ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Laboratory Bulletin

DATE:	14 November 2023
TO:	Edmonton Zone – Physicians, Nurses, and Managers
FROM:	Edmonton Zone, Alberta Precision Laboratories (APL)
RE:	**Implementation of Beckman High Sensitivity Troponin I (hs-TnI) and new 2-hr Chest Pain Pathway at specified Edmonton Zone sites**

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- On **November 20, 2023**, 4 Edmonton Zone sites currently using Siemens Stratus conventional Troponin I assays will switch to Beckman high sensitivity troponin I (hs-TnI) assay and the new 2-hr Beckman hs-TnI chest pain pathway. This will apply to:
    - Devon General Hospital (DEV)
    - East Edmonton Health Centre (EEHC)
    - Fort Saskatchewan Community Hospital (FSH)
    - Redwater Health Centre (RED)
- The Beckman hs-TnI assay requires sample collection in lime green Barricor™ blood collection tubes instead of light green PST tubes. For additional information refer to: Order of Draw and Order of Transfer PA03-005 (albertahealthservices.ca), and Appendix 1.
- At the same time, 4 other Edmonton sites currently using Beckman hsTnI assay and 3-hr chest pain pathway will adopt the new 2-hr chest pain pathway for Beckman hs-TnI (same assay):
    - Leduc Community Hospital (LEH)
    - Northeast Community Health Centre (NEC)
    - Strathcona Community Hospital (SPK)
    - Westview Health Centre (STO)
- The change will involve a new reference interval (i.e., assay's 99th percentile upper reference limit), reporting limits, rule-in/rule-out cut points, delta values, critical limits and interpretative comments (see Table 2, Table 3, Figure 1).

Table 1. Implementation of Beckman hsTnI assay and 2-hr Chest Pain pathway in Edmonton Zone

Site	Current Assay	Current Pathway	New Assay	New Pathway
DEV EEHC FSH RED	Siemens Stratus conventional troponin I	N/A	Beckman hs-TnI	2-hr Beckman hs-TnI
LEH NEC SPK STO	Beckman hs-TnI	3-hr Beckman hs-TnI	No change	2-hr Beckman hs-TnI

- At Edmonton Zone sites with the Beckman hsTnI assay, for troponin collected in the outpatient/community setting only, critical troponin I levels (≥ 50 ng/L) will be phoned to the ordering provider (Table 2).
- There will be no changes to Edmonton sites that have Roche hs-TnT assay (University of Alberta Hospital, Misericordia Community Hospital, Grey Nuns Community Hospital, Royal Alexandra Hospital, Sturgeon Community Hospital).

Why this is important

- Implementation of Beckman hs-TnI is part of a large-scale provincial project to standardize chemistry instrumentation. Adoption of this 2-hr Beckman hs-TnI chest pain pathway with rapid rule-in/rule-out will gradually expand across the province.
- This initiative will reduce the variation of hs-Tn assays and chest pain protocols in the province.
- These changes will assist clinicians with evidence-based interpretation of troponin results and guide optimal patient management in conjunction with this chest pain pathway.

Background

- Evidence supports that a 2-hr chest pain pathway for Beckman hs-TnI is effective and safe for rule-in/rule-out of acute myocardial infarction (AMI).[1]
- Changes are consistent with clinical practice guidelines and are recommended by the Cardiovascular Health and Stroke Strategic Clinical Network (SCN), in consultation with Emergency Medicine SCN and Laboratory Medicine provincially.
- **SCN Recommendation:** A 2-hour hs-TnI pathway, including a single undetectable hs-TnI concentration at the time of ED arrival to rule out MI in patients with an onset of symptoms greater than 3h prior to presentation, be included in reporting and decision support for the Beckman hs-TnI assay.

