Effective August 12, 2013, the clinical laboratory will change methodologies for Tacrolimus (FK506). The switch will be from the Diasorin PRO-TRAC II FK506 ELISA to the Abbott ARCHITECT Tacrolimus Chemiluminescent Microparticle Immunoassay. Tacrolimus levels are used to help maintain effective immunosuppression.

The Abbott ARCHITECT assay is used by over 75% of the clinical labs that submit results for CAP surveys. Manufacturer results compared the ARCHITECT method to LC/MS/MS with a slope of 1.07, an intercept of 0.22, and a correlation coefficient of 0.92. The 95% CI for ng/mL difference bias was 0.31 to 0.71 ng/mL.

In house validation studies showed the Abbott ARCHITECT assay to recover results lower than the previous ELISA assay. Deming regression studies showed the Abbott ARCHITECT method when compared to the ELISA to have a slope of 0.75 with a y-intercept of 2.4 ng/mL. The correlation coefficient was 0.96.

**Reference Interval:**
Dependent upon individualized treatment protocol.
Many factors influence the determination of appropriate tacrolimus blood levels at any individual transplant center and for any single patient. The results from an update of the Lake Louise Consensus indicate that whole blood concentrations of tacrolimus should be monitored and blood levels should be maintained in the range of 5 to 15 ng/mL for optimal efficacy and minimal toxicity in kidney transplant recipients. Higher concentrations are associated with an increased incidence of adverse effects.³

**Acceptable sample types will continue to be:**
EDTA whole blood: 4 mL

**Testing performed in:**
Specially Testing Center Toxicology/Special Chemistry Department daily. Specimens should be received in SESP lab by 10 am.


For clinical and technical questions please call Dr. Ishwarlal Jialal (734-6590) or Teri Cook (734-0283). For other questions or additional information please contact Laboratory Client Services at 916-734-7373 or email pathologyclientservices@ucdmc.ucdavis.edu.