MAYO CLINIC LABORATORIES

Test Definition: DULOX

Duloxetine, Serum

Overview

Useful For

Monitoring duloxetine serum concentration during therapy

Evaluating potential duloxetine 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

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Red top (serum gel/SST are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL Serum
Collection Instructions:
1. Draw blood immediately before the next scheduled dose (trough).
2. Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Forms

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

Specimen Minimum Volume

Serum: 0.5 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

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 for patients with kidney failure.

Reference Values

30-120 ng/mL

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 obtained using gel tube or anticoagulant collections can cause falsely decreased results or an 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;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;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;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;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(2):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;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

Day(s) Performed
Wednesday

Report Available
1 to 8 days

Specimen Retention Time
14 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 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

80299

LOINC® Information

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

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