



Implementation date:

November 9, 2020

Sites involved:

North East Community Hospital,
Westview Health Centre,
Strathcona Community Hospital, and
Leduc Community Hospital
University of Alberta Hospital (switched to Roche hs-TnT assay in June 2022),
Royal Alexandra Hospital (switched to Roche hs-TnT assay in September 2022)
Misericordia Hospital (switched to Roche hs-TnT assay in July 2022)
Grey Nuns Hospital (switched to Roche hs-TnT assay in July 2022)
Sturgeon Hospital (switched to Roche hs-TnT assay in June 2022)

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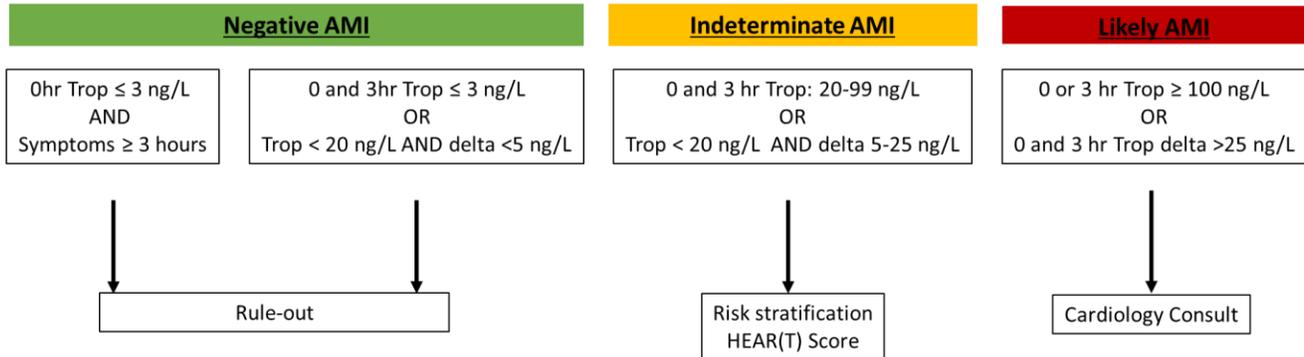


1. Background on hs-TnI and diagnosis of AMI

- Chest pain is a common emergency department (ED) presentation.
- History, physical, ECG and cardiac biomarker testing are the gold standards for diagnosing acute coronary syndrome (ACS).
- In most urban EDs, effective and efficient approaches to STEMI exist.
- For NSTEMI and chest pain NYD, practice variation is widespread.
- For many years 0- and 6-hour conventional troponin (Tn) testing has been the standard testing practice; however, with the advent of high-sensitivity tests (hs-Tn), accelerated protocols have become widely implemented.
- Rapid protocols have been adopted in EDs around the world using hs-Tn. Moreover, Calgary has successfully implemented a rapid protocol using hs-TnT.
- The new troponin assay to be adopted in Edmonton is called Beckman Coulter high sensitivity Troponin I (hs-TnI). The Beckman hs-TnI assay has improved analytical performance, especially at low levels, compared to the older conventional TnI assay¹⁻³.
- Hs-TnI assays allows for more accurate and precise troponin results at very low levels, which permits for the use of an accelerated chest pain algorithm for rapid rule-out/ rule-in of AMI.
- Adoption of hs-TnI also permits a threshold of detection to be more precise.
- The use of the hs-TnI assay has significant implications for EDs by enabling more sensitive detection of significant cardiac events, as well as decreasing time to reach a clinical decision.
- Based on clinical trials in the literature, the Beckman hs-TnI assay has a clinical sensitivity and negative predictive value for rule out AMI of 97-99%, and 99.6%, respectively⁴⁻⁶. The clinical specificity and positive predictive value for rule-in AMI is 95-99% and 60-74%, respectively^{1,4-6}.
- The new hs-TnI reporting protocol will involve reporting results in **ng/L** (compared to the previous **µg/L**).
- All sites with either conventional TnI or hs-TnI will be reporting values in ng/L.
- The new hs-TnI protocol recommended for use in the Edmonton zone will utilize troponin testing at time point zero and three hours, thereby effectively halving the time currently needed in some EDs.
- This will allow more rapid decision making for the clinician and decreased wait time for patients.

2. Edmonton rapid chest pain protocol

The below schematic outlines the Edmonton rapid chest pain protocol using the Beckman hs-TnI assay.



