TEST CHANGE

Tacrolimus by Tandem Mass Spectrometry

0090612, TACRO

Specimen Requirements:	
Patient Preparation:	Predose~~Pre-dose~~ (trough) levels should be drawn.
Collect:	Lavender (EDTA) or pink (K2EDTA).
Specimen Preparation:	Transport 1 mL whole blood. (Min: 0.25 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Serum or plasma. Specimens left at room temperature for longer than 24 hours. Clotted specimens.
Remarks:	
Stability:	Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Tacrolimus (Prograf) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable, and the measured tacrolimus whole blood concentration depends on the methodology used. Reference ranges may vary according to the specific immunoassay or HPLC-MS/MS test. Generally, immunoassays have been reported to have a positive bias relative to HPLC-MS/MS assays due to the detection of antibody cross-reactivity with tacrolimus metabolites.
CPT Codes:	80197
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Therapeutic range is based on a whole blood specimen drawn 12 hours postdose~~post-dose~~ or prior to next dose (the trough). The optimal therapeutic range for a given patient may differ from this suggested range based on the indication for therapy, treatment phase (initiation or maintenance),

use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

~~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:

Effective February 18, 2014

	Therapeutic Range:
Kidney transplant:	0-3 months post-transplant: 7.0-20.0 ng/mL 3 months and older: 5.0-15.0 ng/mL
Heart transplant:	0-3 months post-transplant: 10.0-20.0 ng/mL 3 months and older: 5.0-15.0 ng/mL
Liver transplant:	1-12 months post-transplant: 5-20 ng/mL
Toxic value:	Greater than 25 ng/mL