



1001 NW Technology Drive, Lee's Summit, MO 64086 // (800) 305-5198 // (816) 347-0143 Fax // info@viracoribt.com

Norovirus Real-time RT-PCR

TEST CODE: 2400

CPT CODE:87798 (x2)

Clinical Utility

Noroviruses are a major cause 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 HSCT and should always be considered in the differential diagnosis of gut GVHD. Real-time reverse-transcriptase qPCR 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 Genogroup II assays show slight cross-reactivity with high titers of Norovirus Genogroup IV RNA.

Assay Range

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

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 draw date is >96 hours from receipt at Viracor-IBT.

Turnaround Time

Same day, (within 8 to 12 hours of receiving specimen) Monday through Saturday

Shipping

Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name



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and collection date. A Viracor-IBT test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor-IBT Laboratories, 1001 NW Technology Dr, Lee's Summit, MO 64086

Specimen Type & Specimen Handling

fecal - Collect 2mL of fecal material that takes the shape of a container, then transfer to screw top tube for shipment. Ship at ambient temperature Monday thru Friday. Specimen must arrive within 96 hrs of collection. Note: Specimen may also be stored at 2 to 8°C or frozen in a non-self-defrosting freezer and shipped with frozen gel packs or dry ice for overnight delivery at Viracor-IBT.

Disclaimer

Specimens are approved for testing in New York only when indicated in the Specimen Type and Specimen Handling field above.

The CPT codes provided are based on Viracor-IBT's 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-IBT assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.