MAYO CLINIC LABORATORIES

Test Definition: CRYPS

Cryptosporidium Antigen, Feces

Overview

Useful For

Establishing the diagnosis of intestinal cryptosporidiosis

Testing Algorithm

For other diagnostic tests that may be of value in evaluating patients with diarrhea; the following algorithms are available:

-Parasitic Investigation of Stool Specimens Algorithm

-Laboratory Testing for Infectious Causes of Diarrhea

Special Instructions

- Parasitic Investigation of Stool Specimens Algorithm
- Laboratory Testing for Infectious Causes of Diarrhea

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Fecal

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Preserved feces
Supplies:
-Formalin 10% Buffered Neutral 15 mL (T466)
-Stool Collection Kit, Random (T635)
Container/Tube:
Preferred: Stool container with 10% buffered formalin preservative
Acceptable: SAF (sodium acetate formalin)
Specimen Volume: 5 grams
Specimen Stability Information: Ambient (preferred) 60 days

Specimen Type: Unpreserved feces
Supplies:

-Stool container, Small (Random), 4 oz (T288)
-Stool Collection Kit, Random (T635)
Container/Tube: Stool container
Specimen Volume: 5 grams
Specimen Stability Information: Frozen 60 days

Forms

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

Specimen Minimum Volume

1 gram

Reject Due To

Grossly bloody (containing no visible feces) Very mucoid feces Specimen preserved in ECOFIX (green cap), C and S (orange cap), or methiolate formalin (MF) Duodenal aspirates Small bowel aspirates	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Varies		

Clinical & Interpretive

Clinical Information

Cryptosporidia are small apicomplexan protozoan parasites that infect the intestinal tract of humans and animals. They were conventionally categorized as coccidia but are now known to be more closely related to the gregarines. Many species may infect humans, with the most common being *Cryptosporidium hominis* and *Cryptosporidium parvum*.

Infected humans and animals shed small (4-6 micrometer in diameter) infectious oocysts in their stool, and these can subsequently contaminate and survive in recreational and drinking water supplies.

Infection of humans occurs by the fecal-oral route or via ingestion of contaminated water or food. Infection is easily acquired, with an infectious dose of approximately 100 oocysts. Waterborne transmission is a primary mode of transmission and is commonly responsible for human outbreaks. This is because *Cryptosporidium* species oocysts are resistant to cold temperatures and chlorine and require extensive filtration or water treatment to remove them from drinking water.

The incubation period is typically 7 to 10 days following exposure. While most patients have symptoms, approximately 30% of infected individuals are asymptomatic. When symptoms are present, they usually include profuse, watery diarrhea, malaise, anorexia, nausea, crampy abdominal pain, and low-grade fever. Infection is usually self-limited in immunocompetent individuals, with resolution of symptoms in 10 to 14 days. However, diarrhea can be prolonged and life-threatening in immunocompromised patients such as those with AIDS, infants, and older adults, and result in severe dehydration and wasting.

The fecal ova and parasite examination is an insensitive method for detecting *Cryptosporidium,* given the small size of the oocysts and their lack of trichrome staining. Instead, use of this test, or the multiplex gastrointestinal polymerase chain reaction (PCR) panel (GIP / Gastrointestinal Pathogen Panel, PCR, Feces), is recommended for sensitive and specific detection. This antigen test is ideal for situations in which cryptosporidiosis is highly suspected (eg, outbreak scenarios), whereas the PCR panel allows for simultaneous detection of multiple parasitic, viral, and bacterial causes of diarrhea.

For more information about diagnostic tests that may be of value in evaluating patients with diarrhea, see the following:
-Parasitic Investigation of Stool Specimens Algorithm
-Laboratory Testing for Infectious Causes of Diarrhea

Reference Values

Negative

Interpretation

A positive enzyme-linked immunosorbent assay result indicates the presence of antigens of cryptosporidium and is interpreted as evidence of infection with that organism.

Interpretation of results should be correlated with patient symptoms and clinical picture.

Cautions

Examination of at least 2 fecal specimens may be required to detect *Cryptosporidium* using antigen testing.

Feces containing large amounts of white or red blood cells may produce false-positive results.

Supportive Data

The sensitivity, specificity, positive predictive value and negative predictive value of the enzyme-linked immunosorbent assay were 98%, 98%, 98%, and 98.5%, respectively, as determined by examination of 130 fecal specimens by conventional microscopy and by enzyme-linked immunosorbent assay.

Clinical Reference

1. Centers for Disease Control and Prevention (CDC): Parasites-*Cryptosporidium* (also known as "Crypto"). CDC; Updated July 1, 2019. Accessed October 31, 2022. Available at www.cdc.gov/parasites/crypto/index.html
2. Garcia LS, Arrowood M, Kokoskin E, et al. Practical guidance for clinical microbiology laboratories: Laboratory diagnosis of parasites from the gastrointestinal tract. Clin Microbiol Rev. 2017;31(1):e00025-17. doi:10.1128/CMR.00025-17

Performance

Method Description

Cryptosporidium antigens present in the fecal supernatant are captured by the antibody-coated microtiter wells. A second antibody is added that binds to the complex. This signal is amplified by the addition of antibody biotin conjugate and streptavidin peroxidase. The resulting blue color development indicates the presence of cryptosporidium antigens in the feces. The reaction is completed with acid, which changes the blue to yellow and the test is read on a spectrophotometer.(Ungar BL. Enzyme-linked immunoassay for detection of cryptosporidium antigens in fecal specimens. J Clin Microbiol. 1990;28(11):2491-2495. doi:10.1128/jcm.28.11.2491-2495.1990; Rosenblatt JE, Sloan LM. Evaluation of an immunoassay for the detection of cryptosporidium in stool specimens. J Clin Microbiol. 1993;31:1468-1472. doi:10.1128/jcm.31.6.1468-1471.1993; package insert: ProSpecT Cryptosporidium Microplate Assay. Oxoid; 04/2012)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 days

Specimen Retention Time

Fresh/Frozen: 1 week; Preserved specimens: 1 week

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.

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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

87328

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CRYPS	Cryptosporidium Ag, F	6371-9

Result ID	Test Result Name	Result LOINC® Value
24086	Cryptosporidium Ag, F	6371-9