

## Overview

### Useful For

Monitoring adequacy of serum concentration during gentamicin therapy in specimens for which no collection timing information is provided

### Method Name

Turbidimetric Immunoassay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

#### Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 0.5 mL

#### Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and aliquoted 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    Reject

### Specimen Minimum Volume

0.25 mL

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	14 days	
	Ambient		

## Clinical & Interpretive

**Clinical Information**

Gentamicin is an antibiotic used to treat life-threatening blood infections caused by gram-negative bacilli, particularly *Citrobacter freundii*, *Acinetobacter* species, *Enterobacter* species, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Providencia stuartii*, *Pseudomonas aeruginosa*, and *Serratia* species. It is often used in combination with beta-lactam therapy.

A gentamicin minimal inhibitory concentration (MIC) of less than or equal to 4.0 mcg/mL is considered susceptible for gram-negative bacilli. A MIC of less than or equal to 500 mcg/mL is considered synergistic when combined with appropriate antibiotics for treatment of serious enterococcal infections.

Conventional dosing of gentamicin is usually given 2 to 3 times per day by intravenous or intramuscular injections in doses to achieve peak blood concentration between 3.0 to 12.0 mcg/mL depending on the type of infections.

Gentamicin also may be administered at higher doses (usually 5-7 mg/kg) once per day to patients with good renal function (known as pulse dosing). Dosing amount or interval must be decreased to accommodate for reduced renal function.

Ototoxicity and nephrotoxicity are the primary toxicities associated with gentamicin. This risk is enhanced in presence of other ototoxic or nephrotoxic drugs. Monitoring of serum levels and symptoms consistent with ototoxicity is important. For longer durations of use, audiology/vestibular testing should be considered at baseline and periodically during therapy.

**Reference Values**

Gentamicin, Peak

Therapeutic: 3.0-12.0 mcg/mL

Toxic: >12.0 mcg/mL

Gentamicin, Trough

Therapeutic: <2.0 mcg/mL

Toxic: >2.0 mcg/mL

**Interpretation**

Goal peak concentrations levels depend on the type of infection being treated. Goal trough levels should be less than 2.0 mcg/mL. Peak targets are generally between 3.0 and 12.0 mcg/mL for conventional dosing. Prolonged exposure to either peak levels exceeding 12.0 mcg/mL or to trough levels exceeding 2.0 mcg/mL may lead to toxicity.

**Cautions**

Patient samples that contain the drug sisomicin will yield falsely elevated values for gentamicin. However, this drug is not usually coadministered with gentamicin.

High concentrations of penicillins or cephalosporins have been shown to inactivate gentamicin in vitro. The degree of inactivation is dependent on the particular aminoglycoside being measured, the type and concentration of the penicillin or cephalosporin that is also present and the storage conditions of the sample. For patients receiving additional antibiotics of these types, 5 to 7 samples should be assayed immediately or stored frozen.

In very rare cases, patient samples may contain heterophile antibodies, which may produce low results with the QMS Gentamicin assay.

Interfering heterophile antibodies occur at low frequency in the general population. These antibodies can cause autoagglutination of the microparticle reagent leading to undetected erroneously low results.

**Clinical Reference**

1. Hammett-Stabler CA, Johns T: Laboratory Guidelines for Monitoring of Antimicrobial Drugs. Clin Chem

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1998;44(5):1129-1140

2. Moyer TP: Therapeutic drug monitoring. In Tietz Textbook of Clinical Chemistry. Fourth edition. Edited by CA Burtis, ER Ashwood, Philadelphia, WB Saunders Company, 2006

3. Wilson JW, Estes LL: Mayo Clinic Antimicrobial Therapy Quick Guide. Mayo Clinic Scientific Press and Information Healthcare USA, 2008

## Performance

### Method Description

The assay is a homogeneous particle-enhanced turbidimetric immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the gentamicin antibody reagent. The gentamicin-coated microparticle reagent is rapidly agglutinated in the presence of the antigentamicin antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically. When a sample containing gentamicin is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained with maximum rate of agglutination at the lowest gentamicin concentration and the lowest agglutination rate at the highest gentamicin concentration. (Package insert: Roche Gentamicin reagent, Roche Diagnostic Corp, Indianapolis, IN 01/2018)

### PDF Report

No

### Specimen Retention Time

1 week

### Performing Laboratory Location

Rochester

## Fees & Codes

### 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

80170