Beginning 08/17/2015 the Toxicology Section of the Department of Pathology and Laboratory Medicine will change methodologies for Cyclosporin. The switch will be from the High Performance Liquid Chromatography (HPLC) method to the Abbott ARCHITECT i1000 Cyclosporin Chemiluminescent Microparticle Immunoassay.

The Abbott ARCHITECT assay is used by over 50% of the clinical labs that submit results for CAP surveys. Manufacturer results compared the ARCHITECT method to LC/MS/MS with a slope of 0.93, an intercept of -24.65, and a correlation coefficient of 0.99. The 95% confidence interval of the ng/mL difference bias was 33.4 ng/mL to 56.4 ng/mL.

In house validation studies showed the Abbott ARCHITECT assay to recover results higher than the previous HPLC assay. Abbott ARCHITECT values appear to be higher by approximately 30-35% throughout the concentration range, with a large variance in bias between individual samples. This variance did not appear to be related to individual patients, but rather individual samples. In house Abbott ARCHITECT results compared to HPLC with a slope of 1.31, an intercept of 9.59, and a correlation coefficient of 0.97. Positive bias between immunoassay methods and HPLC due to metabolite cross reactivity is commonly recognized.

Once we begin patient testing, we will baseline all specimens. The HPLC result will be reported in a comment attached to the Cyclosporin Abbott ARCHITECT result. We will continue to baseline these patients for 2 months, ending on 10/17/2015. 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 8/17/15 – 10/17/15 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
**Unacceptable Conditions:** Any specimen other than EDTA whole blood, clotted specimens, heat inactivated specimens or specimens with obvious microbial contamination.

**Reference Interval:** 50 – 500 ng/mL

Generally recommended trough values vary between 50 and 500 ng/mL. This broad range has been adopted by the UCDHS lab with the comments stated below:

No firm therapeutic range exists for Cyclosporin in whole blood. The complexity of clinical state, individual differences in sensitivity to immunosuppressve and nephrotoxic effects of Cyclosporin, co-administration of other immunosuppressants, type of transplant, time post-transplant, and a number of other factors contribute to different requirements for optimal blood levels of Cyclosporin. Therefore, individual Cyclosporin values cannot be used as the sole indicator for making changes in treatment regimen and each patient should be thoroughly evaluated clinically before changes in treatment regimens are made. Users must establish their own ranges based on clinical experience.

**Routine Testing:** 7 days a week on day shift

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