Action Required

- For sites transitioning from Siemens Stratus conventional TnI to Beckman hs-TnI be aware of the changes in assay, container type, and reporting. Collect samples for Beckman hs-TnI in Barricor tubes.
    - Be aware of the following requirements for the Barricor tube:
        - Drawing of blood into a syringe followed by transfer into the Barricor via a metal needle is UNACCEPTABLE. This practice risks puncturing the tube's mechanical separator.
        - Order of draw is PST first, followed by Barricor.
        - Add-on requests will be considered on a case-by-case basis.
    - Ensure unit carts are stocked with an adequate supply of Barricor tubes. Warehouse product number: 324476
- Be familiar with laboratory reporting changes and the new 2 hr chest pain pathway.
- Be aware of different troponin assays used within the Edmonton Zone (Appendix 2). Do not interpret results across sites with different assays.

Questions/Concerns

- Dr. Miranda Brun, Clinical Biochemist, DEV, EEHC, FSH, LEH, NEC, RED, SPK, STO
780-722-4123 or Miranda.brun2@aplabs.ca

ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Approved by

- Dr. Kareena Schnabl, Section Chief, Clinical Biochemistry, North Sector, APL
- Dr. Michael Mengel, Medical Director, North Sector, APL
- Dr. Michael D. Hill, MD MSc FRCPC, Senior Medical Director – Cardiovascular SCN, AHS

References

1. Nestelberger T. et al., Clin Chem (2019)

Effective September 1, 2023, APL has become the sole provider of all public lab services in Alberta. As a result, community lab services formally provided by DynaLIFE Medical Labs will become the responsibility of Alberta Precision Labs (APL). This change impacts all zones.

Table 2: Summary of new reporting for the Beckman hs-TnI assay

	Siemens Stratus (Current)	3-hr Chest Pain Pathway (Current)	2-hr Chest Pain Pathway (New)	Notes
Sites	DEV EEHC FSH RED	LEH NEC SPK STO	DEV EEHC FSH RED LEH NEC SPK STO	
Collection tube	Lithium heparain PST (light green)	Barricor PST (lime green)	Barricor PST (lime green)	Refer to Appendix 2
Rapid Chest Pain Pathway	N/A	3-hour	2-hour	
Units	ng/L (whole numbers)	ng/L (whole numbers)	ng/L (whole numbers)	N/A
Reference interval	<150 ng/L	<20 ng/L	<18 ng/L	99th percentile of assay Values above this limit will be flagged as high
Critical value	N/A	≥100 ng/L	≥ 50 ng/L	Only outpatient/community troponin critical values will be phoned to the ordering provider
Reporting limits	100 ng/L to 27 000 ng/L	3 ng/L to 27 000 ng/L	3 ng/L to 260 000 ng/L	Reportable range extended
Delta Value	none	Reported for 0-3 hr delta	Reported for 0-2 hour delta	Reported if a previous hs-TnI value on the same patient and same method is within 4 hours
Comments		Pathway interpretative comments And Method identification comments	Pathway interpretative comments And Method identification comments	Interpretative comments have changed (Table 3)

