Test Definition: AMIO

Amiodarone, Serum

Overview

Useful For

Monitoring amiodarone therapy, especially when amiodarone is coadministered with other drugs that may interact

Evaluating possible amiodarone toxicity

Assessing patient compliance

Method Name

Liquid Chromatography 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: 1.5 mL
Collection Instructions:
1. Draw blood no sooner than 12 hours (trough value) after last dose or immediately before next scheduled dose.
2. Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send one of the following with the specimen:
-Therapeutics Test Request (T831)
-Cardiovascular Test Request (T724)

Specimen Minimum Volume

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	24 hours	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Amiodarone is an antiarrhythmic agent used to treat life-threatening arrhythmias; it is typically categorized as a Class III drug (antiarrhythmic agents that are potassium channel blockers) but shows several mechanisms of action. The US Food and Drug Administration approved the use of amiodarone for recurrent ventricular fibrillation and recurrent hemodynamically unstable ventricular tachycardia only after demonstrating lack of response to other antiarrhythmics, but more recent studies have shown amiodarone to be the antiarrhythmic agent of choice for many situations, including atrial fibrillation.(1)

Amiodarone can be administered orally or intravenously for cardiac rhythm control. It is approximately 95% protein bound in blood, with a volume of distribution of 60 L/kg. Amiodarone elimination is quite prolonged, with a half-life of 26-107 days for oral, chronic dosing. Cytochrome P450 (CYP) 3A4 converts amiodarone to its equally active metabolite, *N*-desethylamiodarone (DEA), which displays very similar pharmacokinetics and serum concentrations compared with the parent drug.(2) Current therapeutic ranges are based solely on amiodarone, but most individuals will have roughly equivalent concentrations of DEA at steady state.(3)

Numerous side effects have been associated with amiodarone. The most common adverse effect is disruption of thyroid function (hypo- or hyperthyroidism) due to amiodarone's structural similarity to thyroid hormones. Neurological and gastrointestinal toxicities are concentration-dependent, whereas thyroid dysfunction, pulmonary fibrosis, and hepatotoxicity are more loosely linked to drug concentration. There is significant potential for drug interactions involving amiodarone, including several other cardioactive drugs (eg, digoxin, verapamil, class I antiarrhythmics [sodium channel blockers]), warfarin, statins, and CYP3A4 substrates.

Reference Values

AMIODARONE
Trough Value
0.5-2.0 mcg/mL: Therapeutic concentration
>2.5 mcg/mL: Toxic concentration

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

Interpretation

Clinical effects generally require serum concentrations above 0.5 mcg/mL.

Increased risk of toxicity is associated with amiodarone concentrations above 2.5 mcg/mL.

Although therapeutic and toxic ranges are based only on the parent drug, the active metabolite N-desethylamiodarone should be present in similar concentrations to amiodarone.

Cautions

Numerous drug interactions have been observed for amiodarone. Clinical follow-up is essential for optimal use of amiodarone. Therapeutic drug monitoring for amiodarone and coadministered medications is highly recommended.

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

Clinical Reference

1. Goldschlager N, Epstein AE, Naccarelli GV, et al. A practical guide for clinicians who treat patients with amiodarone: 2007. Heart Rhythm. 2007;4(9):1250-1259
2. Klotz U. Antiarrhythmics: elimination and dosage considerations in hepatic impairment. Clin Pharmacokinet. 2007;46(12):985-996
3. Campbell TJ, Williams KM. Therapeutic drug monitoring: antiarrhythmic drugs. Br J Clin Pharmacol. 2001;52 Suppl1(Suppl 1):21S-34S
4. Milone MC, Shaw LM. Therapeutic drugs and their management. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:420-453
5. Valdes R Jr, Jortani SA, Gheorghiade M. Standards of laboratory practice: cardiac drug monitoring. Clin Chem. 1998;44(5):1096-1109
6. Joseph SP, Holt DW. Electrophysiological properties of mexiletine assessed with respect to plasma concentrations. Eur J Cardiol. 1980;11:115-121
7. Josephson ME, Buxton AE, Marchlinski FE. The tachyarrhythmias: tachycardias. In Harrison's Principles of Internal Medicine. In: Wilson JD, Braunwald E, Isselbacher KJ, et al eds. 12th ed. McGraw-Hill Book Company; 1991:915
8. Antman EM, Beamer AD, Cantillon C, McGowan N, Goldman L, Friedman PL.. Long-term oral propafenone therapy for suppression of refractory symptomatic atrial fibrillation and atrial flutter. J Am Coll Cardiol. 1988;12(4):1005-1011

Performance

Method Description

Protein is precipitated from serum using an organic solvent-based internal standard. Following centrifugation, the supernatant is diluted and analyzed by liquid chromatography tandem mass spectrometry.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 to 5 days

Specimen Retention Time

2 weeks

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

80151

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AMIO	Amiodarone, S	55152-3

Result ID	Test Result Name	Result LOINC® Value
9247	Amiodarone, S	3330-8
2485	Desethylamiodarone	6774-4