

## TEST CHANGE

### Clozapine and Metabolites, Serum or Plasma, Quantitative

2013433, CLOZAP SP

#### Specimen Requirements:

**Patient Preparation:** Timing of specimen collection: Predose(trough) draw ~~2-2~~ at steady ~~2~~-state concentration.

**Collect:** Plain red. Also acceptable: Lavender (K2 or K3EDTA) or pink (K2EDTA).

**Specimen Preparation:** Separate serum or plasma from cells within 2 hours of collection. Transfer 1 mL serum or plasma to an ARUP standard transport tube. (Min: 0.5 mL)

**Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Whole blood. Gel separator tubes, light blue (citrate), or yellow (SPS or ACD solution).

#### Remarks:

**Stability:** After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 3 months

**Methodology:** Quantitative Liquid Chromatography-Tandem Mass Spectrometry

**Performed:** Sun-Sat

**Reported:** 1-5 days

#### Note:

**CPT Codes:** 80159

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

#### Interpretive Data:

~~The Therapeutic ranges are not well established. Clozapine is metabolized to norclozapine and clozapine-N-oxide. Clozapine concentrations between 100 and 700 ng/mL may correlate more with clinical response; however, nonresponsiveness may also occur within this range. For refractory schizophrenia, clozapine concentrations greater than 350 ng/mL are suggested to achieve a therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration, response.~~

**Toxicity:** Adverse effects to clozapine therapy may include tachycardia, hematologic disorders, neuroleptic malignant syndrome, elevation of liver enzymes, drowsiness, hypotension, and



seizures, and tardive dyskinesia.

Therapeutic and toxic ranges are not well established in children.  
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:

Test Number	Therapeutic Range Toxic Level	Not well established Total Clozapine and Metabolites: Greater than or equal to 1500 ng/mL	Components	Reference Interval
			Clozapine-N-Oxide, S/P, Quant	Therapeutic and toxic ranges are not well established
			Norclozapine, S/P, Quant	Therapeutic and toxic ranges are not well established
			Clozapine, S/P, Quant	
				Therapeutic Range: 350-600 ng/mL Toxic: Greater than or equal to 1000 ng/mL

Deleted Cells

Inserted Cells

Inserted Cells