

## 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 in Special Instructions:

[-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 (T466); Stool Collection Kit, Random (T635)

**Container/Tube:**

**Preferred:** Stool container with 10% buffered formalin preservative

**Acceptable:** SAF (sodium acetate formalin)

**Specimen Volume:** 5 g

**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 g

**Specimen Stability Information:** Frozen 60 day

### Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

[-Gastroenterology and Hepatology Client Test Request \(T728\)](#)

[-Microbiology Test Request \(T244\)](#)

### Specimen Minimum Volume

1 g

### Reject Due To

Other	Grossly bloody (containing no visible feces); very mucoid feces, colonic wash, in ECOFIX(green cap)
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### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Varies		

## Clinical and 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 *C 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 due to the fact that *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 the elderly, 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 the *Cryptosporidium* antigen test (CRYPS / *Cryptosporidium* Antigen, Feces) or the multiplex gastrointestinal PCR panel (GIP / Gastrointestinal Pathogen Panel, PCR, Feces) is recommended for sensitive and specific detection. The 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.

See [Parasitic Investigation of Stool Specimens Algorithm](#) and [Laboratory Testing for Infectious Causes of Diarrhea](#) in Special Instructions for more information about diagnostic tests that may be of value in evaluating patients with diarrhea.

### Reference Values

Negative

### Interpretation

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

The sensitivity, specificity, and positive predictive value of the ELISA were 87%, 99%, and 98%, respectively, as determined by examination of 231 fecal specimens by conventional microscopy and by ELISA.

### Cautions

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

### Clinical Reference

Centers for Disease Control and Prevention: Parasites-*Cryptosporidium* (also known as "Crypto"). Accessed 10/16/2019. Available at [www.cdc.gov/parasites/crypto/index.html](http://www.cdc.gov/parasites/crypto/index.html)

### 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. Enzyme-linked immunosorbent assay-positive results on fecal specimens received in fixative are confirmed by direct fluorescent assay (DFA) before reporting. Frozen fecal specimens cannot be confirmed with DFA testing. (Ungar BL: Enzyme-linked immunoassay for detection of cryptosporidium antigens in fecal specimens. J Clin Microbiol 1990;28:2491-2495; Rosenblatt JE, Sloan LM: Evaluation of an immunoassay for the detection of cryptosporidium in stool specimens. J Clin Microbiol 1993;31:1468-1472) (Package insert: ProSpecT Cryptosporidium Microplate Assay. April 2012)

#### PDF Report

No

#### Day(s) and Time(s) Test Performed

Monday through Saturday; 1 p.m.

#### Analytic Time

Same day/1 day

**Maximum Laboratory Time**

3 days

**Specimen Retention Time**

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

**Performing Laboratory Location**

Rochester

**Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared or approved by the U.S. 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