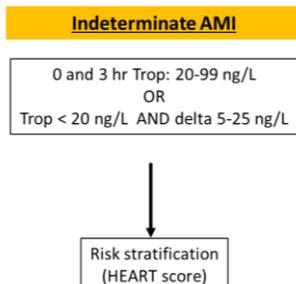
- Assuming biomarkers are collected at least 3 hours following the start of chest pain/symptoms suggestive of ACS:
 - Levels of \leq 3 ng/L are considered safe for rule-out with a single test.
 - Levels of \geq 100 ng/L are considered safe for rule-in;
 - Levels of 4-99 are indeterminate and need additional hs-TnI testing in 3 hours to determine the delta (or change) in hs-TnI:
 - Delta < 5 ng/L are safe for rule-out;
 - Delta 5 – 25 ng/L require risk stratification using HEAR(T) score;
 - Delta > 25 are considered rule-in.
- **Negative AMI** patients (expected ~70% of cases) – follow-up with regular primary care provider.
- **Likely AMI** patients (expected ~10% of cases) – consult Cardiology.
- **Indeterminate AMI** category (expected ~20% of cases) – risk stratify:
 - Low Risk HEAR(T) Score – outpatient referral for EST/maximize medical management;
 - Moderate Risk HEAR(T) Score – suggested outpatient referral for **urgent stress testing**;
 - High-Risk HEAR(T) Score – consultation with Cardiologist.
- HEART SCORE⁷
 - Clinical decision rule allowing rapid risk stratification of undifferentiated chest pain patients, according to their short-term risk for a Major Adverse Cardiac Event (MACE).
 - Cumulative score 0 – 10 of increasing risk for MACE.
 - MACE defined as all-cause mortality, myocardial infarction, or coronary revascularization within 30 days.
 - HEAR(T) categories (MACE Risk):
 - 0-3 = low risk (1-2%);
 - 4-6 = moderate risk (12-17%);
 - 7-10 = high risk (50-65%).

Caution: HEART score not validated with hs-TnI.

- Modified HEART Score → HEAR
 - A study published this year in the *Emerg Med Journal* by Smith, LM *et al.* looked to stream line assessment of low risk chest pain patients⁸. This study examined assessing patients without incorporating troponin results (HEAR).
 - The HEART score utilizes conventional troponin assays, which will no longer apply with the adoption of the new assay.
 - In order to assist in risk stratifying the patients that fall into the Indeterminate category with respect to the hs-Tn values we propose utilizing the HEAR aspects of the HEART score: History, ECG, Age, Risk Factors.

History	<table border="1"> <tr><td>Slightly suspicious</td><td>0</td></tr> <tr><td>Moderately suspicious</td><td>+1</td></tr> <tr><td>Highly suspicious</td><td>+2</td></tr> </table>	Slightly suspicious	0	Moderately suspicious	+1	Highly suspicious	+2
Slightly suspicious	0						
Moderately suspicious	+1						
Highly suspicious	+2						
EKG 1 point: No ST deviation but LBBB, LVH, repolarization changes (e.g. digoxin); 2 points: ST deviation not due to LBBB, LVH, or digoxin	<table border="1"> <tr><td>Normal</td><td>0</td></tr> <tr><td>Non-specific repolarization disturbance</td><td>+1</td></tr> <tr><td>Significant ST deviation</td><td>+2</td></tr> </table>	Normal	0	Non-specific repolarization disturbance	+1	Significant ST deviation	+2
Normal	0						
Non-specific repolarization disturbance	+1						
Significant ST deviation	+2						
Age	<table border="1"> <tr> <td><45</td> <td>0</td> <td>45-64</td> <td>+1</td> <td>≥65</td> <td>+2</td> </tr> </table>	<45	0	45-64	+1	≥65	+2
<45	0	45-64	+1	≥65	+2		
Risk factors Risk factors: HTN, hypercholesterolemia, DM, obesity (BMI >30 kg/m ²), smoking (current, or smoking cessation ≤3 mo), positive family history (parent or sibling with CVD before age 65); atherosclerotic disease: prior MI, PCI/CABG, CVA/TIA, or peripheral arterial disease	<table border="1"> <tr><td>No known risk factors</td><td>0</td></tr> <tr><td>1-2 risk factors</td><td>+1</td></tr> <tr><td>≥3 risk factors or history of atherosclerotic disease</td><td>+2</td></tr> </table>	No known risk factors	0	1-2 risk factors	+1	≥3 risk factors or history of atherosclerotic disease	+2
No known risk factors	0						
1-2 risk factors	+1						
≥3 risk factors or history of atherosclerotic disease	+2						

