

## Overview

### Useful For

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

Evaluation of possible amiodarone toxicity

Assessment of patient compliance

### Method Name

Liquid Chromatography-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:** 1.5 mL

#### Collection Instructions:

1. Draw blood no sooner than 12 hours (trough value) after last dose or immediately before next scheduled dose.
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.

### 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	
	Frozen	28 days	
	Ambient	24 hours	

## 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.

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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 Sep;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. Rifai N, Horwath AR, Wittwer CT: In: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018

**Performance****Method Description**

Protein is precipitated from serum and 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 Saturday

**Report Available**

3 to 5 days

**Specimen Retention Time**

2 weeks

**Performing Laboratory Location**

Rochester

**Fees & Codes**

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**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 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