

Lab Updates

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April/May 2011

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Changes in Troponin I Reference Range

Cardiac Troponin (cTn) has emerged as the preferred biomarker for diagnosing myocardial infarction and for risk stratification of acute coronary syndrome (ACS). New, more sensitive Troponin assays hold the promise of earlier diagnosis of ACS as well as better risk stratification. As the assays have become more sensitive, the current recommendations on which cutoff to use have not been adopted universally. Presently, some labs use the ROC cut point, others the 10% CV, while others use the recommended cutoff of the 99th percentile.

NACB and IFCC Committee for standardization of markers for cardiac damage in 2007 recommended that assays for cardiac biomarkers should strive for a total imprecision (%CV) of <10% at 99th percentile limit.

2007 Joint ESC/ACCF/AHA/WHF Task Force defined the criteria for AMI, "Detection of rise and/or fall of cardiac biomarkers (preferably Troponin) with at least one value above the 99th percentile reference limit together with evidence of ischemia with at least one of the following:

- Symptoms of ischemia
- ECG changes indicative of new ischemia (new ST-T changes or new LBBB)
- Development of pathological Q waves in the ECG
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality



Photo: Kevin Vance

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UMass Memorial Clinical Laboratories performs Troponin I testing by Beckman Access Immunoassay. Based on the validation and performance studies, the total imprecision of <10% at 99th percentile is at 0.04 ng/mL. Currently it is flagged as 0.03 ng/mL. **Effective May 16, 2011**, the reference range will be changed to 0.04 ng/mL.

Troponin -I		
Interpretation	Result	Critical Range
Normal	≤ 0.04 ng/mL	≥ 0.50 ng/mL
Grey Zone	0.05 – 0.49 ng/mL	
AMI	≥ 0.50 ng/mL	



If you have questions, comments or suggestions, please contact:

- Dr. L.V. Rao, Director of Core Laboratories at 774-442-9615 or via email at Lokinendi.Rao@umassmemorial.org
- Ms. Judy Barron, Manager of Automated Chemistry at 774-442-9616 or via email at Judy.Barron@umassmemorial.org

Change in Laboratory Testing for D-Dimer

Effective May 3, 2011, the Hematology Laboratory will be using a new reagent for reporting the D-dimer assay. The INNOVANCE™ D-Dimer assay from Siemens Healthcare Diagnostics will replace the current Advanced D-Dimer reagent. This change will allow for the following:

- Consistent cut-off of 0.50 mg/L FEU between instruments
- Minimal susceptibility to interfering substances
- Higher specificity
- Validated high sensitivity and negative predictive value
- Excellent precision

In a multicenter study using INNOVANCE D-Dimer at a clinical cut-off of 0.50 mg/L FEU, the Negative Predictive Value of 98% was established for ED patients with clinically suspected VTE evaluated using the Wells Pretest Probability Model and diagnosed by standard objective tests.

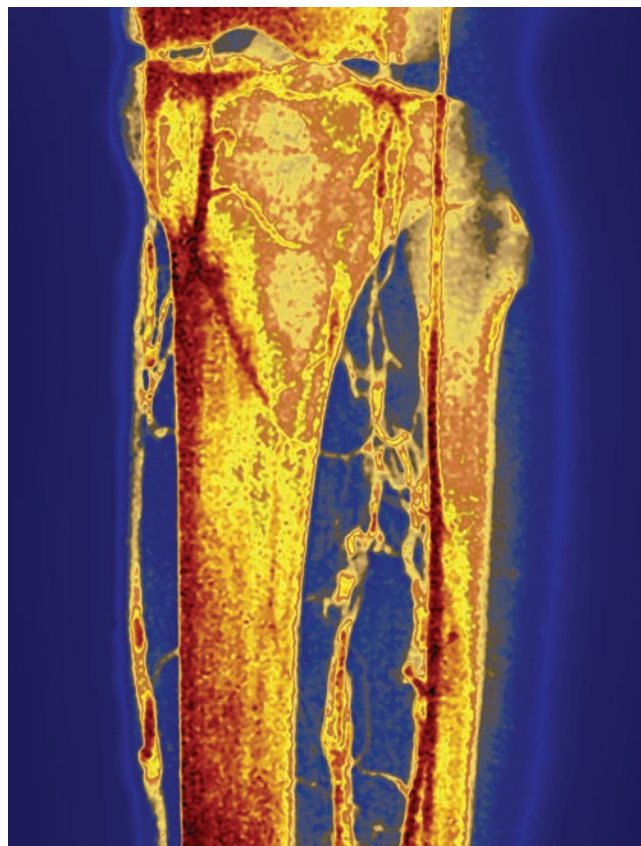
The INNOVANCE D-Dimer assay is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

With this new method, the following will be reported out with patient results:

Clinical Cut off: 0.50 mg/L FEU

A very low percentage of patients with DVT may yield D-dimer results below the cut-off of 0.50 mg/L FEU. This is known to be more prevalent in patients with distal DVT.

- ▶ **Please Note: Results of D-dimer assays should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.**



If you have questions, comments or suggestions, please contact:

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This publication is made possible by Kevin Vance, Senior Director, Business Development and Marketing

Total T4 in Pregnancy

The manufacturer of Total T4 assay has informed us that the levels of total T4 in pregnant women could be low (20%) when use Beckman Access Total T4 assay. Because of this potential for low recovery in this specific population, they recommend that Total T4 assay should not be used as the **only** marker for evaluating pregnant patients for thyroid disorders. All other Thyroid assays (TSH, FREE T4, Total T3, Free T3, T uptake) are not affected.

ACOG, AACE, ATA guidelines recommend that assessment of thyroid function during pregnancy be performed using TSH and assessment of free, and not total thyroid hormones, with clinical evaluation of the patient's symptoms.

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