SIROLIMUS (RAPAMUNE)  
LABP000093

Beginning 12/8/2015 the Toxicology Section of the Department of Pathology and Laboratory Medicine will change methodologies for Sirolimus (RAPAMUNE). The switch will be from the liquid chromatography-mass spectrometry (LC/MS/MS) method to the Abbott ARCHITECT i1000 Sirolimus Chemiluminescent Microparticle Immunoassay.

The Abbott Architect i1000 values were higher than the LC/MS/MS method by approximately 1.76 ng/mL throughout the concentration range during validation studies.

**Once we begin patient testing, we will baseline all specimens. The LC/MS/MS result will be reported in a comment attached to the Sirolimus Abbott ARCHITECT result. We will continue to baseline these patients for 1 month, ending on 1/8/2016. Sufficient sample volume must be submitted for dual testing – 2.0 mL.**

**Sample Requirements:**

**Collect:**  
EDTA (4 mL) Minimum sample volumes of EDTA whole blood is 0.5 mL (2.0 mL total during from 12/8/2015 – 1/8/2016 for baseline testing).

**Patient Preparation:**  
Sample should not be drawn from any line through which the drug has been infused. Contact pharmacy for specific procedure for drawing samples from a central line.

**Specimen Preparation:**  
DO NOT SPIN

**Storage/Transport:**  
Transport EDTA tube at 2-8°C if sample will not reach lab on same day. Stability of whole blood: Room temperature 24 hours, 2-8°C for 7 days, and frozen for 2 months.

**Unacceptable Conditions:**  
Any specimen other than EDTA whole blood, specimens where plasma has been removed, clotted specimens, heat inactivated specimens or specimens with obvious microbial contamination.

**Reference Interval:**  
4 – 20 ng/mL  
Optimal ranges depend upon the patient's clinical state, individual differences in sensitivity to immunosuppressive and adverse effects of Sirolimus, co-administration of other immunosuppressants, and time post-transplant. The stated therapeutic range is based on a trough sample in maintenance phase, for kidney transplants on Sirolimus in combination with Cyclosporin A (CsA) as well as Sirolimus alone.

**Routine Testing:**  
2 days a week on day shift; Tuesday and Friday

If you have questions or need additional information please contact Laboratory Client Services at (916) 734-7373 or email pathologyclientservices@ucdmc.ucdavis.edu.