ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Laboratory Bulletin

DATE:	27 November 2023
TO:	North Zone – Physicians, Nurses, and Managers
FROM:	North Zone, Alberta Precision Laboratories (APL)
RE:	**Implementation of Beckman Access 2 Instruments - High Sensitivity Troponin I (hs-TnI) with 2-hr Chest Pain Pathway, quantitative serum beta HCG and BNP**

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- Effective **December 11, 2023**, Alberta Precision Labs will begin the implementation of a new chemistry immunoassay instrument, Beckman Access 2, across nineteen (19) rural hospitals in the North Zone.
    - Sites going live on December 11, 2023: Athabasca, Beaverlodge, Bonnyville, Hinton, Mayerthorpe, Westlock
- All nineteen sites will offer the Beckman high sensitivity troponin I (hs-TnI) assay with a 2-hr Beckman hs-TnI chest pain pathway.
- Some sites will offer B-natriuretic peptide (BNP) and/or quantitative serum beta-HCG (bHCG).

Table 1. Beckman Access 2 Instruments in North Zone with Test Menu and Implementation Timeline

Site	Test menu	Implementation Date
Athabasca	hsTnI, BNP	**December 11, 2023**
Barrhead	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*
Beaverlodge	hsTnI, bHCG	**December 11, 2023**
Bonnyville	hsTnI, bHCG, BNP	**December 11, 2023**
Cold Lake	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*
Edson	hsTnI, bHCG, BNP	***To be determined (est. Spring 2024)*
Fairview	hsTnI, bHCG	***To be determined (est. Spring 2024)*
Fort Vermilion*	hsTnI, bHCG, BNP	***To be determined (est. Spring 2024)*
High Level*	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*
High Prairie	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*
Hinton	hsTnI, bHCG	**December 11, 2023**
Lac La Biche	hsTnI, bHCG, BNP	***To be determined (est. Spring 2024)*
Mayerthorpe	hsTnI, BNP	**December 11, 2023**
Peace River	hsTnI, bHCG	***To be determined (est. Spring 2024)*
Slave Lake	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*
St. Paul	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*
Valleyview	hsTnI	*To be determined (est. Spring 2024)*
Westlock	hsTnI, bHCG, BNP	**December 11, 2023**
Whitecourt	hsTnI, bHCG, BNP	***To be determined (est. early 2024)*

* Due to more significant changes in methodology, site specific communication will follow.
** Sites not going live on December 11th will receive a site specific memo to communicate exact date of implementation.

- Troponin:
  - 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.
  - The change will involve new units of measure, 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).
  - At 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). The lab will not phone any troponin results for hospital patients (including ER patients and inpatients).
  - Sites not listed, or not yet implemented will continue with their current methodologies and are not impacted by this change.

- Quantitative serum beta HCG
  - Sites impacted on December 11th: Beaverlodge, Bonnyville, Hinton, Westlock
  - Quantitative serum beta HCG will replace the current iSTAT method used in the North Zone.
  - All quantitative beta HCG's collected on site will be performed locally. This is a change from current practice, where only samples done for ruling out ectopic pregnancies are tested on site.
    - Exception: Peace River will move from Minividas to Beckman Access 2. Site specific communication to follow.
  - There is a bias between different quantitative beta HCG methods. The Beckman Access method does not compare to the other methods in Alberta and should not be used for trending.

- B-natriuretic Peptide (BNP)
  - While methodology will be changing at some sites, collection tube type and reference intervals are not changing. Methodology change is of no clinical impact.

Why this is important

- The provincial rural immunoassay analyzer project is a large-scale provincial project which will improve access to vital laboratory testing in many of Alberta's rural hospitals and improve standardization in instrumentation.
- Adoption of the 2-hr Beckman hs-TnI chest pain pathway with rapid rule-in/rule-out cut points is gradually expanding across the province and improving flow of patients through emergency rooms.
- This initiative will reduce the variation of troponin 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.
- On site access to quantitative beta-HCG with improved turnaround time supports women's health and management of people presenting with pregnancy complications

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]

- The recommended pathway is consistent with clinical practice guidelines and is 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

- Troponin:
    - Please 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.
        - In locations where nursing staff perform collections, 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 North Zone (Appendix 2). Do not interpret results across sites with different assays.

- Quantitative beta HCG:
    - Please be aware of the change in methodologies. Patients having serial monitoring at the time of transition may need a new baseline for comparison.

Questions/Concerns

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Approved by

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References

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

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

	iSTAT conventional Troponin I (Current)	Beckman hs-TnI 2-hr Chest Pain Pathway (New)	Notes
Collection tube	Lithium heparain PST (light green)	Barricor PST (lime green)	Refer to Appendix 2
Rapid Chest Pain Pathway	N/A	2-hour	
Units	ug/L (2 decimels)	ng/L (whole numbers)	Units are changing by a factor of 1000x
Reference interval	<=0.04 ug/L	<18 ng/L	99th percentile of assay Values above this limit will be flagged as high
Critical value	>0.10 ug/L	≥ 50 ng/L	Only outpatient/community troponin critical values will be phoned to the ordering provider
Reporting limits	0.02 ug/L to 50 ug/L	3 ng/L to 260 000 ng/L	Reportable range extended
Delta Value	none	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	Interpretive 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	Normal

	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.	
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, provided that more than 6 hours have passed from the onset of symptoms. Patients less than 6-hours from onset or who have concerning clinical presentations should undergo repeat troponin testing 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 and suggest an additional troponin measurement 4 hours after the initial sample, serial ECG testing and clinical re-evaluation. - 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 and suggest an additional troponin measurement 4 hours after the initial sample, serial ECG testing and clinical re-evaluation. - A 2-hour delta (change) of 20 ng/L or more suggests an acute myocardial 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	High
≥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

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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.

