TEST CHANGE

Sirolimus by Tandem Mass Spectrometry

0098467, RAPAMUNE

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: 1 week; Frozen: 2 months
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Sirolimus (Rapamune) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable and the measured sirolimus 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 sirolimus metabolites.
CPT Codes:	80195
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

A range of 12-20 ng/mL has been suggested for liver transplant. 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 (in combination with Cyclosporine):	4-12 ng/mL
Toxic value:	Greater than 25 ng/mL