ALBERTA PRECISION LABORATORIES
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Laboratory Bulletin

DATE:	22 April 2024
TO:	Central Zone – All Physicians, Nurses, and Managers
FROM:	Clinical Biochemistry, 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**

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Key Message

- Effective **April 25, 2024**, implementation of a new chemistry immunoassay instrument, Beckman Access 2, will begin across sixteen (16) rural hospitals in the Central Zone.
    - Initial sites going live on April 25, 2024: Ponoka, Wainwright
- All sixteen sites will offer the high sensitivity troponin I (hs-TnI) assay with the 2-hr Beckman hs-TnI chest pain pathway, as well as B-natriuretic peptide (BNP) and quantitative serum Beta hCG

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

Site	Test menu	Implementation Date
Camrose	hs-TnI, Beta hCG, BNP	*To be determined (est. end-May 2024)*
Drayton Valley		*To be determined (est. Fall 2024)*
Drumheller		*To be determined (est. Summer 2024)*
Innisfail		*To be determined (est. Summer 2024)*
Lacombe		*To be determined (est. Fall 2024)*
Olds		*To be determined (est. Fall 2024)*
Ponoka		**April 25, 2024**
Rimbey		*To be determined (est. Winter 2024-2025)*
RMH		*To be determined (est. end-May 2024)*
Stettler		*To be determined (est. Fall 2024)*
Sundre		*To be determined (est. Fall 2024)*
Three Hills		*To be determined (est. Summer 2024)*
Vegreville		*To be determined (est. Winter 2024-2025)*
Vermilion		*To be determined (est. Winter 2024-2025)*
Wainwright		**April 25, 2024**
Wetaskiwin		*To be determined (est. Summer 2024)*

* Sites not going live on April 25, 2024 will receive a future site specific memo to communicate date of implementation.

- Troponin:
    - The Beckman hs-TnI assay requires sample collection in lime green Barricor™ blood collection tubes. Light green PST tubes are no longer acceptable.
        - For additional information refer to: Appendix 1 and “Order of Draw and Order of Transfer” (link found at: https://www.albertaprecisionlabs.ca/tc/Page13858.aspx → Provincial → Blood Collection: Order of Draw and Order of Transfer)
    - The change will involve new units of measure, a new reference interval (i.e. 99th percentile upper

reference limit of the assay), reporting limits, rule-in/rule-out cut points, delta values, critical limits and interpretative comments (Table 2, Table 3, Figure 1).

- At sites with the Beckman hs-TnI assay, critical hs-TnI concentrations (≥ 50 ng/L) will be phoned to the ordering provider ONLY for hs-TnI samples collected in the outpatient/community setting only (Table 2).
  - Lab will not phone any troponin results for hospital patients (including ER patients and inpatients).
- Sites not listed in Table 1, or that have not yet implemented a Beckman Access 2 instrument will continue with current methodologies. They are not impacted by this change.

- Quantitative serum Beta hCG
  - Quantitative serum Beta hCG testing will move from the current Abbott i-STAT instrument to the Beckman Access 2 instrument.
  - All quantitative Beta hCG sample collected on site will be performed locally. This is a change from current practice, where only samples for ruling out ectopic pregnancies are tested on site.
  - 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 at this time.
    - Work is underway to minimize reporting variation between Beta hCG methods in Alberta.

- 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 and reporting.
- 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 and investigation of abdominal complaints.

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 Central 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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- Dr. Michael D. Hill, MD MSc FRCPC, Senior Medical Director – Cardiovascular SCN, AHS

References

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

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

	i-STAT conventional TnI (Current)	Beckman hs-TnI 2-hr Chest Pain Pathway (New)	Notes
Collection tube	Lithium heparin PST (light green)	Barricor PST (lime green)	Refer to Appendix 2
Rapid Chest Pain Pathway	N/A	2-hour	
Units	ug/L (2 decimals)	ng/L (whole numbers)	Units change 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 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, 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