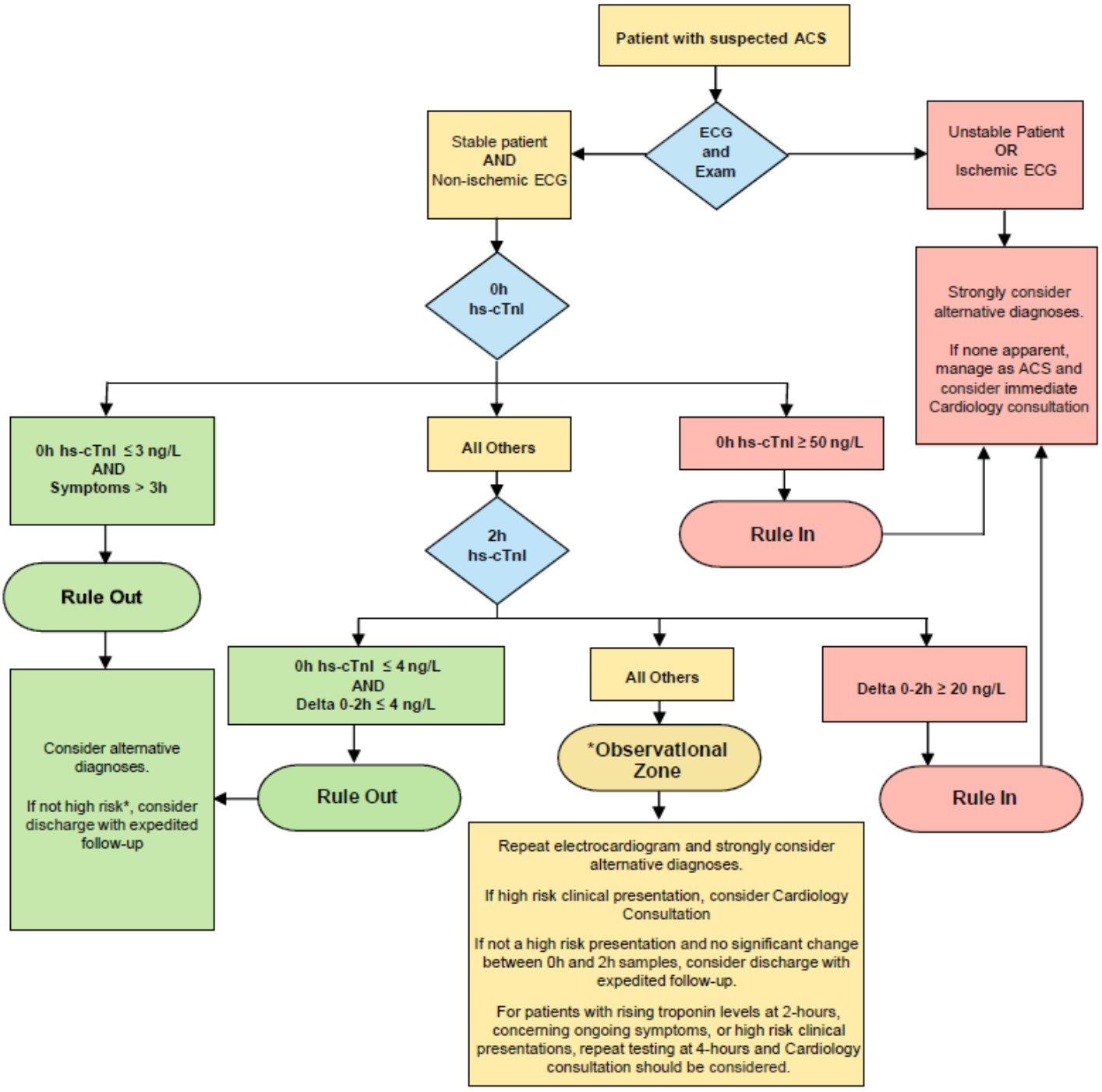
Table 3: Interpretative comments reported with Beckman hs-TnI

hs-TnI result (ng/L)	Comment	Flagging
≤ 3	For patients with a non-ischemic ECG, a Troponin I, High Sensitivity of 3 ng/L or less on presentation is highly sensitive for excluding acute myocardial infarction, provided the specimen was collected more than 3-hours from symptom onset. However, for patients with symptoms less than 3-hours duration or concerning clinical presentations, repeat troponin testing at 2-hours after the initial sample is recommended. Please note that patients with ischemic ECG changes and/or high-risk clinical presentations should be considered for further evaluation irrespective of troponin results.	Normal
4-17	Troponin I, High Sensitivity is below the upper reference limit (18 ng/L) and results are not consistent with myocardial infarction (MI) or injury. However, patients with acute symptoms (less than 6-hours) or concerning clinical presentations should undergo repeat troponin testing at 2-hours after the initial sample. - Troponin I, High Sensitivity of 4 ng/L or less on presentation AND a 2-hour delta (change) of 4 ng/L or less is highly sensitive for excluding acute myocardial infarction (MI) - A 2-hour delta (change) of 5-19 ng/L may indicate acute myocardial injury. - A 2-hour delta (change) of 20 ng/L or more suggests an acute myocardial injury and may represent acute myocardial infarction in the appropriate clinical scenario. Please note that patients with ischemic ECG changes and /or high-risk clinical presentations should be considered for further evaluation irrespective of troponin results.	Normal
18-49	Troponin I, High Sensitivity has a non-specific/non-diagnostic elevation. Interpretation is highly dependent on clinical presentation and patient history. New elevations are concerning; however, many patients have chronic elevations in troponin and measured concentrations near the patient's baseline are reassuring. However, patients with acute symptoms (less than 6-hours) or concerning clinical presentations should undergo repeat troponin testing at 2-hours after the initial sample. - A 2-hour delta (change) of 4 ng/L or less is highly sensitive for excluding acute myocardial infarction. - A 2-hour delta (change) of 5-19 ng/L may indicate acute myocardial injury. - A 2-hour delta (change) of 20 ng/L or more suggests an acute myocardial injury and may represent acute myocardial infarction in the appropriate clinical scenario.	High

