MAYO CLINIC LABORATORIES

Test Definition: GENPA

Gentamicin, Peak, Serum

Overview

Useful For
Monitoring adequacy of drug clearance during gentamicin therapy

Method Name
Colorimetric

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
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 the serum aliquoted into a 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
0.25 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Ambient	72 hours	

	Frozen	14 days	

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 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 and 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

Peak: 3.0-12.0 mcg/mL
Toxic peak: >12.0 mcg/mL

Interpretation

Goal levels depend on the type of infection being treated. Peak targets are generally between 5.0 and 8.0 mcg/mL for less severe infections and 8.0 and 10.0 mcg/mL for severe infections. Prolonged exposure to peak levels exceeding 12.0 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 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 Informa Healthcare USA, 2008

Performance

Method Description

The CEDIA Gentamicin II Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme beta-galactosidase, which has been genetically engineered into two inactive fragments: enzyme acceptor and enzyme donor . These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically. In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of beta-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments to form active enzymes. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive beta-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed, and resultant absorbance change are directly proportional to the amount of drug present in the sample.(Package insert: CEDIA Gentamicin II Assay. Thermo Scientific; 09/2022)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 day

Specimen Retention Time

1 week

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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 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

80170

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
GENPA	Gentamicin, Peak, S	3663-2

Result ID	Test Result Name	Result LOINC® Value
GENPA	Gentamicin, Peak, S	3663-2