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|--------------|---|
| DATE: | 9 June 2025 |
| TO: | Calgary Zone – All Physicians, Nurses and Managers |
| FROM: | Clinical Biochemistry, Alberta Precision Laboratories (APL) |
| RE: | Implementation of High Sensitivity Troponin I (hs-TnI) on the Quidel TriageTrue with 2-hr Chest Pain Pathway in Rural Sites |

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Key Message

- Effective June 19, 2025, implementation of a new high sensitivity troponin I (hs-TnI) assay on the QuidelOrtho TriageTrue as a backup method to the Beckman Access 2 assay will begin across 13 hospitals in the Calgary Zone (Table 1).

Table 1. TriageTrue high sensitivity troponin I method implementation timeline

| | |
|--------------------------------------|---------------|
| Airdrie Community Health Centre* | June 19, 2025 |
| Mineral Springs Hospital* | June 19, 2025 |
| Canmore General Hospital* | June 19, 2025 |
| Claresholm General Hospital* | June 19, 2025 |
| Cochrane Community Health Centre* | June 19, 2025 |
| Didsbury District Health Services* | June 19, 2025 |
| High River General Hospital* | June 19, 2025 |
| Oilfields General Hospital* | June 19, 2025 |
| Okotoks Health and Wellness Centre* | June 19, 2025 |
| Sheldon M. Chumir Healthcare Centre* | June 19, 2025 |
| South Calgary Health Centre* | June 19, 2025 |
| Strathmore District Health Services* | June 19, 2025 |
| Vulcan Community Hospital* | June 19, 2025 |

*Backup assay to the primary Beckman Access 2 assay

- Sites using the TriageTrue hsTnI assay will offer the new *2-Hour Chest Pain Pathway for Quidel TriageTrue High Sensitivity Troponin-I Assay* (Appendix 1).
- The TriageTrue hs-TnI assay requires sample collection in lavender EDTA blood collection tubes. No other sample collection tubes are acceptable.
 - For additional information refer to the APL reference: [Order of Draw and Order of Transfer](#)
- This troponin assay change will involve new: units of measure, reference interval (i.e. 99th percentile upper reference limit of the assay), reporting limits, rule-in/rule-out chest pain pathway, delta values, critical limits and interpretative comments (Table 2).
- At sites with the TriageTrue hs-TnI assay, critical troponin concentrations (≥ 60 ng/L) will be phoned to the ordering provider ONLY for troponin samples collected in the outpatient/community setting.
 - Lab will **not** phone troponin results for hospital patients (including ER patients and inpatients).

Background

- Evidence supports that a 2-hour chest pain pathway for TriageTrue hs-TnI is effective and safe for rule-in/rule-out of acute myocardial infarction (AMI).
- The recommended pathway is consistent with clinical practice guidelines and is recommended by the Cardiovascular Program Improvement and Integration Network (PIN) in consultation with Emergency Medicine PIN and Laboratory Medicine provincially.



Why this is important

- The provincial rural immunoassay analyzer project is a large-scale provincial project that will improve access to vital laboratory testing in many of Alberta's rural hospitals and will improve standardization in instrumentation and reporting.
- Adoption of the 2-hour hs-TnI chest pain pathway with rapid rule-in/rule-out 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.

Action Required

- When the primary method for testing is unavailable, collect samples for TriageTrue hs-TnI in lavender EDTA tubes.
- Be familiar with changes in assay reporting, container type and the new 2 hr chest pain pathway for TriageTrue hs-TnI.
- Be aware of different troponin assays used within the Calgary Zone.
- Do not interpret results across sites with different assays.