	Please note that patients with ischemic ECG changes and /or high-risk clinical presentations should be considered for further evaluation irrespective of troponin results.	
≥50	Clear elevation of Troponin I, High Sensitivity consistent with acute myocardial injury or infarction in the appropriate clinical context. Repeat troponin testing at 2-hours after the initial sample may be helpful to assess for ongoing myocardial injury.	Critical

ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Figure 1. New 2-hr Chest Pain Pathway for Beckman hs-TnI outlining the risk management of patients present with suspected acute myocardial infarction in the acute care setting.



ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Figure 1. Continued

Note:

* For all patients with abnormal hs-cTnI results, check the medical record for prior results. Many patients have stable abnormalities in hs-cTnI and measured concentrations similar to the patient's baseline are reassuring.

ESC 2015 Guidelines advise that patients are unlikely to have an acute MI if:
- hs-cTn < Upper Limit of Normal (i.e., hs-cTnI < 18 ng/L) **AND,**
- >6hrs since symptom onset **AND,**
- pain-free **AND,**
- the clinical presentation is Low Risk.

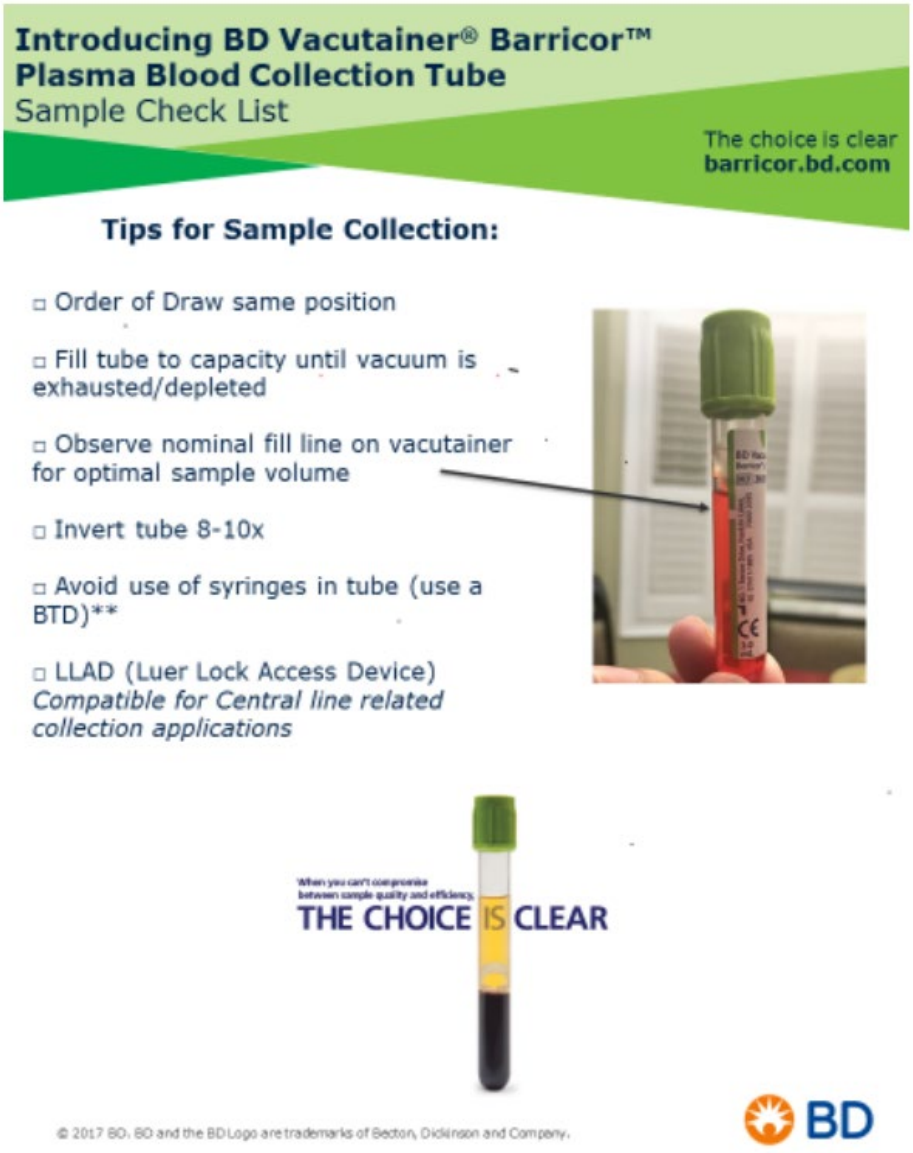
However, coronary ischemia has not been definitively excluded and unstable angina must be considered. Disposition after a single hs-cTnI < 18 ng/L should only be considered for low risk patients with >6 hrs since symptom onset and should be used cautiously.

