TEST CHANGE

Everolimus by Tandem Mass Spectrometry

0092118, EVEROLIMUS

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 weeks
Methodology:	Quantitative Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	1-2 days ~~Within 24 hours~~
Note:	Everolimus (Zortress, Certican, Afinitor) whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable, and the measured everolimus whole blood concentration depends on the methodology used, and reference ranges may vary according to specific immunoassay or HPLC/MS/MS test. Generally, immunoassays have been reported to have a positive test bias relative to HPLC-MS/MS assays, due to the detection of antibody cross-reactivity with everolimus metabolites.
CPT Codes:	80169
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Everolimus marketed as Zortress is FDA approved for prophylaxis of organ rejection in adult patients receiving a kidney and liver transplant.

Everolimus marketed as Afinitor is FDA approved for the treatment of renal cell carcinoma and for the treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) in patients who are not candidates for curative surgical resection. The suggested therapeutic range for treatment of SEGA is 5-15 ng/mL, which is based on a predose (trough) specimen.

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):	3-8 ng/mL
Liver transplant (in combination with Tacrolimus):	3-8 ng/mL
Toxic value:	Greater than 15 ng/mL