Questions/Concerns

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Approved by

- Dr. Allison Venner, Clinical Biochemistry Section Chief, South Sector, APL
- Dr. Kate O'Connor, Associate Medical Director, South Sector, APL



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

| | Beckman hs-TnI 2- hr Chest Pain Pathway (Current) | TriageTrue hs-TnI 2- hr Chest Pain Pathway (New) | Notes |
|---------------------------------|--|--|--|
| Collection Tube | Barricor PST (lime green) | Lavender EDTA | |
| Rapid Chest Pain Pathway | 2-hour | 2-hour | |
| Reporting Units | ng/L (whole numbers) | ng/L (whole number) | |
| Reference Interval | <18 ng/L | < 21 ng/L | |
| Critical Value | ≥ 50 ng/L | ≥ 60 ng/L | |
| Reporting Limits | 3 ng/L to 260 000 ng/L | 2 to 1000 ng/L | |
| Delta Value | Reported for 0-2 hour delta | Reported for 0-2 hour delta | |
| Comments | Pathway interpretative comments And Method identification comments | Pathway interpretative comments And Method identification comments | Interpretative comments have changed (Table 3) |

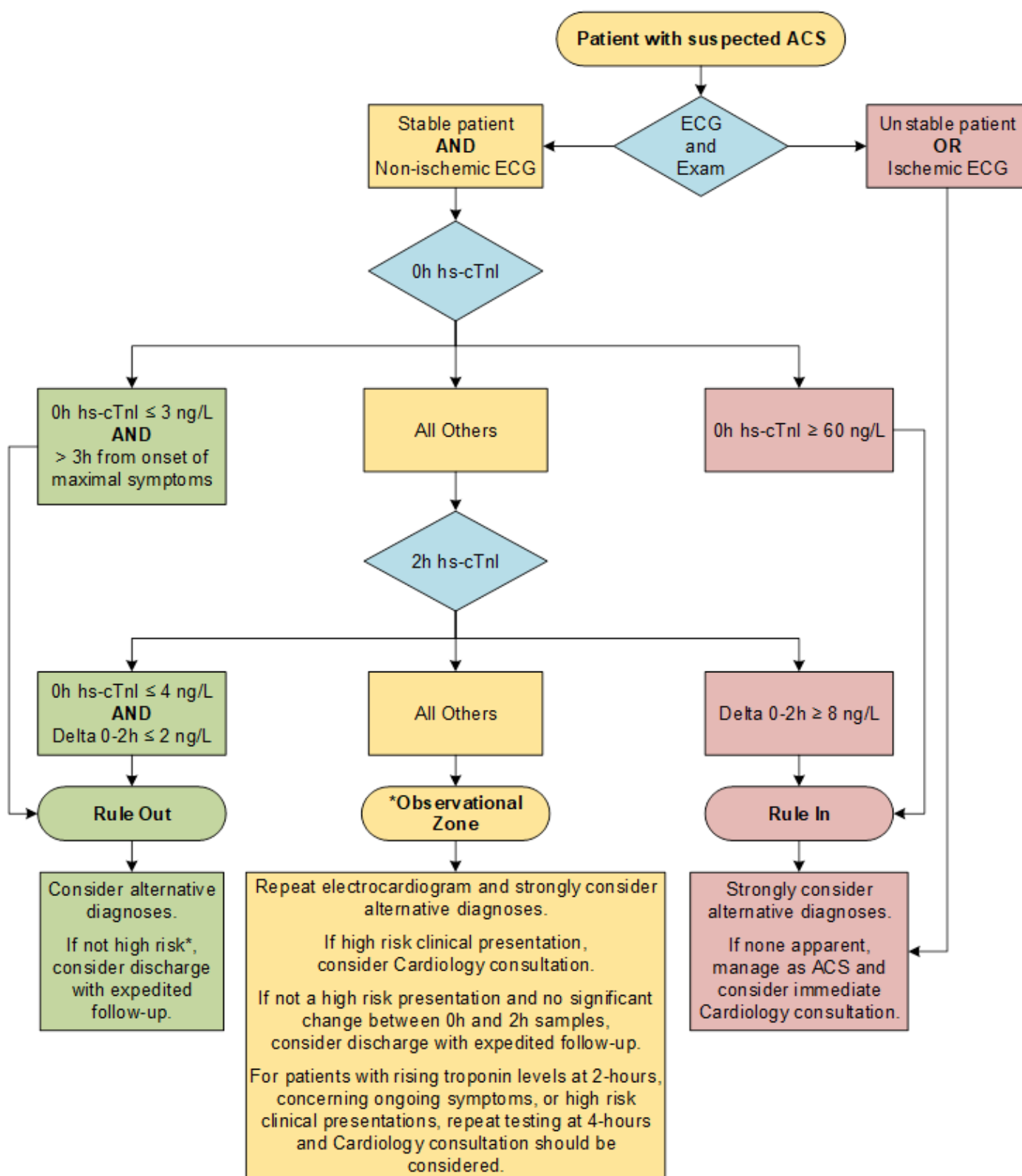


Table 3: Interpretative comments reported with Quidel TriageTrue hs-TnI

| hs-TnI result (ng/L) | Comment | Flagging |
|----------------------|---|----------|
| < 4 | <p>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.</p> <p>Please note that patients with ischemic ECG changes and/or high-risk clinical presentations should be considered for further evaluation irrespective of troponin results.</p> | Normal |
| 4 – 20 | <p>Troponin I, High Sensitivity is below the upper reference limit (21 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.</p> <ul style="list-style-type: none"> - Troponin I, High Sensitivity of 4 ng/L or less on presentation AND a 2-hour delta(change) of 2 ng/L or less is highly sensitive for excluding acute myocardial infarction (MI) - A 2-hour delta (change) of 3-7 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 8 ng/L or more suggests an acute myocardial injury and may represent acute myocardial infarction in the appropriate clinical scenario. <p>Please note that patients with ischemic ECG changes and /or high-risk clinical presentations should be considered for further evaluation irrespective of troponin results</p> | Normal |
