

## 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.

### Method Name

Only orderable as a reflex. For more information see ULFA / *Cryptococcus* Antigen Screen, Lateral Flow Assay, Random, Urine.

Lateral Flow Assay (LFA)

### NY State Available

Yes

## Specimen

### Specimen Type

Urine

### Specimen Required

Only orderable as a reflex. For more information see ULFA / *Cryptococcus* Antigen Screen, Lateral Flow Assay, Random, Urine.

**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.

### Specimen Minimum Volume

0.5 mL

### Reject Due To

Gross hemolysis	Reject
Turbid;	Reject

Colored	
---------	--

## 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

Only orderable as a reflex. For more information see ULFA / *Cryptococcus* Antigen Screen, Lateral Flow Assay, Random, Urine.

Negative

### 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.

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

Chang CC, Harrison TS, Bicanic TA, et al. Global guideline for the diagnosis and management of cryptococcosis: an initiative of the ECMM and ISHAM in cooperation with the ASM [published correction appears in Lancet Infect Dis. 2024 Aug;24(8):e485. doi: 10.1016/S1473-3099(24)00426-2]. Lancet Infect Dis. 2024;24(8):e495-e512. doi:10.1016/S1473-3099(23)00731-4

## Performance

### Method Description

The *Cryptococcus* antigen (CrAg) 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**

Rochester

**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

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
ULFAT	Cryptococcus Ag Titer, LFA, U	93766-4

Result ID	Test Result Name	Result LOINC® Value
604369	Cryptococcus Ag Titer, LFA, U	93766-4