovirus Rapid Test Cassette (Feces) is a qualitative, lateral flow immunofluor assay for the detection of Norovirus in human feces specimens.

The assay uses Genogroup 1 and Genogroup 2 specific monoclonal antibodies coated on the membrane. During testing, the feces specimen migrates upward on the membrane chromatographically by capillary action to react with the conjugate antibodies. The illness is acute, lasting for about 1 or 2 days. In general, children experience more vomiting than adults.

**[SPECIMEN COLLECTION AND PREPARATION]**

**[PRINCIPLE]**

The test contains Genogroup 1 and Genogroup 2 monoclonal antibodies coated on the membrane.

**[CAUTIONS]**

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test cassette should remain in the sealed pouch until use.
- Do not store near heat, fire, or in direct sunlight.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Obtain established precautions against microbial hazards throughout testing and follow standard procedures for specimen disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be incinerated according to local regulations.
- Humidity and temperature can adversely affect results.

**[INTERPRETATION OF RESULTS]**

- **T1 POSITION:** 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 Genogroup 1 region (T1).
- **T2 POSITION:** 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 Genogroup 2 region (T2).

**[INDEX OF SYMBOLOGY]**

- **T1** 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 Genogroup 1 region (T1).
- **T2** 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 Genogroup 2 region (T2).

**[BIBLIOGRAPHY]**


**[QUALITY CONTROL]**

An internal procedural control is included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural techniques. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**[LIMITATIONS]**

1. The test result is interpretative and should not be used as the sole criteria for the diagnosis of Norovirus infection.

**REFERENCES**

**[PRODUCT INFORMATION]**

**[INTERPRETATION OF RESULTS]**

1. **T1 POSITION:** 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 Genogroup 1 region (T1).
2. **T2 POSITION:** 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 Genogroup 2 region (T2).

**[EXPECTED VALUES]**

The norovirus rapid test cassete has been compared with RT-PCR method, hemagglutination inhibition and agar gel double diffusion methods. The results show that the sensitivity of the Norovirus Rapid Test Cassette (Feces) is 95.65% and the relative specificity is 91.67%.

**[PERFORMANCE CHARACTERISTICS]**

**[SIGNIFICANCE]**

The performance of the Norovirus Rapid Test Cassette has been evaluated with 70 clinical specimens collected from children and adults and compared with RT-PCR method. The results show that the sensitivity of the Norovirus Rapid Test Cassette (Feces) is 95.65% and the relative specificity is 91.67%.

**[QUALITY CONTROL]**

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**[LIMITATIONS]**

1. The test result is interpretative and should not be used as the sole criteria for the diagnosis of Norovirus infection.