

Overview
Useful For

Verifying systemic absorption of orally administered itraconazole

The test is indicated in patients with life-threatening fungal infections and in patients considered at risk for poor absorption or rapid clearance of itraconazole.

Method Name

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

NY State Available

Yes

Specimen
Specimen Type

Serum Red

Specimen Required

Collection Container/Tube:Red top

Submission Container/Tube:Plastic vial

Specimen Volume:1 mL

Specimen Minimum Volume

0.18 mL

Reject Due To

| | |
|-----------|-------------------|
| Hemolysis | Mild OK; Gross OK |
| Lipemia | Mild OK; Gross OK |
| Icterus | Mild OK; Gross OK |
| Other | Serum gel tube |

Specimen Stability Information

| Specimen Type | Temperature | Time |
|---------------|--------------------------|---------|
| Serum Red | Refrigerated (preferred) | 29 days |
| | Ambient | 29 days |
| | Frozen | 29 days |

Clinical and Interpretive

Clinical Information

Itraconazole is a synthetic triazole antifungal drug approved for treatment and prophylaxis of a variety of fungal infections. Its activity results from inhibition of fungal synthesis of ergosterol, an integral component of fungal cell membranes.

Concerns about adequate absorption and drug interactions are some of the major indications for therapeutic drug monitoring. Mean oral bioavailability approximates 55% but is highly variable; absorption can be enhanced by food or acidic drinks. Hepatic enzyme inducers can cause low serum itraconazole levels, and coadministration of these drugs has been associated with itraconazole therapeutic failure.

Itraconazole therapeutic efficacy is greatest when serum concentrations exceed 0.5 mcg/mL for localized infections, or 1.0 mcg/mL for systemic infections. An active metabolite, hydroxyitraconazole, is present in serum at roughly twice the level of the parent drug. These concentrations refer to analysis by HPLC; quantitation by bioassay results in considerably higher apparent drug measurements, due to reactivity with the active metabolite.

Reference Values

ITRACONAZOLE (TROUGH)

>0.5 mcg/mL (localized infection)

>1 mcg/mL (systemic infection)

HYDROXYITRACONAZOLE

No therapeutic range established; activity and serum concentration are similar to parent drug.

Interpretation

A lower cutoff concentration has not been defined that applies in all cases. The serum concentration must be interpreted in association with other variables, such as the nature of the infection, the specific microorganism, and minimal inhibitory concentration (MIC) results, if available. Localized infections are more likely to respond when serum itraconazole is >0.5 mcg/mL (by HPLC); systemic infections generally require drug concentrations >1.0 mcg/mL.

Cautions

Enteropathy, H2-histamine receptor blockers, hepatic enzyme inducers, and other variables can result in low to nondetectable serum levels with concomitant high risk of therapeutic failure.

AIDS patients and organ transplant patients receiving immunosuppressive therapy tend to have lower serum itraconazole levels on standard doses and are thus at high risk of therapeutic failure.

Clinical Reference

- Andes D, Pascual A, Marchetti O: Antifungal therapeutic drug monitoring: established and emerging indications. *Antimicrob Agents Chemother* 2009;53(1):24-34
- Hope WW, Billaud EM, Lestner J, Denning DW: Therapeutic drug monitoring for triazoles. *Curr Opin Infect Dis* 2008;21:580-586

Performance

Method Description

Itraconazole and hydroxyitraconazole are extracted by mixing serum samples with acetonitrile to precipitate proteins. The supernatant is removed, and analyzed by an in-house developed liquid chromatography-tandem mass spectrometry (LC-MS/MS) method.(Unpublished Mayo method)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday-Friday; 8 a.m.

Analytic Time

Same day/1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

2 weeks

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

80299

LOINC® Information

| Test ID | Test Order Name | Order LOINC Value |
|---------|-----------------|-------------------|
| ITCON | Itraconazole, S | 10989-2 |

| Result ID | Test Result Name | Result LOINC Value |
|-----------|---------------------|--------------------|
| 81247 | Itraconazole, S | 10989-2 |
| 5122 | Hydroxyitraconazole | 18337-6 |