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

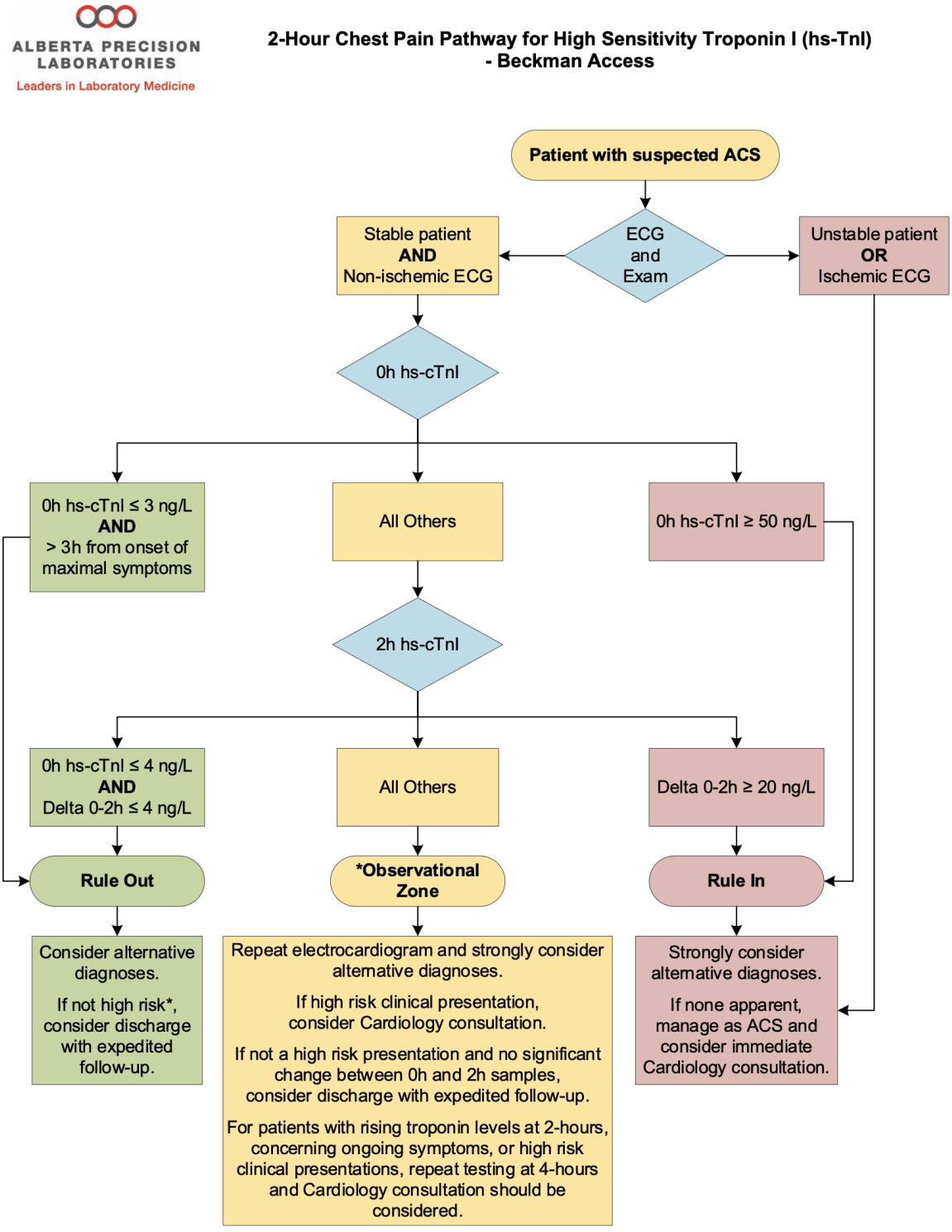


Figure 1. Continued

Note:
*For all patient 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.

