

DIAGNOSTIC SERVICES OF MANITOBA SERVICES DE DIAGNOSTIC DU MANITOBA



## High-Sensitivity Troponin T (hsTnT)

A new assay for high-sensitivity troponin will be implemented in Winnipeg and Brandon on **December 12, 2011**.

The new assay is a modification of the 4<sup>th</sup> generation cTnT assay. The detection antibody was genetically reengineered, with a region in the monoclonal mouse FAB fragment being replaced with a human region. This reduces the susceptibility to interferences by heterophilic antibodies. Sensitivity and precision are greatly improved.

The universal revised definition of Acute Myocardial Infarction (AMI) requires a rise and/or fall of troponin to be demonstrated in patients with the symptoms of acute coronary syndrome (ACS), with at least one value above the 99<sup>th</sup> percentile of the upper reference level measured with a coefficient of variation (CV) of <10%. The hsTnT assay is the first to meet this required level of sensitivity and precision.

The 99<sup>th</sup> percentile is **14 ng/L**. This is also the level at which <10% variation is reached.

4th genera		hsTNT		signifi	significant $\Delta$ change		
0.01	mcg/L		14	ng/L	7	ng/L	
0.03	mcg/L	_	40	ng/L	50%	6 at 99th %ile	

While there is no current consensus recommendations for the hsTnT delta change in serial sampling, there is strong evidence to support an absolute change of **7 ng/L** (or 50% at the 99<sup>th</sup> ile) in samples measured **2 hours** apart.

	AUC (95% CI)	Р	ROC Cutoff	Sensitivity	Specificity	PPV	NP
cTnT							
< 0.014 $\mu$ g/L at presentation							
1 h (n=540, 7 with AMI)							
Absolute change ( $\Delta$ )	0.85 (0.61-1.00)	0.027	0.004	86	95	19	10
Relative change ( $\Delta$ %)	0.83 (0.59-1.00)		45	86	90	10	9
2 hours (n=396, 6 with AMI)							
Absolute change (A)	0.98 (0.96-1.00)	0.052	0.005	100	95	22	10
Relative change (A%)	0.95 (0.91-0.99)		39	100	86	10	10

Measurement of hsTnT may be considered at the time of presentation, at 6 hours, and at 8-9 hours after the onset of pain. Repeat measurements may be performed at 2 hour intervals.

Results down to 3 ng/L will be reported. While there is preliminary evidence that a level of <3 ng/L at presentation may have a NPV of 99.4%, this cannot be recommended until a consensus is reached to use such an early rule-out approach.



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All levels of >14 ng/L are significant. However, a rising level is required in order to diagnose an acute NSTEMI. An elevated troponin may be due to renal insufficiency, chronic cardiac conditions, pericarditis, pulmonary embolism and a number of other conditions. For more detailed information on how to interpret troponin measurements, please refer to the MB Guideline: <u>http://www.dsmanitoba.ca/professionals/files/MBTroponinGuideline.pdf</u>

Critical values for TnT are currently called for all patients except those currently in critical care areas, but including all Emergency patients discharged prior to test reporting. The critical value for the 4<sup>th</sup> generation TnT assay was >0.03 mcg/L, the critical value for the hsTnT assay will be >40 ng/L.

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