

TEST CHANGE

Clozapine and Metabolites, Serum or Plasma, Quantitative

2013433, CLOZAP SP

Specimen Requirements:

Patient Preparation: Timing of specimen collection: ~~Pre-dose~~ **Pre-dose** (trough) draw - ~~at~~ **At** steady ~~s~~-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.~~ **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~~ **5-weeks**; Refrigerated: ~~1 week~~ **2-months**; Frozen: ~~3~~ **2** months

Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Performed: Sun-Sat

Reported: 1-3 days

Note:

CPT Codes: 80159

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

Interpretive Data:

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~~ **non-responsiveness** may also occur within this range. For refractory schizophrenia, clozapine concentrations greater than 350 ng/mL are suggested to achieve a therapeutic response.

Toxicity: Adverse effects to clozapine therapy may include tachycardia, drowsiness, hypotension, and seizures.

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:

Therapeutic Range	Not well established
Toxic Level	Total Clozapine and Metabolites: Greater than or equal to 1500 ng/mL