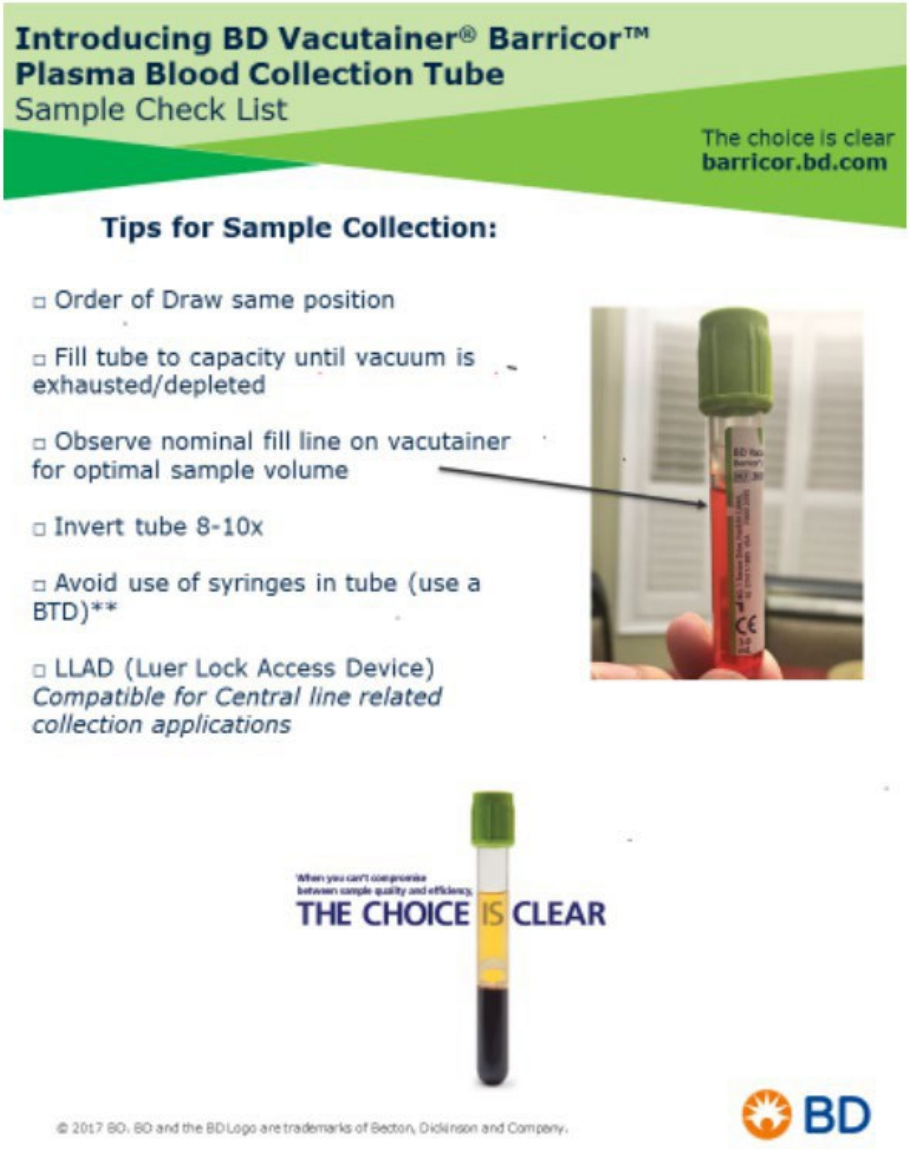
For patients presenting >6 hours from symptoms onset, ESC Guidelines advise that patients are unlikely to have an acute MI if:
- hs-cTn < Upper Limit of Normal (i.e. hs-cTnI <18 ng/L) AND,
- >6 hours since symptom onset AND,
- pain-free AND,
- the clinical presentation is Low Risk.

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 hours since symptoms onset and should be used cautiously.

All patients presenting <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. Clinicians may consider using a structured risk score such as the HEART score to guide decision making for patients in the observational zone.

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 ☐ Obesity ☐ Family hx CAD ☐ HTN (diagnosed) ☐ HL (diagnosed)	≥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 (55 ng/L or greater)	**2**	
		1-3x normal limit (18-54 ng/L)	**1**	
		< normal limit (<18 ng/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



Appendix 2. Summary of different troponin assays in Central Zone <u>after</u> full implementation of Beckman Access 2 (anticipated Winter 2024-2025)

Site	Troponin assay	Chest Pain Protocol
Red Deer Regional Hospital Centre (RDRHC)	Roche hs-TnT	2-hr hs-TnT (Roche)
*Camrose	Beckman hs-TnI	2-hr hs-TnI (Beckman)
*Drayton Valley		
*Drumheller		
*Innisfail		
*Lacombe		
*Olds		
*Ponoka		
*Rimbey		
*RMH		
*Stettler		
*Sundre		
*Three Hills		
*Vegreville		
*Vermilion		
*Wainwright		
*Wetaskiwin		
**Centennial Centre for Mental Health & Brain Injury in Ponoka	i-STAT TnI	Not applicable
Castor		
Consort		
Coronation		
Daysland		
Hardisty		
Killam		
Lamont		
Provost		
Sylvan Lake		
Tofield		
Two Hills		
Viking		

*Future state, not yet implemented
Note: Different assays are not comparable and should not be used for trending.

**In case iSTAT is not available on-site, samples will be routed to Ponoka Hospital for testing on Beckman Access 2 hs TnI method

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.