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UChicago Medicine

Clinical Laboratories

To: Medical Staff, House staff, Nursing Staff, Patient Care Centers, and Outpatient Clinics

From: Clarence Chan, MD, PhD, DABCC
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Date: 8/29/2025

Subject: Tacrolimus Testing Method Change at UCM Clinical Chemistry Lab - Hyde Park

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Effective Date: 9/3/2025

Laboratory Section: Chemistry

Summary:

Effective September 3, 2025, the Hyde Park Clinical Chemistry Laboratory will implement tacrolimus testing by immunoassay (IA) on our automation lines, replacing the current mass spectrometry-based method.

Key Changes and Rationale:

- *Improved Turnaround Time:* Tacrolimus testing by immunoassay will be performed daily in multiple batches at predetermined intervals, established in coordination with Pharmacy, resulting in significantly improved turnaround times compared with the current method and workflow.
- *Analytical Performance:* In-house studies have demonstrated that the immunoassay method performs reliably and compares favorably with mass spectrometry, particularly in the trough range. The tacrolimus reference range will remain unchanged.
- *Sensitivity:* The immunoassay has a lower limit of quantification of 0.8 ng/mL, making it more sensitive than the current method.

Test Information:

Test Name [Procedure] (Code): Tacrolimus, Immunoassay [LABCHTACROI] (878757)
Availability: Batched testing performed 24 hours/day, 7 days/week
Acceptable Specimen Types: EDTA whole blood (lavender-top tubes)
Clinically Reportable Range: 0.8–90.0 ng/mL
Reference Range (Trough): 5-20 ng/mL

Important Consideration:

The tacrolimus immunoassay is susceptible to biotin interference, which may cause a positive bias in reported results. In our validation studies, specimens with biotin concentrations up to 100 ng/mL demonstrated ≤10% bias. Patients should be advised to avoid biotin supplementation for at least 2 days prior to testing whenever possible.

If there are any questions regarding this change, please contact:

The UCM Clinical Chemistry Lab – Hyde Park at 773-702-1772.
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