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Laboratory Bulletin

DATE:	13 May 2024
TO:	Calgary 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**

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- Effective **May 22, 2024**, implementation of the new Beckman Access 2 chemistry immunoassay instrument will begin across thirteen (13) rural hospitals and urban health centres in the Calgary Zone.
  - Initial sites going live on May 22, 2024: Strathmore, Didsbury
- All thirteen sites will offer the high sensitivity troponin I (hs-TnI) assay with the 2-hr Beckman hs-TnI chest pain pathway and B-natriuretic peptide (BNP). See Table 1.
  - Three sites (Banff, Canmore and High River) will offer quantitative serum beta hCG.
  - Note that BNP will now be reported, which is a change for sites that currently report NT-proBNP.

Table 1. Beckman Access 2 Instruments in Calgary Zone Implementation Timeline

Site	Implementation Date
Airdrie Community Health Centre	**To be determined (est. Winter 2024-2025)*
Mineral Springs Hospital - Banff	**To be determined (est. end-June 2024)*
Canmore General Hospital	**To be determined (est. Winter 2024-2025)*
Claresholm General Hospital	**To be determined (est. Summer 2024)*
Cochrane Community Health Centre	**To be determined (est. Winter 2024-2025)*
Oilfields General Hospital - Diamond Valley	**To be determined (est. end-June 2024)*
Didsbury District Health Services	**May 22, 2024**
High River General Hospital	**To be determined (est. Winter 2024-2025)*
Okotoks Health and Wellness Centre	**To be determined (est. Winter 2024-2025)*
Sheldon M. Chumir Health Centre	**To be determined (est. Winter 2024-2025)*
South Calgary Health Centre	**To be determined (est. Fall 2024)*
Strathmore District Health Services	**May 22, 2024**
Vulcan Community Hospital	**To be determined (est. end-June 2024)*

* Sites not going live on May 22, 2024 will receive a future site specific memo to communicate implementation date.

- Troponin:
  - The Beckman hs-TnI assay requires sample collection in lime green Barricor™ blood collection tubes. Mint green PST and dark green lithium heparin tubes are not acceptable.
    - For additional information refer to: Appendix 1 and "Order of Draw and Order of Transfer" (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
  - Methodology for testing at Banff will now align with Canmore and High River and be tested on the Beckman Access 2.
  - There is a bias between different quantitative beta hCG methods. The Beckman Access 2 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)
  - The change to the Beckman Access 2 requires a change from current NT-proBNP to BNP. This requires changes to collection requirements and reporting information (reference intervals and interpretative comments)
  - The required collection container is lavender EDTA (www.albertaprecisionlabs.ca/tc/Page13858.aspx → Provincial → Blood Collection: Order of Draw and Order of Transfer)

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.

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:
  - Be aware of changes in assay, container type, and reporting.
  - Collect samples for Beckman hs-TnI in lime Barricor tubes that have the following requirements:

        - 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 mint PST first, followed by lime 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 lime 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 Calgary Zone (Appendix 2). Do not interpret results across sites with different assays.

- Quantitative Beta hCG:
    - Please be aware of the methodology. Patients having serial monitoring at the time of transition may need a new baseline for comparison.
- BNP:
    - Please be aware of the change in test. Do not directly compare NT-proBNP and BNP results.
    - Be familiar with laboratory reporting changes and new collection requirements.

Questions/ Concerns

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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

	Siemens Stratus conventional TnI (Claresholm, Didsbury, Diamond Valley, Strathmore, Vulcan)	**Mini-Vidas hs-TnI 2-hr Chest Pain Pathway** (Airdrie, Banff, Cochrane, Okotoks, South Calgary, Sheldon Chumir)	**Beckman hs-TnI 2-hr Chest Pain Pathway** (New)	**Notes**
Collection tube	Lithium heparin PST (light green)	Lithium heparin PST (light green)	Barricor PST (lime green)	Refer to Appendix 2
Rapid Chest Pain Pathway	N/A	2-hour	2-hour	
Units	ug/L (2 decimals)	ng/L (whole numbers)	ng/L (whole numbers)	Units change by a factor of 1000x
Reference interval	< 0.08ug/L	<19 ng/L	<18 ng/L	99th percentile of assay Values above this limit will be flagged as high
Critical value	>0.50 ug/L	> 99 ng/L	≥ 50 ng/L	Only outpatient/community troponin critical values will be phoned to the ordering provider
Reporting limits	0.00 ug/L to 50 ug/L	6 ng/L to 160,000 ng/L	3 ng/L to 260 000 ng/L	Reportable range extended
Delta Value	none	Reported for 0-2 hour 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	Interpretive comments And Method identification 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, 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 outling the risk management of patients that present with suspected acute myocardial infarction in the acute care setting.

