

Overview

Useful For

Detection of *Enterocytozoon bieneusi* and *Encephalitozoon* species in fecal and urine specimens to support the clinical diagnosis of microsporidiosis

Highlights

This test is intended to be used for immunocompromised patients with persistent, watery diarrhea. See the [Parasitic Investigation of Stool Specimens Algorithm](#).

This test is intended to be used for the detection of *Enterocytozoon bieneusi* and *Encephalitozoon* species DNA in fecal and urine specimens to support the clinical diagnosis of microsporidiosis. Other sources should be tested using MTBS / Microsporidia Stain, Varies.

A negative result indicates the absence of detectable DNA from *Enterocytozoon bieneusi* and *Encephalitozoon* species in the specimen, but does not rule out ongoing microsporidiosis. See Interpretation for more information.

Testing Algorithm

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

Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available

Yes

Specimen

Specimen Type

Varies

Advisory Information

For specimens other than feces or urine, MTBS / Microsporidia Stain, Varies should be ordered since it will detect other microsporidia that are not targeted by this assay.

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Preferred:
Specimen Type: Unpreserved feces

Supplies: Stool container, Small (Random), 4 oz (T288); Stool Collection Kit, Random (T635)

Container/Tube: Fecal container (T288)

Specimen Volume: 5g

Specimen Type: Preserved feces

Supplies: ECOFIX Stool Transport Vial (Kit) (T219); Stool Collection Kit, Random (T635)

Container/Tube: ECOFIXpreservative

Specimen Volume:5 g

Specimen Type: Urine

Container/Tube: Sterile container

Specimen Volume: 5mL

Collection Instructions: Mid-stream, clean-catch, suprapubic aspirates and catheterization collections are acceptable. Please submit in a clean, sterile container free from preservatives. The first portion of the voided urine (first void) is also acceptable.

Forms

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

[-Microbiology Test Request \(T244\)](#)
[-Gastroenterology and Hepatology Client Test Request \(T728\)](#)
Specimen Minimum Volume

Feces: 1 g

Urine: 0.5 mL

Reject Due To

Other	Urine containing preservatives Prostate secretions and samples Feces in preservatives other than ECOFIX
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	
	Ambient	7 days	

Specimen Type	Temperature	Time	Special Container
	Frozen	7 days	

Clinical and Interpretive

Clinical Information

Microsporidia are highly specialized fungi that cause a wide variety of clinical syndromes in humans. The most common microsporidia are *Enterocytozoon bieneusi* and *Encephalitozoon intestinalis*, which infect the gastrointestinal tract and cause a diarrheal illness, and *Encephalitozoon cuniculi* and *Encephalitozoon hellem* that can infect the conjunctiva, respiratory tract, and genitourinary system. Human infections have been reported most frequently in patients with AIDS, but also can occur in other immunocompromised patients, including solid organ allograft recipients and, sporadically, immunocompetent hosts. Less commonly, other microsporidia such as *Vittaforma corneae* and *Brachiola* species can cause disseminated or organ-specific disease. This assay detects only the most common microsporidia, *Enterocytozoon bieneusi* and *Encephalitozoon* species, and not microsporidiosis due to other species.

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

Reference Values

Negative

Interpretation

A positive result indicates the presence of *Enterocytozoon bieneusi* and *Encephalitozoon* species DNA and is consistent with an active or recent infection. Since microsporidia DNA may be present in feces or urine in the absence of clinical symptoms, results should be correlated with clinical presentation.

A negative result indicates absence of detectable DNA from *Enterocytozoon bieneusi* and *Encephalitozoon* species in the specimen, but does not always rule out ongoing microsporidiosis since the organism may be present at very low levels or may be sporadic.

Other tests to consider in the evaluation of a patient presenting with acute or chronic watery diarrhea include cultures or specific assays for bacterial, viral, and parasitic pathogens.

Cautions

This test only detects DNA from *Enterocytozoon bieneusi* and *Encephalitozoon* species and does not detect the less common microsporidia. These 2 genera are the most common causes of intestinal and renal microsporidiosis.

While this assay is designed to detect symptomatic infection with *Enterocytozoon bieneusi* and *Encephalitozoon* species, it may detect asymptomatic carriage and should only be used for patients with a clinical history and symptoms consistent with microsporidiosis.

Supportive Data

In a study using 205 clinical specimens and 254 spiked specimens, the Microsporidia PCR assay had 90% to 100% sensitivity and 100% specificity in all specimen types accepted for this assay. The limit of detection is between 500 to 5,000 target DNA copies/mL of specimen. When 10-fold dilutions of fresh stool specimens containing *Enterocytozoon bieneusi* spores were tested by both PCR and microscopy, PCR showed significantly greater sensitivity, with the ability to detect at *Enterocytozoon bieneusi* at 1 to 2 dilutions lower than microscopy.

Clinical Reference

1. Didier ES, Weiss LM: Microsporidiosis: Not just in AIDS patients. *Curr Opin Infect Dis* 2011;24(5):490-495
2. Nagpal A, Pritt BS, Lorenz EC, et al: Disseminated microsporidiosis in a renal transplant recipient: case report and review of the literature. *Transpl Infect Dis*. 2013 Oct;15(5):526-532
3. Verweij JJ, Stensvold CR: Molecular Testing for Clinical Diagnosis and Epidemiological Investigations of Intestinal Parasitic Infections. *Clin. Microbiol. Rev.* April 2014;27:371-418
4. Wolk DM, Schneider SK, Wengenack NL, et al: Real-time PCR method for detection of *Encephalitozoon intestinalis* from stool specimens. *J Clin Microbiol* 2002 Nov;40(11):3922-3928

Performance**Method Description**

Nucleic acid is extracted from feces and urine using the automated MagNA Pure bead-based system (Roche Molecular Systems). The extract is then transferred to individual self-contained capillary cuvettes for amplification. The LightCycler is a self-contained automated instrument that amplifies and monitors the development of target nucleic acid (amplicon) after each cycle of PCR.

The DNA target for PCR assay is the 18S rRNA gene of *Enterocytozoon bieneusi*, *Encephalitozoon intestinalis*, *Encephalitozoon hellem*, and *Encephalitozoon cuniculi*.

This assay utilizes 2 primers and 2 probes, which are specific for *E bieneusi* and 3 primers and 2 probes specific for *Encephalitozoon* species. The specific base pair DNA target sequence is first amplified by PCR using the target-specific primers. Amplicon is then detected during melting curve analysis using fluorescence resonance energy transfer (FRET) probes, which utilizes one hybridization probe with a donor fluorophore, fluorescein, at the 3' end and a second hybridization probe with an acceptor fluorophore, at the 5' end. Fluorescence is produced when the 2 probes anneal to the target sequence in close proximity to one another. The LC-Red 670 emits a measurable and quantifiable light signal at a specific wavelength when *E bieneusi* is present and the LC-Red 610 emits a measurable and quantifiable light signal in the presence of *Encephalitozoon* species. (Cockerill FR, Uhl FR: Applications and challenges of real-time PCR for the clinical microbiology laboratory. In *Rapid Cycle Real-Time PCR*. Edited by U Reischl, C Wittwer, F Cockerill. Springer, NY 2002

PDF Report

No

Day(s) and Time(s) Test Performed

Tuesday through Friday; 6 a.m.

Analytic Time

2 days

Maximum Laboratory Time

4 days

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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

87798

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
LCMSP	Microsporidia PCR	94332-4

Result ID	Test Result Name	Result LOINC Value
MSPS	Specimen Source	31208-2
36744	Encephalitozoon species	94333-2
36745	Enterocytozoon bienewisi	94334-0