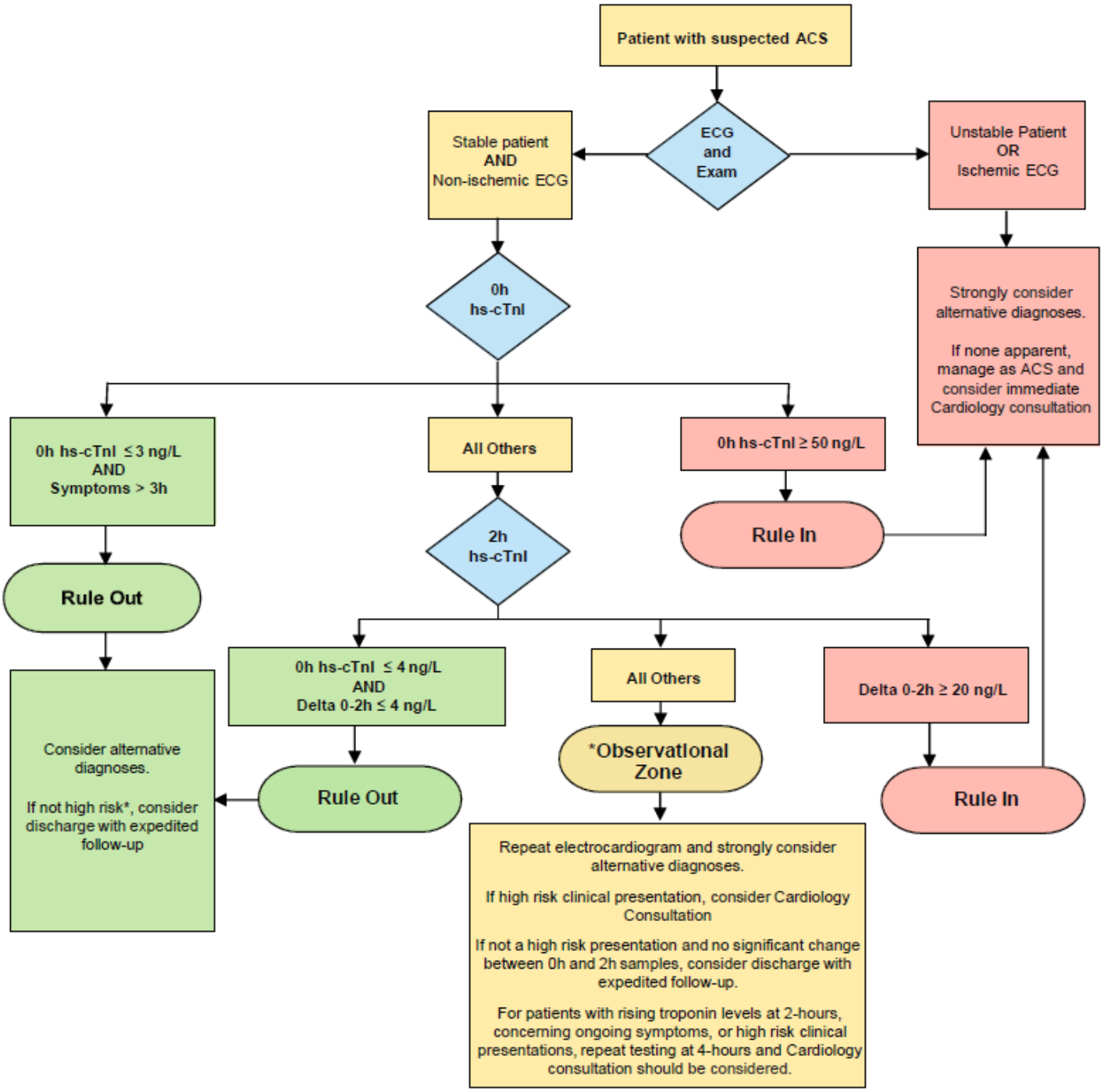

Figure 1. Continued

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 unllikely 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

Introducing BD Vacutainer® Barricor™ Plasma Blood Collection Tube
Sample Check List

The choice is clear
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Tips for Sample Collection:

- ☐ Order of Draw same position
- ☐ Fill tube to capacity until vacuum is exhausted/depleted
- ☐ Observe nominal fill line on vacutainer for optimal sample volume
- ☐ Invert tube 8-10x
- ☐ Avoid use of syringes in tube (use a BTD)**
- ☐ LLAD (Luer Lock Access Device) *Compatible for Central line related collection applications*

When you can't compromise between sample quality and efficiency,
THE CHOICE IS CLEAR

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Appendix 2. Summary of different troponin assays in North Zone after implementation of Beckman Access 2 (anticipated Spring 2024)

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

Site	Troponin assay	Chest Pain Protocol
Grande Prairie Regional Hospital (GPRH)	Roche hs-TnT	2-hr hsTnT (Roche)
Northern Lights Regional Health Care Centre (FMH)	Siemens Dimension EXL TnI	Not applicable
Athabasca	Beckman hs-TnI	2-hr hs-TnI (Beckman)
**Barrhead		
Beaverlodge		
Bonnyville		
**Cold Lake		
**Edson		
**Fairview		
**Fort Vermillion		
**High Level		
**High Prairie		
Hinton		
**Lac La Biche		
Mayerthorpe		
**Peace River		
**Slave Lake		
**St. Paul		
**Valleyview		
Westlock		
**Whitecourt		
Boyle	iSTAT TnI	Not applicable
Elk Point		
Fox Creek		
Grande Cache		
Grimshaw		
Jasper		
La Crete		
Manning		
McLennan		
Smoky Lake		
Spirit River		
Wabasca		

**Future state, not yet implemented

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.