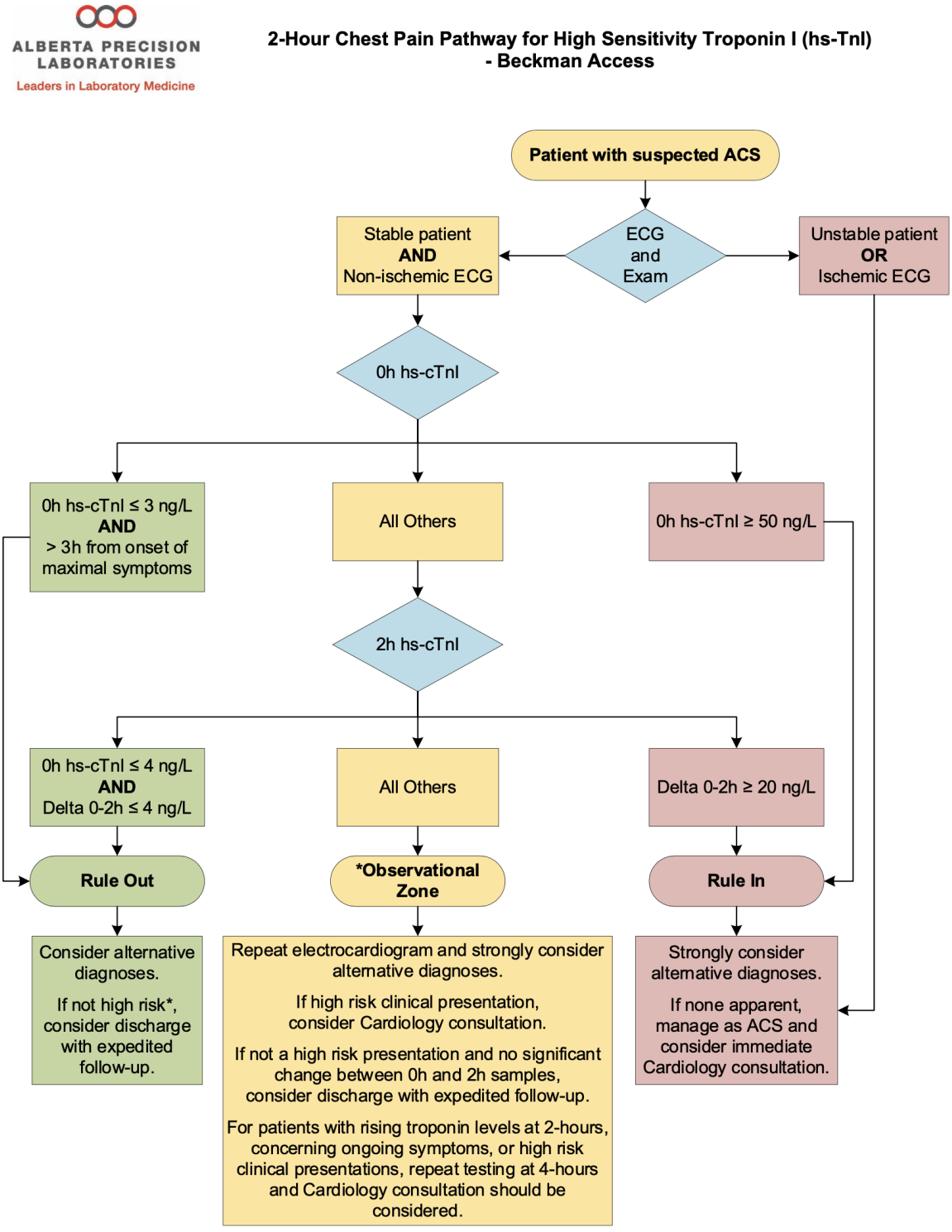

Figure 1. Continued

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 lime 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

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

Site	Troponin assay	Chest Pain Protocol
Foothills Medical Centre	Roche hs-TnT	2-hr hs-TnT (Roche)
Peter Lougheed Centre		
Rockyview General Hospital		
South Health Campus		
Alberta Children's Hospital		
*Airdrie Community Health Centre	Beckman hs-TnI	2-hr hs-TnI (Beckman)
*Mineral Springs Hospital - Banff		
Canmore General Hospital (Currently using 2-hour Protocol)		
*Claresholm General Hospital		
*Cochrane Community Health Centre		
*Oilfields General Hospital - Diamond Valley		
Didsbury District Health Services		
High River General Hospital (Currently using 2-hour Protocol)		
*Okotoks Health and Wellness Centre		
*Sheldon M. Chumir Health Centre		
*South Calgary Health Centre		
Strathmore District Health Services		
*Vulcan Community Hospital		

*Future state, not yet implemented

Note: Different assays are not comparable and should not be used for trending

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.