





MEMORANDUM # 109

TO: UNC Hospitals Attending Physicians, Housestaff, Nursing Coordinators,
Department Heads and Supervisors

FROM:  Catherine Hammett-Stabler, PhD, Director, Core Laboratory
 Herbert C. Whinna, MD, PhD, Director, McLendon Clinical Laboratories

DATE: August 28, 2012

SUBJECT: **Core Laboratory Announces a change in the method for Methotrexate Monitoring**

The Core Laboratory announces a change in the method used for methotrexate monitoring. Beginning August 28, 2012 patient samples will be tested using a new immunoassay manufactured by ARK Diagnostics, Inc. The assay received FDA approval earlier this year and provides better specificity compared to the previous methods used in the laboratory.

Samples from patients currently receiving or completing a methotrexate cycle will be tested using the old method. Patients just starting a cycle will be tested using the new method.

Assay specifications include:

- No cross-reactivity with 7-hydroxymethotrexate, the major metabolite of MTX. This is an improvement over previous methods available which were found to have some (low) cross-reactivity.
- Less cross-reactivity reported with potentially co-administered drugs. There is slight cross-reactivity with triamterene (2-3%) and trimethoprim (0.2-0.5%).
- Less interference from hemolysis, icterus and lipemia.
- Significant cross-reactivity is seen with the minor metabolite, 2,4-diamino-N10-methylptericoic acid (DAMPA). Cross-reactivity ranges from 60-100% with this metabolite. For this reason, this immunoassay should not be used when glucarpidase (carboxypeptidase G2) rescue is used as the concentration of DAMPA can be high. In these cases, testing using LC tandem MS is preferred; however, there are few laboratories using this methodology. Please notify the laboratory when glucarpidase rescue is anticipated to be used.

Collection criteria is unchanged: 2 mL royal blue top, plain red top tube or bullet (no gel).
Protocols typically recommend collection at 24, 47, and 72 hours post dose.

Testing is available stat and routine 24 hours /7 days per week.

Therapeutic recommendations are the same and dependent on dose and time.

Reference Ranges and more information on second page.

Reference Ranges: Methotrexate

Collection Time (Hrs. post dose.)	Therapeutic ($\mu\text{m/L}$)*	Toxic ($\mu\text{m/L}$)
24	<10.0	>10.0
48	<1.0	>1.0
72	<0.1	>0.1
	* Dependent upon malignancy and treatment protocol.	

For questions, please contact Dr. Catherine Hammett-Stabler, Core Laboratory Director, 966-3724.