Test Definition: ULFA

Cryptococcus Antigen Screen, Lateral Flow Assay, Random, Urine

Overview

Useful For

Aiding in the diagnosis of infection with *Cryptococcus neoformans* or *Cryptococcus gattii*

This test **should not be used** as a test of cure.

This test **should not be used** as a screening procedure for the general population.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
ULFAT	Cryptococcus Ag Titer, LFA, U	No	No

Testing Algorithm

If this screen is positive, the antigen titer will be performed at an additional charge.

Highlights

Detection of *Cryptococcus* antigen in urine may be used as an adjunct method for diagnosis of disseminated infection with *Cryptococcus neoformans* or *Cryptococcus gattii* alongside culture and other serologic methods (eg, *Cryptococcus* antigen testing on serum or cerebrospinal fluid).

A negative result should not be used to rule out infection.

Method Name

Lateral Flow Assay (LFA)

NY State Available

Yes

Specimen

Specimen Type

Urine

Specimen Required

Supplies: Urine Tubes, 10 mL (T068)
Submission Container/Tube: Plastic, 10-mL urine tube
Specimen Volume: 1 mL

Collection Instructions:

1. Collect a random urine specimen.
2. No preservative.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Turbid; Colored	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Cryptococcosis is an invasive fungal infection caused by *Cryptococcus neoformans* or *Cryptococcus gattii*. The organism has been isolated from several sites in nature, particularly weathered pigeon droppings.

Infection is usually acquired via the pulmonary route. Patients are often unaware of any exposure history. Approximately half of the patients with symptomatic disease have a predisposing immunosuppressive condition such as AIDS, steroid therapy, lymphoma, or sarcoidosis. Symptoms may include fever, headache, dizziness, ataxia, somnolence, and cough. While the majority of *C neoformans* infections occur in immunocompromised patient populations, *C gattii* has a predilection for infection of healthy individuals.

In addition to the lungs, cryptococcal infections frequently involve the central nervous system (CNS), particularly in patients infected with HIV. Mortality associated with CNS cryptococcosis approaches 25% despite antifungal therapy, while untreated CNS cryptococcosis is invariably fatal. Disseminated disease may affect any organ system and usually occurs in immunosuppressed individuals.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

The presence of cryptococcal antigen (CrAg) in any body fluid is strongly suggestive of infection with *Cryptococcus neoformans* or *Cryptococcus gattii*.

Declining titer results are suggestive of clinical response to therapy. However, monitoring CrAg titers should not be used as a test of cure, as low-level titers may persist for extended periods of time following appropriate therapy and disease resolution.

In addition to testing for CrAg, patients with presumed disease due to *C neoformans* or *C gattii* should have appropriate clinical specimens (eg, blood, bronchoalveolar lavage fluid) submitted for routine smear and fungal culture.

Cautions

A negative result does not preclude the diagnosis of cryptococcosis, particularly if only a single specimen has been tested and the patient shows symptoms consistent with cryptococcal infection.

A positive result is suggestive of cryptococcosis; however, all test results should be interpreted considering other clinical findings.

Testing should not be performed as a screening procedure for the general population and should only be performed when clinical evidence suggests the cryptococcal disease.

Although rare, extremely high concentrations of cryptococcal antigen (CrAg) can result in weak-positive or false-negative results.

Patients with trichosporonosis or *Capnocytophaga* species infection may yield false-positive results.

If followed for clinical purposes, CrAg titers should be followed using the same assay.

Clinical Reference

1. Hazen KC, Howell SA. Candida, Cryptococcus, and other yeasts of medical importance. In: Murray PR, Baron EJ, Jorgensen JH, et al, eds. Manual of Clinical Microbiology. 9th ed. ASM Press; 2007:1762-1788
2. Bruner KT, Franco-Paredes C, Henao-Martinez AF, Steele GM, Chastain DB. Cryptococcus gattii complex infections in HIV-infected patients, Southeastern United States. Emerg Infect Dis. 2018;24(11):1998-2002. doi:10.3201/eid2411.180787

Performance

Method Description

The CrAg (*Cryptococcus* antigen) lateral flow assay is a sandwich immunochromatographic assay. Specimens and diluent are added to a test tube, and the lateral flow device is added. The test uses specimen wicking to capture gold-conjugated anti-cryptococcal antigen monoclonal antibodies and gold-conjugated control antibodies deposited on

the test membrane. If cryptococcal antigen is present in the specimen, it binds to the gold-conjugated anti-cryptococcal antigen antibodies. This complex wicks up the membrane and interacts with the test line, which has immobilized anti-cryptococcal antigen monoclonal antibodies. The antigen-antibody complex forms a sandwich at the test line causing a visible line to form. A valid test shows a visible line at the control line. Positive test results create 2 lines (control and specimen), while negative results form only the control line.(Package insert: CrAg Lateral Flow Assay. IMMY; Rev 06/27/2019)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
1 to 4 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87899
87899 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ULFA	Cryptococcus Ag Screen, LFA, U	16693-4

Result ID	Test Result Name	Result LOINC® Value

604095	Cryptococcus Ag Screen, LFA, U	16693-4