- Patients in Indeterminate category for rapid chest pain protocol:



- Low Risk HEAR(T) Score (0-3 points) – outpatient referral for EST/maximize medical management;
- Moderate Risk HEAR(T) Score (4-6 points) – if dynamic ST and T-wave changes identified in the ED, cardiology consultation is recommended. If not, outpatient referral for **urgent (< 48 hour)** cardiac testing/maximize medical management, or consultation with Cardiology Staff if testing cannot be reliably obtained;
- High-Risk HEAR(T) Score (7-10 points) – consultation with Cardiologist.



3. Clinical Vignettes

Case #1

49 yo female presents to the ED with stuttering epigastric/retrosternal chest pain over the past day. She denies having had pain like this before. She identifies nausea and mild shortness of breath with the pain. She is pain free in the ED when assessed. She states that she is otherwise healthy and is a non-smoker. You identify her to be PERC negative and you do not identify any concerning features on her ECG. Hs-TnI comes back at ≤ 3 ng/L (**Negative AMI**). She has a family doctor and you can discharge her back into his/her care.

Case #2

64 yo male brought in by EMS with left sided chest pain that began last night and the patient tried to sleep it off. The patient has had chest pain NYD in the past, often with exertion, and states that this pain feels very similar to those events. The ECG indicates non-specific ST segment changes. The hs-TnI test is reported as 137 ng/L (**Likely AMI**). You initiate NSTEMI management and consult Cardiology.

Case #3

61 yo female presents to the ED with chest pain that began four hours ago while the patient was at work. She has T2DM, hypertension and is still smoking cigarettes but she tells she is trying to quit. You do not note any specific changes on the ECG, possibly hyperacute T waves. You send off a cardiac workup, place the patient on cardiac monitoring, ask for a repeat ECG and order ASA. Initial hs-TnI comes back at 51 ng/L (**Indeterminate AMI**). You are managing this patient's discomfort and order a 3 hour troponin. Your repeat ECG does not show any ST segment elevation, but you wonder about possibly some subtle depression evolving. Repeat hs-TnI is 75 ng/L. This result still remains below the 100 ng/L cutoff, and the delta is 24 ng/L (**5-25 ng/L**), which keeps her within the indeterminate range of the chest pain protocol. Using the HEAR assessment, the patient is scored as $1+1+1+2 = 5$, which puts her in the moderate risk category. You place a call to Cardiology on call who agrees with you and assists in arranging a stress test for this patient for the following morning.

4. Laboratory changes to troponin reporting

Sites using the Beckman hs-TnI method in conjunction with the rapid chest pain protocol

- North East Community Hospital
- Westview Health Centre
- Strathcona Community Hospital
- Leduc Community Hospital



**High Sensitivity Troponin I (hs-TnI) Survival Guide: What you need to know
for the Edmonton hs-TnI rapid chest pain protocol**

Summary of overall changes to troponin reporting using Beckman hs-TnI method:

	Old TnI reporting	New hs-TnI reporting	Notes
Units	µg/L (decimal places)	ng/L (whole numbers)	0.15 µg/L = 150 ng/L
Reference intervals	0.04 µg/L, except UAH 0.15 µg/L at UAH only	< 20 ng/L	Result will flag “high” if hsTnI ≥ 20 ng/L
Reporting limits	0.04 to 27 µg/L, except 0.10 to 27 µg/L at UAH only	3 to 27,000 ng/L	-
Delta value	Not reported	Reported	Reported if a previous hs-TnI value on the same patient and method is within 6 hours
Comments	None	Pathway comments Method identification comments	-

Interpretive comments reported with hsTnI results:

