

## Overview

### Useful For

Monitoring digoxin therapy

### Method Name

Electrochemiluminescent Immunoassay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Patient Preparation:** For 12 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

#### Collection Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 mL

#### Collection Instructions:

1. Draw blood 6 to 8 hours after the last dose of digoxin.
2. Serum gel tubes should be centrifuged within 2 hours of collection.
3. Red-top tubes should be centrifuged, and the serum aliquoted into a plastic vial within 2 hours of collection.

### Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-[Cardiovascular Test Request Form](#) (T724)

-[Therapeutics Test Request](#) (T831)

### Specimen Minimum Volume

0.5 mL

### Reject Due To

Gross hemolysis	Reject
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	180 days	

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

Compounds in the digitalis family of glycosides consist of a steroid nucleus, a lactone ring, and a sugar. Digoxin is widely prescribed for the treatment of congestive heart failure and various disturbances of cardiac rhythm. Digoxin improves the strength of myocardial contraction, and results in the beneficial effects of increased cardiac output, decreased heart size, decreased venous pressure, and decreased blood volume. Digoxin therapy also results in stabilized and slowed ventricular pulse rate. These therapeutic effects are produced through a network of direct and indirect interactions upon the myocardium, blood vessels, and the autonomic nervous system.

Digoxin is well absorbed after oral administration and is widely distributed to tissues, especially the heart, kidney, and liver. A number of factors can alter normal absorption, distribution, and bioavailability of the drug, including naturally occurring enteric bacteria in the bowel, presence of food in the gut, strenuous physical activity, ingestion of quinine or quinidine, and concomitant use of a wide range of drugs. Children generally require higher concentrations of digoxin.

After oral administration, there is an early rise in serum concentration. Equilibration of serum and tissue levels occurs at approximately 6 to 8 hours. For this reason, blood specimens for digoxin analysis should be drawn at least 6 to 8 hours after drug administration. Digoxin is excreted primarily in the urine. The average elimination half-life is 36 to 40 hours but may be considerably prolonged in those with renal disease, causing digoxin accumulation and toxicity.

Symptoms of digoxin toxicity often mimic the cardiac arrhythmia's for which the drug was originally prescribed (eg, heart block and heart failure). Other typical symptoms of toxicity include gastrointestinal effects, such as anorexia, nausea, vomiting, abdominal pain and diarrhea, and neuropsychologic symptoms, such as fatigue, malaise, dizziness, clouded or blurred vision, visual and auditory hallucination, paranoid ideation, and depression. Toxicity of digoxin may reflect several factors: the drug has a narrow therapeutic window (a very small difference exists between therapeutic and toxic tissue levels); individuals vary in their ability to metabolize and respond to digoxin; absorption of various oral forms of digoxin may vary over a 2-fold range; susceptibility to digitalis toxicity apparently increases with age.

**Reference Values**

<16 years:

Therapeutic ranges have not been established for patients who are less than 16 years of age.

> or =16 years:

Therapeutic range: 0.6-1.2 ng/mL

Toxic concentration: > or =4.0 ng/mL

**Interpretation**

The therapeutic range is 0.6 to 1.2 ng/mL.

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Levels of 4.0 ng/mL and above may be potentially life-threatening.

**Cautions**

Patients vary in their responsiveness to the drug, and renal dysfunction permits accumulation of digoxin in the serum.

This assay measures both bound and free digoxin, so high values will be found in patients undergoing treatment with digibind (antibody fragment therapy).

"Digoxin-like" immunoreactive factors may cause falsely-elevated values in some neonates and patients with advanced liver or renal disease.(1)

In patients undergoing therapy with high biotin doses (>5 mg/day), do not draw specimens until at least 8 hours have elapsed since the last biotin administration.

**Clinical Reference**

1. Datta P, Hinz V, Klee G: Comparison four digoxin immunoassays with respect to interference from digoxin-like immunoreactive factors. *Clin Biochem.* 1996;29(6):541-547
2. Moyer TP, Boeckx RL, eds: *Applied Therapeutic Drug Monitoring.* Vol 2. American Association for Clinical Chemistry; 1984
3. Jortani SA, Voldew R Jr: Digoxin and its related endogenous factors. *Crit Rev Clin Lab Sci.* 1997;34:225-274
4. Dickstein K, Cohen-Solal A, Filippatos G, et al: ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the diagnosis and treatment of acute and chronic heart failure 2008 of the European Society of Cardiology. *Eur Heart J.* 2008;29:2388-2442
5. Milone MC, Shaw LM: Therapeutic drugs and their management. In: Rifai N, Horvath AR, Wittwer CT, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. Elsevier; 2018:800-831

**Performance****Method Description**

The cobas digoxin method is a competitive electrochemiluminescence immunoassay that employs a monoclonal antibody, directed against digoxin. Digoxin in the specimen competes with the added digoxin derivative labeled with biotin for the binding sites on the ruthenylated antibody-complex. Streptavidin-coated microparticles are added and the mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Application of voltage to the electrode induces the chemiluminescent emission, which is then measured.(Package insert: DIGOXIN. Roche Diagnostics;04/2020)

**PDF Report**

No

**Day(s) Performed**

Monday through Sunday

**Report Available**

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Same day/1 to 2 days

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Rochester

**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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

80162

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
DIG	Digoxin, S	83093-5

Result ID	Test Result Name	Result LOINC® Value
DIG	Digoxin, S	83093-5