



UNC  
HEALTH CARE

**MEMORANDUM #104**

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

**FROM:** Catherine Hammett-Stabler, Ph.D., Director, Core Laboratory *CS*  
Herbert C. Whinna, M.D., Director, McLendon Clinical Laboratories *HW*

**SUBJECT: Discontinuation of TDx FLM Assay for Fetal Lung Maturity**

**DATE:** January 4, 2012

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After nearly 30 years in existence, Abbott Diagnostics has decided to discontinue manufacturing of the **TDx FLM assay** for fetal lung maturity (Test number 1257, alternate name is Fetal Lung Maturity surfactant/albumin ratio). The Core Laboratory expects to discontinue the test on January 31, 2012, or earlier dependent upon available supplies.

Two tests for the assessment of fetal lung maturity remain available:

Lamellar Body Count (LB), Test number 1177, 0.5 mL amniotic fluid, available stat, 24 h/d - this is an in-house developed method that uses the Advia 2120 Automated Hematology Cell Counter (Siemens Healthcare Diagnostics) to quantify the number of lamellar bodies present in the sample. Numerous outcome studies have shown LBC methods to have diagnostic sensitivities of 83 -100% and diagnostic specificities of 54-89%. In these studies, the clinical performance of the LBC has been similar to the TDx FLM. Since the two tests measure different parameters, results from one do disagree with the other from time to time. Studies performed at UNCH lead to the adoption of  $\geq 35,000$  counts/microliter as suggestive of probable maturity. Results vary considerably between different hematology cell counters and the cutoff specific to the testing laboratory should be used when interpreting the results. Samples should be placed in a plastic-screw cap tube and transported to the laboratory as soon as possible after amniocentesis.

PG Amniostat , Test number 1155, 2 mL amniotic fluid, available stat, 24 h/d – this slide agglutination method (Irvine Scientific) detects the compound phosphatidyl glycerol in amniotic fluid. PG, when present  $\geq 0.5$  microgram/ mL, correlates with lung maturity. PG is one of the last indicators of lung maturity to rise during gestation. The primary use is for complicated near-term cases in which the amniotic sample is not suitable for LB counts (due to blood, or other contamination). Samples should be placed in a plastic-screw cap tube and transported to the laboratory as soon as possible after amniocentesis.

For more information or questions, please contact Dr. Catherine Hammett-Stabler or Margaret Gearhart at 966-2361.