



MEMORANDUM

To: All Regional Medical Laboratory, Inc. (RML) Clients
From: Regional Medical Laboratory, Inc.
Ryan Hatley, MHA, C(ASCP)^{CM}, Manager of Chemistry
Caitlin Schein, MD, Clinical Director, RML Central Laboratory Chemistry and LCMS
Departments
Date: April 16, 2018
Subject: Transplant Assay Re-baseline Studies

In late May 2018, RML will transition **Cyclosporine** and **Tacrolimus** testing by immunoassay to the Abbott *i* System which utilizes chemiluminescent microparticle immunoassay (CMIA) technology. The Abbott *i* System will bring workflow efficiencies and improved assay performance compared with existing processes while maintaining high sensitivity and specificity. RML currently offers Cyclosporine and Tacrolimus testing by cloned enzyme donor immunoassay (CEDIA) and quantitative microsphere system (QMS) immunoassay, respectively.

Patient **Tacrolimus** results will be lower by approximately 16% using the new assay, and new therapeutic ranges will reflect this. Therapeutic ranges may vary depending on type of transplant, concomitant immunosuppression therapy, clinical/institutional protocol, and time elapsed since transplant, and further depends on appropriate timing (trough sample immediately before a scheduled dose). Suggested therapeutic range for Tacrolimus by CMIA is 5.0-15.0 ng/mL, and results should be interpreted in conjunction with the clinical context and any signs or symptoms of rejection or toxicity.

Patient **Cyclosporine** results within therapeutic range correlate very well between CEDIA and CMIA, therefore no change will be made to interpretive data for this assay.

From **April 23rd** through **May 21st**, RML will assay and report results from both methods together to facilitate re-baselining of patients who are subject to long-term monitoring. During this time, the patient will be charged for only the current assay.

Ordering and collection information for these tests will remain the same.

Tests Included during Re-baseline Period	Mnemonic	Order Code
Tacrolimus with Tacrolimus Rebase	PROGRAF	4503275
Cyclosporine with Cyclosporine Rebase	CYCLOSPORN	3604000
Cyclosporine Peak with Cyclosporine Rebase	CYCLO PEAK	2015325
Cyclosporine Trough with Cyclosporine Rebase	CYCLO TROU	2015525

If you have any questions or concerns about this update, please contact Dr. Caitlin Schein or Ryan Hatley at 918-744-2553.