Norovirus Real-time RT-PCR
Test Code: 2400

Clinical and Procedure

Clinical Utility
Noroviruses are a major cause of nonbacterial acute gastroenteritis, accounting for as many as 50% of viral gastroenteritis cases. Symptoms include acute diarrhea, vomiting, abdominal cramps, headache, nausea, fatigue, and low-grade fever. Most cases are self-limiting, but complications can occur, particularly in the young, the elderly, and immunocompromised individuals. In immunocompromised patients, norovirus infection can cause life-threatening gastroenteritis after hematopoietic stem cell transplantation and should always be considered in the differential diagnosis of gut GVHD. Real-time reverse-transcriptase PCR has been shown to be a sensitive, specific method for early assessment of norovirus infections, contributing to positive clinical outcomes.

Procedure
Extraction of norovirus nucleic acid from fecal specimens, followed by reverse transcription of viral RNA, then amplification and detection of cDNA using real-time PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. The assay design includes multiple primers and probes to ensure comprehensive detection of norovirus groups I and II, which cause the majority of infections. The multiple-target assay design also accounts for viral mutations, significantly reducing the incidence of false negative results. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
This assay demonstrates no cross-reactivity with other known gastroenteritis pathogens. Genogroup I and Gengroup II assays show slight cross-reactivity with high titers of Norovirus Genogroup IV RNA.

Turnaround Time
Same day (within 12 - 24 hours from receipt of specimen), Monday through Friday.

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>fecal</td>
<td>2408</td>
<td>87799</td>
<td>Yes</td>
<td>Size of pea, or 2 mL liquid stool</td>
<td>Detected/Not Detected</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect fecal material and place into screw top tube for shipment.
- Ship at ambient temperature Monday through Friday.
- Specimen must arrive within 96 hrs. of collection.
- Specimen may also be stored at 2-8°C or frozen in a non-self-defrosting freezer and shipped with frozen gel packs or dry ice for overnight delivery to Viracor Eurofins.

Qualitative result (Detected/Not Detected). The assay differentiates between Norovirus Group I and Group II.

Assay Limitations
Detection of norovirus RNA in the stool does not definitively indicate that norovirus is the causative agent of gastrointestinal disease. Asymptomatic shedding of norovirus, especially in immunocompromised patients, has been reported in peer reviewed scientific literature. Results should be used in conjunction with clinical findings, and should not form the sole basis for a diagnosis or treatment decision.

Shipping
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086

**Causes for Rejection**
Fecal specimens that have been stored at ambient temperature for >96 hrs. If storage longer than 96 hours is needed, fecal samples should be frozen at -20°C or colder. Unless indicated as stored frozen, the fecal specimen will be rejected if the collection date is >96 hours from receipt at Viracor Eurofins.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.