DIAGNOSTIC LABORATORY SERVICES, INC.

Memorandum

To: Clients / DLS Staff

From: Dr. Wesley J. Kim

Date: May 7, 2012

Subject: Troponin I

Cardiac Troponin is presently the preferred biomarker for the detection of myocardial injury. The current definition of myocardial infarction is the presence of a cardiac biomarker (preferably troponin) level above the 99th % of the upper reference limit, together with evidence of myocardial ischemia as evidenced by at least one of the following: clinical symptoms of ischemia, pathologic changes on EKG, or imaging evidence of myocardial damage or loss. In some cases, serial sampling may be required to detect the typical temporal rise and fall of troponin levels characteristic of an MI. In the case where an increased value for troponin is present, but other evidence of myocardial ischemia is absent, a careful search for other possible etiologies for cardiac injury is warranted.

Beginning May 21, 2012, DLS will be changing from the current Beckman Access platform, to a new manufacturer's platform for measuring TnI. The new Abbott Architect Troponin I assay is a chemiluminescent microparticle immunoassay that allows the quantitative measurement of cTnI in either serum or plasma. The assay shows improved analytical sensitivity, good precision performance, and does not require a separate EDTA plasma sample to analyze as the current platform requires. Testing can now be performed on the same lithium heparin plasma tubes or serum tubes used for other general chemistry tests. The analytic assay time is 15 minutes.

The recommended 99th % cutoff for the current assay is < 0.05 ng/mL. Based on the manufacturer's data and our own in-house validation studies, TnI values on the new Abbott TnI assay are essentially equivalent in numerical value with no statistically significant bias pattern compared to the current assay. Based on this correlation and a limited reference range verification in-house study, the reference range cutoff for normal versus abnormal is not going to change and will remain at < 0.05 ng/mL. At that cutoff, the assay shows good precision, with an approximate CV of 10%.

Ordering Information

Test Name	Test Code	CPT
Troponin I (TNI)	4586	84484

Specimen Requirements:

- Optimum volume: 1.0 ml
- Lithium Heparin plasma (Green) or Serum in SST (Gold)

Specimen rejection: Hemolyzed, lipemic, thawed, insufficient quantity, older than stability limits.

Processing: If testing is delayed more than 8 hours, remove plasma or serum from the cells, clot or gel. Store refrigerated up to 72 hours. Or freeze for up to 30 days.

Transport: Prior to shipping, remove the plasma or serum from the cells, clot or gel.

- Transport refrigerated (Oahu)
- Transport frozen (Airline)

Specimen stability:

- Refrigerated (2-8 °C) for up to 3 days
- Frozen for up to 30 days

STAT Turnaround Time: 1 hour (from receipt in lab to result release)

If you have any questions please contact DLS client services at 589-5101 or Dr. Wesley J Kim at 589-5131.