Hs-TnI result (ng/L)	Comment	Flagging
≤ 3	High sensitivity troponin I is below detection limit. Acute myocardial injury is unlikely. If symptoms present for 3 hours or less, repeat in 3 hours.	Normal
4-19	High sensitivity troponin I (hsTnI) is detectable, but does not confirm acute myocardial injury. If clinically indicated, repeat hsTnI in 3 hours for evaluation of delta (change) and risk assessment of acute myocardial injury: Delta 0-4 ng/L: acute myocardial injury ruled out; Delta 5-25 ng/L: acute myocardial injury is indeterminate (risk assessment with HEAR(T) score); Delta >25 ng/L: acute myocardial injury is possible. Outpatient coronary risk stratification in patients with symptoms of stable angina.	Normal
20-99	High sensitivity troponin I (hsTnI) is moderately elevated, but does not confirm acute myocardial injury. If clinically indicated, repeat hsTnI in 3 hours for evaluation of absolute value and delta (change) for risk assessment of acute myocardial injury: Delta: 0-4 ng/L – acute myocardial injury is unlikely (risk assessment with HEAR(T) score); Delta: 5-25 ng/L – acute myocardial injury is indeterminate (risk assessment with HEAR(T) score); Delta >25 ng/L – acute myocardial injury is possible. Outpatient coronary risk stratification in patients with symptoms of stable angina.	High
≥ 100	High sensitivity troponin I is elevated, consistent with acute myocardial injury.	High



Sites using the Siemens Stratus conventional TnI assay

Note: This assay is not hs-TnI. Result cannot be used in conjunction with the rapid chest pain protocol. The only change at these sites are switching of units to ng/L.

- East Edmonton Health Centre
- Devon Community Hospital
- Fort Saskatchewan Community Hospital
- Redwater Health Centre

Summary of overall changes to troponin reporting at Siemens Stratus TnI sites:

	Old reporting	New reporting	Notes
Units	µg/L (decimal place)	ng/L (whole number)	0.15 µg/L = 150 ng/L
Reference intervals	0.15 µg/L	150 ng/L	No change
Reporting limits	0.10 to 27 µg/L	100 to 27,000 ng/L	No change
Delta value	Not reported	Not reported	-
Comments	No	Method identification comments	-

Community/outpatient troponin collected at DynaLIFE or hospital labs:

- Outpatient/community troponin will be only be phoned to the ordering provider based on the following thresholds:
 - Hospital sites using Beckman hsTnI: > 100 ng/L
 - Hospital sites using Siemens Stratus conventional TnI: >150 ng/L (no change)
 - DynaLIFE: > 45 ng/L

5. Screen shot examples of hs-TnI reports

Epic Chart Review screenshot

Note: a similar reporting format will be seen for Netcare and EDIS reports

The screenshot displays a Troponin I report with the following details:

- Component:** Troponin I, High Sensitivity
- Ref Range & Units:** <20 ng/L
- Result:** 150 ^ (Elevated)
- Comment:** High sensitivity troponin I is elevated, consistent with acute myocardial injury.
- Method Used:** Beckman high-sensitivity troponin I. **WARNING:** Different methods give potentially significantly different numerical values. Do not compare results from method to method.
- Delta:** 6
- Resulting Agency:** EDM UAH LAB
- Specimen Collected:** 25/09/20 14:31
- Last Resulted:** 25/09/20 16:32

Navigation links at the bottom include: Lab Flowsheet, Order Details, View Encounter, Lab and Collection Details, Routing, and Result History.

6. References

1. Christenson, R.H., et al., Analytical and clinical characterization of a novel high-sensitivity cardiac troponin assay in a United States population. *Clinical biochemistry*, 2020. 83: p. 28-36.
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4. Nestelberger, T., et al., Two-Hour Algorithm for Rapid Triage of Suspected Acute Myocardial Infarction Using a High-Sensitivity Cardiac Troponin I Assay. *Clinical chemistry*, 2019. 65(11): p.1437-1447.
5. Beckman Access hsTnI Clinical Information Bulletin
6. Greenslade, J.H., et al., Diagnostic Accuracy of a New High-Sensitivity Troponin I Assay and Five Accelerated Diagnostic Pathways for Ruling Out Acute Myocardial Infarction and Acute Coronary Syndrome. *Annals of emergency medicine*, 2018. 71(4): p. 439-451 e3.



7. Six A.J., Backus B.E., Kelder J.C. Chest pain in the emergency room: value of the HEART score. *Neth Heart J.* 2008;16:p.191–196.
8. Smith LM, et al. Identification of very low-risk acute chest pain patients without troponin testing *Emerg Med J* 2020;0:p.1–6.