

**TEST CHANGE**

**Leflunomide Metabolite, Serum or Plasma**

2007460, LEFLUMETSP

**Specimen Requirements:**

**Patient Preparation:** Timing of specimen collection: Predose (trough). Obtain specimen 12 - 24 hours after last dose.

**Collect:** Plain red. Also acceptable: Lavender (EDTA), pink (K2EDTA), green (sodium heparin), or gray (sodium fluoride).

**Specimen Preparation:** Separate from cells within 2 hours of draw. Transfer 1 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.2 mL)

**Transport Temperature:** Refrigerated. Also acceptable: Room temperature or frozen.

**Unacceptable Conditions:** Whole blood. Potassium oxalate or separator tubes.

**Remarks:**

**Stability:** Ambient: 7 days; Refrigerated: 17 days; Frozen: 90 days

**Methodology:** [High-Performance](#)-Liquid Chromatography-Tandem Mass Spectrometry

**Performed:** Sun, Wed, Fri

**Reported:** 1-~~7~~<sup>6</sup> days

**Note:**

**CPT Codes:** 80193

**New York DOH Approval Status:** This test is New York DOH approved.

**Interpretive Data:**

Therapeutic and toxic ranges are not well established. Concentrations greater than 40.000 µg/mL tend to correlate with improved patient outcome. A proposed therapeutic range is 50.000 - 100.000 µg/mL. Adverse reactions to Leflunomide, such as diarrhea, hypertension, and liver toxicity, do not correlate well with serum drug concentrations. Leflunomide has a potential risk for teratogenesis. For women being treated with Leflunomide who desire to become pregnant, enhanced drug elimination should be performed until plasma teriflunomide concentrations are lower than 0.020 µg/mL on two separate tests taken at least 14 days apart.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Reference Interval:

|                   |                           |
|-------------------|---------------------------|
| Therapeutic Range | Greater than 40.000 ug/mL |
| Toxic Level       | Not well established.     |

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