MAYO CLINIC LABORATORIES

Test Definition: ROTA

Rotavirus Antigen, Feces

Overview

Useful For

Investigation of patients with diarrhea, particularly infants, the elderly, and immunocompromised patients

Investigation of nosocomial diarrhea

Testing Algorithm

For information on other diagnostic tests that may be useful in the evaluation of a patient with diarrhea, see Laboratory Testing for Infectious Causes of Diarrhea.

Special Instructions

- Laboratory Testing for Infectious Causes of Diarrhea

Method Name

Enzyme Immunoassay (EIA)

NY State Available

Yes

Specimen

Specimen Type

Fecal

Specimen Required

Specimen Type: Fresh unpreserved feces
Supplies: Stool Collection Kit, Random (T635)
Container/Tube:
Preferred: Sterile fecal container
Acceptable: Swab
Specimen Volume: 5 to 10 grams
Collection Instructions: Place specimen in a tightly sealed plastic bag.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Microbiology Test Request (T244)
-Gastroenterology and Hepatology Test Request (T728)

Specimen Minimum Volume

1 gram

Reject Due To

Grossly bloody (containing no visible feces) Very mucoid feces Feces received in any preservative (example: Ecofix, formalin, PVA, C and S media)	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Frozen (preferred)	7 days	
	Refrigerated	72 hours	

Clinical & Interpretive

Clinical Information

Rotavirus is a major cause of nonbacterial gastroenteritis, especially in infants and very young children (6 months-2 years of age) who have not received the rotavirus vaccine. Infection may be entirely asymptomatic or produce a spectrum of disease ranging from mild gastroenteritis to severe diarrhea and vomiting with dehydration. Infection usually begins acutely and lasts for 4 to 8 days. In temperate climates, rotaviral infections are seasonal; they peak in frequency during the winter months and are uncommon during the summer. Rotaviral gastroenteritis is, therefore, sometimes called "winter vomiting disease."

Infection is more likely to be symptomatic in preterm infants, immunosuppressed patients, and elderly individuals, especially those living in nursing homes or other confined quarters. In other children and adults, rotavirus infections are usually subclinical and may be associated with asymptomatic shedding of rotavirus in the feces.

Rapid and accurate detection of rotavirus antigens in fecal specimens may lead to better patient management, particularly in hospitalized or institutionalized patients.

Reference Values

Negative

Interpretation

Peak viral counts are reported to occur on days 3 to 5 after onset of symptoms. The virus is eliminated from the infected

individual within a few days following acute infection. Specimens collected 8 days or more after onset of symptoms may not contain enough rotavirus antigen to produce a positive reaction.

A prolonged carrier state has been recognized with rotavirus infection.

The rate of positive test results may vary due to age, weather, seasonal factors, geographic location, and the general health environment for the group under study.

Information on other diagnostic tests that may be of value in evaluating patients with diarrhea can be found in Laboratory Testing for Infectious Causes of Diarrhea.

Cautions

Fecal specimens should be collected as soon after onset of symptoms as possible.

Do not collect specimens in containers having media, preservatives, animal serum, or detergent as any of these may interfere with the assay.

A positive result does not preclude the presence of other pathogenic organisms. While the relationship between rotavirus and gastroenteritis is well established, coinfection with bacterial or parasitic pathogens is possible. If suspected, testing for other enteric pathogens should be performed in parallel with the rotavirus antigen test.

Results of the rotavirus antigen assay must be interpreted with caution. A negative result does not exclude the possibility of rotavirus infection, as too small a quantity of virus or inadequate or improper sampling may cause a false-negative result.

Supportive Data

This enzyme immunoassay antigen detection method has 100% sensitivity and 92% specificity when compared to transmission electron microscopy (EM), the method initially used to detect virus in fecal and intestinal biopsy specimens and the standard to which rotavirus diagnostic tests are compared. When compared to EM and RNA analysis, in combination, the specificity increases to 97%.

Clinical Reference

Centers for Disease Control and Prevention: Rotavirus. Updated March 26, 2021. Accessed August 28,2023. Available at www.cdc.gov/rotavirus/index.html

Performance

Method Description

This US Food and Drug Administration-approved kit utilizes monoclonal antibodies in a solid-phase sandwich type enzyme immunoassay (EIA). Plastic microtiter wells are coated with a monoclonal antibody directed against the product of the sixth viral gene (VP6), which is the group-specific antigen for all known human rotaviruses. An aliquot of fecal suspension is added to the well and incubated simultaneously with an anti-rotavirus monoclonal antibody conjugated to horseradish peroxidase, resulting in the rotavirus antigen being sandwiched between the solid-phase and enzyme-linked antibodies. After 60 minutes incubation at ambient temperature, the specimen well is washed to remove unbound

enzyme-labeled antibodies. Enzyme substrate (urea peroxidase) and chromogen tetra methylbenzidine are added to the wells and incubated for 10 minutes at ambient temperature. The enzyme bound in the wells converts the colorless substrate to a blue color. The intensity of the blue color is directly proportional to the concentration of rotavirus antigen in the specimen.(Package insert: Premier Rotaclone EIA for detection of Rotavirus Antigen in Human Fecal Samples. Meridian Bioscience; 01/2015)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
1 to 3 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87425

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ROTA	Rotavirus Ag, F	5880-0

Result ID	Test Result Name	Result LOINC® Value
24082	Rotavirus Ag, F	5880-0