

Overview**Useful For**

An aid to achieving the desired plasma concentrations of plazomicin

Method Name

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

NY State Available

Yes

Specimen**Specimen Type**

Plasma

Specimen Required**Collection Container/Tube:**

Preferred: Lavender top (K2 EDTA)

Acceptable: K3 EDTA, Na EDTA, Na Citrate, Na Heparin, Li Heparin

Submission Container/Tube: Plastic vial

Specimen Volume: 1.5 mL

Collection Instructions:

1. Trough specimens are preferred for monitoring concentrations and should be drawn immediately before the next scheduled dose.
2. Spin down within 2 hours of draw. Plasma must be separated from cells 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 |
|---------------|--------------------------|---------|-------------------|
| Plasma | Refrigerated (preferred) | 28 days | |
| | Ambient | 28 days | |
| | Frozen | 28 days | |

Clinical and Interpretive

Clinical Information

Plazomicin is an aminoglycoside engineered to overcome the most prevalent aminoglycoside-modifying enzymes, which are a common aminoglycoside-resistance mechanism. Plazomicin levels are intended to be used by clinicians to support clinical decision-making in guiding appropriate dosage adjustments for patients on plazomicin therapy. The safety and effectiveness of plazomicin treatment in an individual patient should ultimately be based on clinical response.

The trough reference range represents plazomicin minimum (trough) concentrations associated with a reduced risk of nephrotoxicity. However, some patients with plasma trough concentrations outside the trough reference range may achieve a satisfactory response.

Reference Values

Complicated urinary tract infections (cUTI):

Trough Reference Range: <3 mcg/mL

(Trough=30 min before second dose, and 30 min before subsequent doses as appropriate)

Interpretation

The plazomicin drug package insert should be consulted for information regarding the utilization of plazomicin concentrations and guidance for therapeutic drug monitoring (TDM).

For patients with complicated urinary tract infections (cUTI) with creatinine clearance (CL_{cr}) values of 15 and higher, but less than 90 mL/min, monitoring of plazomicin plasma trough concentrations is recommended to avoid potentially toxic levels. For this subset of patients, it is recommended that the sample for the plazomicin minimum (trough) concentration measurement be drawn within approximately 30 minutes before administration of the second dose of plazomicin.

Plazomicin dosage should be adjusted to avoid trough levels above 3 mcg/mL. Modeled plazomicin trough concentrations from 377 patients with cUTI in Phase 2 and Phase 3 trials have been determined to range from 0.1 to 3.3 mcg/mL (5-95 percentile range) with a median and geometric mean of 0.8 and 0.7 mcg/mL, respectively. Measured plazomicin trough concentrations by liquid chromatography-tandem mass spectrometry (LC-MS/MS) for 274 trough samples in the Phase 3 Study ACHN-490-009 resulted in similar values (0.2 to 5.7 mcg/mL 5-95 percentile range; 1.1 mcg/mL median and geometric mean). For effective treatment, some patients may require plasma levels outside of these ranges. Therefore, the expected ranges are provided as guidelines, and individual patient results should be interpreted with the aid of the dosage adjustment algorithms in the plazomicin drug package insert and in the context of the patient's other clinical signs and symptoms.

Cautions

No significant cautionary statements

Clinical Reference

1. McKinnell JA: Improved outcomes with plazomicin compared with colistin in patients with bloodstream infections caused by carbapenem-resistant enterobacteriaceae (CRE): Results from CARE study. Poster 1853 IDWeek October 4-8, 2017. San Diego, CA
2. Golan Y et al. Improved outcomes at late follow-up with plazomicin compared with meropenem in patients with complicated urinary tract infections (cUTI) or acute pyelonephritis in the EPIC study. Poster 1859 IDWeek October 4-8, 2017. San Diego, CA
3. Cloutier, D: Plazomicin versus meropenem for complicated urinary tract infection and acute pyelonephritis: diagnosis-specific results from the phase 3 EPIC study. Poster 1855 IDWeek October 4-8, 2017. San Diego, CA
4. Zhanel GG: Comparison of the next-generation aminoglycoside plazomicin to gentamicin, tobramycin, and amikacin. *Expert Rev Anti Infect Ther* 2012;10(4):459-73
5. Begg EJ: A suggested approach to once-daily aminoglycoside dosing. *Br J Clin Pharmacol* 1995;39:605-609

Performance**Method Description**

Plazomicin is extracted from plasma samples and the supernatant is analyzed by an in-house developed liquid chromatography-tandem mass spectrometry (LC-MS/MS) method.(Unpublished Mayo method)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Sunday; Varies

Analytic Time

Same day/1 day

Maximum Laboratory Time

1 day

Specimen Retention Time

14 Days

Performing Laboratory Location

Rochester

Fees and 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 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 U.S. Food and Drug Administration.

CPT Code Information

80299

LOINC® Information

| Test ID | Test Order Name | Order LOINC Value |
|---------|-----------------|-------------------|
| PLAZO | Plazomicin, P | 92024-9 |

| Result ID | Test Result Name | Result LOINC Value |
|-----------|------------------|--------------------|
| 65855 | Plazomicin, P | 92024-9 |