| 21 – 59 | <p>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.</p> <ul style="list-style-type: none"> - A 2-hour delta (change) of 2 ng/L or less is highly sensitive for excluding acute myocardial infarction. - A 2-hour delta (change) of 3-7 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 8 ng/L or more suggests an acute myocardial injury and may represent acute myocardial infarction in the appropriate clinical scenario. <p>Please note that patients with ischemic ECG changes and /or high-risk clinical presentations should be considered for further evaluation irrespective of troponin results</p> | High |
| 60 | <p>Clear elevation of Troponin I, High Sensitivity consistent with acute myocardial injury or infarction in the appropriate clinical context</p> <p>Repeat troponin testing at 2-hours after the initial sample may be helpful to assess for ongoing myocardial injury</p> | Critical |



Appendix 1: 2-Hour Chest Pain Pathway for Quidel TriageTrue High Sensitivity Troponin-I Assay





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.

Per European Society of Cardiology (ESC) Guidelines and 4th universal definition of MI, if the patient is >6h from symptom onset, has a hs-cTnI <21 ng/L (99th percentile upper reference limit), are pain-free, and have a low-risk presentation, they can be considered ruled out.

However, coronary ischemia has not been definitively excluded and unstable angina must be considered. Disposition after a single hs-cTnI <21 ng/L should only be considered for patients with low-risk clinical presentations who are >6 hours since symptoms onset, and should be used cautiously.

Troponin concentration may be elevated in the presence of kidney dysfunction. Patients with an eGFR <60 and an elevated troponin concentration should undergo serial testing to confirm a rising troponin concentration consistent with myocardial injury. Patients with an eGFR <60 who have troponin concentrations in the rule-out zone can be considered to have myocardial injury safely excluded.

| 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 | <input type="checkbox"/> Diabetes <input type="checkbox"/> Current smoker <input type="checkbox"/> Obesity <input type="checkbox"/> Family hx CAD <input type="checkbox"/> HTN (diagnosed) <input type="checkbox"/> 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 (64 ng/L or greater) | | 2 | |
| | 1-3x normal limit (21-63 ng/L) | | 1 | |
| | < normal limit (< 21 ng/L) | | 0 | |
| Total (10 maximum) | | | | |
| HEART Score Interpretation | | | | |
| Low Risk | | | 0-3 | |
| Moderate Risk | | | 4-6 | |
| High Risk | | | 7-10 | |