All patients presenting less than 6-hours since symptom onset, with active symptoms or presentations that are not clearly low risk should have repeat hs-cTnI testing at 2 hours. For patients with rising troponin levels at 2-hours, concerning ongoing symptoms, or high risk clinical presentations, repeat testing at 4-hours and Cardiology consultation should be considered. Consider using a structured risk assessment tool such as the HEART score to aid risk stratification for all patients.

HEART Score Calculation				
History		Highly suspicious	2	
		Moderately suspicious	1	
		Slightly suspicious	0	
ECG		Significant ST-depression	2	
		Non-specific repolarization disturbance, LBBB, LVH, Paced	1	
		Normal	0	
Age		≥ 65 years	2	
		45 – 64 years	1	
		≤ 44 years	0	
Risk Factors	☐ Diabetes ☐ Current smoker ☐ HTN (diagnosed) ☐ HL (diagnosed) ☐ Family hx CAD ☐ Obesity	≥ 3 risk factors or history of atherosclerotic disease	2	
		1 or 2 risk factors	1	
		No risk factors known	0	
hs-cTnI (peak)		> 3x normal limit (55ng/L or greater)	2	
		1-3x normal limit (18-54ng/L)	1	
		< normal limit (<18ng/L)	0	
		Total (10 maximum)		

HEART Score Interpretation	
Low Risk	0-3
Moderate Risk	4-6
High Risk	7-10

Appendix 1. Collection in Barricor blood collection tubes



ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Appendix 2. Summary of different troponin assays in Edmonton Zone as of November 20, 2023

Different assays are not comparable and should not be used for trending.

Site	Troponin assay	Chest Pain Protocol
University of Alberta Hospital	Roche hs-TnT	2-hr hsTnT (Roche)
Royal Alexandra Hospital		
Grey Nuns Community Hospital		
Misericordia Community Hospital		
Sturgeon Community Hospital		
Devon General Hospital	Beckman hs-TnI	2-hr hs-TnI (Beckman)
East Edmonton Health Centre		
Fort Saskatchewan Community Hospital		
Leduc Community Hospital		
Northeast Health Centre		
Redwater Health Centre		
Strathcona Community Hospital		
Westview Health Centre		
Edmonton Base lab (formerly DynaLIFE)	Siemens Attelica hs-TnI	Not applicable