

MEMORANDUM # 67

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

FROM: David G. Grenache, Ph.D., Associate Director, Core Laboratory
John F. Chapman, Dr.PH, Director, Core Laboratory
Mark Brecher, M.D., Director, McLendon Clinical Laboratories

DATE: January 11, 2007

SUBJECT: Serum free light chain assay

Quantitative testing for serum free light chains will be performed in the Core Laboratory effective January 18, 2007. Previously this test was sent out to Mayo Medical Laboratories.

This assay has been cleared by the FDA for diagnosis of monoclonal gammopathy in conjunction with serum protein electrophoresis and for monitoring response to treatment and relapse. The specificity of this assay for the detection of monoclonal light chains relies on the calculated ratio of free kappa to free lambda light chains. The reference ranges for each are: kappa (κ), 0.33–1.94 mg/dL; lambda (λ), 0.57–2.63 mg/dL and the κ/λ ratio: 0.26-1.65.

There are methodological differences between the Core Lab and Mayo which may affect the absolute concentrations of both kappa and lambda free light chains. This is most pronounced at light chain concentrations >100 mg/dL with our method returning results that are ~30% lower for both kappa and lambda light chains. Importantly, there is little effect on the κ/λ ratio (see table).

The κ/λ ratio determined from 78 patient specimens analyzed at Mayo and UNCH.

		Mayo Medical Laboratories		
		<0.26	0.26-1.65	>1.65
UNC Core Laboratory	<0.26	9	0	0
	0.26-1.65	1 ^a	28	0
	>1.65	0	7 ^b	33

^aRatio was 0.17 at Mayo and 0.29 at UNCH.

^bRatios ranged from 1.65 to 2.30.

There is no change in specimen collection requirements. The test will be performed on Tuesday and Thursday each week. Upon request, we will provide a one time comparison to the previous method at no additional cost through April 18, 2007. To receive this parallel testing an add-on requisition indicating the request for testing at Mayo must be faxed to the Core Lab (966-9490).

Please contact Dr. David Grenache (966-3726) or the Core Laboratory (966-2361) for additional information.