**Norovirus Rapid Test Cassette (Feces)**

**Purpose**: Rapid schematic immunofluorosassay for the qualitative detection of Norovirus in human feces specimens to aid in the diagnosis of Norovirus infection. A rapid, one step test for the qualitative detection of Norovirus in human feces. The Norovirus Rapid Test Cassette (Feces) is a rapid chromatographic immunofluorosassay for the qualitative detection of Norovirus in human feces specimens to aid in the diagnosis of Norovirus infection.

**[SUMMARY]**

Noroviruses (NoV) are a genetically diverse group of single stranded RNA, non-enveloped viruses that belong to the Caliciviridae family. For decades they were called "small round structured viruses" (SRSV) or "Norwalk-like viruses" until recently when their taxonomy was revised and they were recognized as a distinct family. Since then, more than 70 genotypes have been recognized, but more recently three genogroups have been identified with the genus Norovirus: Genogroup 1 and Genogroup 2 are associated with human infections while Genogroup 3 is associated with bovine infections.

Noroviruses are a major cause of acute gastroenteritis worldwide, often causing explosive outbreaks in institutions. They are transmitted by the fecal-oral route, with an incubation period of as little as 24 hours, meaning that they can be airborne due to aerosolisation of vomitus, which typically contains abundant infectious virus. Outbreaks of Norovirus infections are often associated with a major public health issue. Outbreaks of Norovirus infection can be associated with restaurants and institutions as diverse as nursing homes, hospitals, and cruise ships. Norovirus infections in children, elderly or frail patients can be fatal if left untreated.

The symptoms of Norovirus illness usually include nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people additionally have a low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the ability of Noroviruses to cause outbreaks in institutions has become a major public health issue. Norovirus is a genetically diverse group of single stranded RNA viruses that cause outbreaks in institutions has become a major public health issue. Norovirus is a genetically diverse group of single stranded RNA viruses that can cause outbreaks in institutions has become a major public health issue.

**DIRECTIONS FOR USE**

Allow the test, specimen, buffer, and/or controls to reach room temperature (15°-30°C) prior to testing.

- **To collect specimens:** Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain enough viral nucleic acids. Best results will be obtained if the assay is performed 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 available to the physician. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Norovirus infection.

**[INTRODUCTION TO RESULTS]**

**[INTERPRETATION OF RESULTS]**

Refer to the illustration above.

- **T1 POSITIVE:** Two distinct colored lines appear. One colored line should be in the control region (R) and another colored line should be in the Genogroup 1 region (T1).
- **T1 and T2 POSITIVE:** Two distinct colored lines appear. One colored line should be in the control region (R) and two colored line should be in the Genogroup 1 region (T1) and Genogroup 2 region (T2). A positive result in the Genogroup 1 region and Genogroup 2 region indicates that the test is positive for Norovirus. In the Genogroup 1 region, two positive results are then the sample.

**NOTE:** The intensity of the color in the test line region (T1) will vary depending on the concentration of the pathogen in the specimen.

- **T2 NEGATIVE:** No colored line appears in the control region (R). No line appears in the test line regions (T1/T2).

**[QUALITY CONTROL]**

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

1. This test should be used for detection of Norovirus antigens in human stool only.
2. The Norovirus Rapid Test Cassette (Feces) is a rapid chromatographic immunofluorosassay for the qualitative detection of Norovirus antigens in human stool only.
3. Stool sample from infant under one year old can produce a false positive result.
4. As with all diagnostic tests, results must be interpreted together with other clinical information available to the physician.

**[EXPECTED VALUES]**

The Norovirus Rapid Test Cassette (Feces) has been compared with RT-PCR method, and the test exhibits a specificity of 94.3%.**1**

**[PERFORMANCE CHARACTERISTICS]**

The performance of the Norovirus Rapid Test Cassette has been evaluated with 70 clinical samples using RT-PCR as the gold standard. The following results show that the sensitivity of the Norovirus Rapid Test Cassette (Feces) is 95.7% and the relative specificity is 99.7%.

**One Step Norovirus Rapid Test Cassette vs. RT-PCR**

<table>
<thead>
<tr>
<th>Method</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norovirus Rapid Test Cassette</td>
<td>Total Positive</td>
</tr>
<tr>
<td>Feces</td>
<td>44</td>
</tr>
<tr>
<td>RT-PCR</td>
<td>46</td>
</tr>
<tr>
<td>Relative Sensitivity: 94.3% (95%CI: 93.01-95.57%)</td>
<td>Relative Specificity: 99.7% (95%CI: 98.30-99.97%)</td>
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</tbody>
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**[REFERENCES]**


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**[BIBLIOGRAPHY]**