Test Definition: LCMSP

Microsporidia species, Molecular Detection, PCR, Varies

Overview

Useful For

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

Testing Algorithm

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

Highlights

This test is intended to be used for patients who are immunocompromised and have 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 *E bieneusi* and *Encephalitozoon* species in the specimen but does not rule out ongoing microsporidiosis. See Interpretation for more information.

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

For specimens other than feces or urine, MTBS / Microsporidia Stain, Varies should be ordered since it will detect other microsporidia 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
Specimen Volume: 5 g

Specimen Type: Preserved feces
Supplies:
-ECOFIX Stool Transport Vial (Kit) (T219)
-Stool Collection Kit, Random (T635)
Container/Tube: ECOFIX preservative
Specimen Volume: 5 g

Specimen Type: Urine
Container/Tube: Sterile container
Specimen Volume: 5 mL
Collection Instructions: Mid-stream, clean-catch, suprapubic aspirates and catheterization collections are acceptable. 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 Test Request (T728)

Specimen Minimum Volume

Feces: 1 g
Urine: 0.5 mL

Reject Due To

Urine containing preservatives Prostate secretions and	Reject

samples Feces in preservatives other than ECOFIX	

Specimen Stability Information

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

Clinical & 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,* which can infect the conjunctiva, respiratory tract, and genitourinary system. Human infections have been reported most frequently in patients with AIDS but can also occur in other patients who are immunocompromised, 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, *E bieneusi* and *Encephalitozoon* species, and not microsporidiosis due to other species.

For other diagnostic tests that may be of value in evaluating patients with diarrhea, see Parasitic Investigation of Stool Specimens Algorithm and Laboratory Testing for Infectious Causes of 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 *E bieneusi* and *Encephalitozoon* species in the specimen. Still, this 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 *E 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 polymerase chain reaction (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 5000 target DNA copies/mcL 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 *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 Oct;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. 2014 Apr;27(2):371-418
4. Wolk DM, Schneider SK, Wengenack NL, Sloan LM, Rosenblatt JE: Real-time PCR method for detection of *Encephalitozoon* intestinalis from stool specimens. J Clin Microbio. 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 polymerase chain reaction (PCR).

The DNA target for PCR assay is the 18S ribosomal RNA 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 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.(Bernard PS, Reiser A, Pritham GH: Mutation detection by fluorescent hybridization probe melting curves. In: Meuer S, Wittwer C, Nakagawara K, eds. Rapid Cycle Real-Time PCR: Methods and Applications. Springer; 2012:11-20)

PDF Report
No

Day(s) Performed
Tuesday through Friday

Report Available
2 to 4 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US 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 bieneusi	94334-0