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## Overview

### Useful For

Monitoring serum concentration during therapy

Evaluating potential toxicity

Evaluating patient compliance

### 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 (serum gel/SST are **not acceptable**)

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 mL

### Collection Instructions:

- [1. Draw blood immediately before the next scheduled dose \(trough\).](#)
2. Centrifuge and aliquot serum into plastic vial within 2 hours of collection.

### Forms

If not ordering electronically, complete, print, and send a [Therapeutics Test Request](#) (T831) with the specimen.

**Reject Due To**

Gross hemolysis OK  
Gross lipemia OK  
Gross icterus OK

**Specimen Minimum Volume**

0.5 mL

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum Red	Refrigerated (preferred)	28 days	
	Ambient	28 days	
	Frozen	28 days	

**Clinical & Interpretive****Clinical Information**

[Duloxetine is an antidepressant of the serotonin-norepinephrine reuptake inhibitor class.](#) It is effective in treating symptoms of depression, including physical pain associated with depression; other uses include therapy of neuropathic pain, fibromyalgia, and urinary stress incontinence. Duloxetine also inhibits serotonin uptake in human platelets and may be associated with potentiation of bleeding.

Duloxetine undergoes extensive hepatic biotransformation to numerous inactive metabolites. The drug is metabolized by cytochrome P450 (CYP) 1A2 and CYP2D6, with moderate potential for drug interactions (duloxetine is both a substrate and a moderate inhibitor of CYP2D6). The mean elimination half-life is 12.5 hours with steady-state concentrations occurring in about 3 days. Specimens for therapeutic monitoring should be collected immediately before the next scheduled dose (ie, trough).

Duloxetine is not recommended for patients with hepatic impairment, substantial alcohol use, or chronic liver disease. Use in patients with kidney disease significantly increases exposure to duloxetine due to decreased elimination. Patients with mild-to-moderate kidney dysfunction should be monitored closely; use of duloxetine is not recommended in end-stage kidney disease.

**Reference Values**

30-120 ng/mL

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**Interpretation**

Therapeutic ranges are not well-established, but literature suggests that patients receiving duloxetine monotherapy for depression responded well when trough concentrations were 30 to 120 ng/mL. Higher levels may be tolerated by individual patients. The therapeutic relevance of this concentration range to other uses of duloxetine therapy is currently unknown.

**Cautions**

Specimens that are obtained from gel tubes or anticoagulate collections can cause assay interference.

**Clinical Reference**

1. Hiemke C, Bergemann N, Clement HW, et al: Consensus Guidelines for Therapeutic Drug Monitoring in Neuropsychopharmacology: Update 2017. *Pharmacopsychiatry*. 2018 Jan;51(1-02):9-62
2. Westanmo AD, Gayken J, Haight R: Duloxetine: a balanced and selective norepinephrine- and serotonin-reuptake inhibitor. *Am J Health-Syst Pharm*. 2005 Dec;62(23):2481-2490
3. Waldschmitt C, Vogel F, Pfuhlmann B, Hiemke C: Duloxetine serum concentrations and clinical effects. Data from a therapeutic drug monitoring (TDM) survey. *Pharmacopsychiatry*. 2009 Sep;42(5):189-193
4. Feighner JP, Cohn JB: Double-blind comparative trials of fluoxetine and doxepin in geriatric patients with major depressive disorder. *J Clin Psychiatry*. 1985 Mar;46(3 Pt 2):20-25
5. Kelly MW, Perry PJ, Holstad SG, Garvey MJ: Serum fluoxetine and norfluoxetine concentrations and antidepressant response. *Ther Drug Monit*. 1989;11:165-170
6. Benfield P, Heel RC, Lewis SP: Fluoxetine: a review of its pharmacodynamic and pharmacokinetic properties, and therapeutic efficacy in depressive illness. *Drugs*. 1986 Dec;32(6):481-508
7. Wille SM, Cooreman SG, Neels, et al: Relevant issues in the monitoring and toxicology of antidepressants. *Crit Rev Clin Lab Sci*. 2008;45(1):25-89

**Performance****Method Description**

Serum samples containing duloxetine are diluted in an aqueous solution containing deuterated internal standard and then injected onto a high-turbulence liquid chromatography system for online extraction. Detection is by tandem mass spectrometry.(Unpublished Mayo method)

**PDF Report**

No

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees & Codes****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 US Food and Drug Administration.

**CPT Code Information**

80299

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
DULOX	Duloxetine, S	46227-5

Result ID	Reporting Name	LOINC®
89305	Duloxetine, S	46227-5