High-Sensitivity Troponin Informational Video: Cardiac Services Didactics (instructure.com)
High-Sensitivity Troponin
MaineHealth Implementation
Go-live: February 28, 2023

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**Initiative Details**

- **Goal:** Transition all MH NorDx hospitals to high-sensitivity troponin (Gen 5) on February 28, 2023
- Educate clinicians on the assay and how to apply the results in practice
- **Background:**
  - AHA/ACC Chest Pain Guidelines recommend High Sensitivity Troponin (hs-cTn) testing
  - 4th Universal Definition of MI and ESC recommend use of hs-cTn
  - More accurate detection and exclusion of MI
  - Current Gen 4 assay will not be supported by manufacturer
- **Scope:** All MH NorDx Hospitals
- **Go-live:** February 28, 2023

**MH NorDx Sites**

- Bramhall
- Brighton
- Pen Bay
- Waldo
- Stephens
- Mid Coast
- Franklin
- Sanford
- Biddeford
- Memorial/NH
- Miles
MH hs-cTnT Transition and Launch Team

Cardiology | MMC ED | Hospital Medicine
MH Performance Improvement | Laboratory Medicine
MaineHealth IT | CT Surgery | Office of DEI | Roche

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- Mark McDonough
- Laurie Desrochers
- Meg Bachmann
- Donna Larrabee
- Eric Gallagher
- Elaine Kelley
- Maegan Callahan
Injury PLUS:

- Symptoms
- ECG changes
- Loss of function
- Thrombus at cath
- Autopsy evidence
Figure 1. Take-Home Messages for the Evaluation and Diagnosis of Chest Pain

**High-Sensitivity Troponins Preferred.** High-sensitivity cardiac troponins are the preferred standard for establishing a biomarker diagnosis of acute myocardial infarction, allowing for more accurate detection and exclusion of myocardial injury.
Conventional assay

μg/L

x 1000

High-sensitivity assay

ng/L

Pathological

Most POCT

0.100

0.030–0.040 CoV of 10%

Likely pathological

0.010 Limit of detection

Likely normal

undetectable

?? 99th percentile

Pathological

50

10–20 99th percentile

Normal

1–5 Limit of detection

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Figure 4. Use of a changing pattern of high-sensitivity cardiac troponin values.
Essential Knowledge

- Use troponin in context of other components required for diagnosis of acute MI (i.e. chest pain, clinical presentation, ECG)
- Know your 99th percentile upper limits of normal
- Timing of sample is important
- Female and Male specific values for negative test/rule-out
- Importance of the Delta between successive samples
- Single value for rule-in
- Understand the distinction between acute and chronic myocardial injury
- Understand differential diagnosis of abnormal hs-cTnT concentration
Cardiac Troponin T (cTnT)
Roche Gen 5 cTnT

• Test principle: Sandwich ImmunoAssay

• Total duration of assay: 9 minutes

• Specimen collection and preparation:
  - Plasma tubes containing separating gel (PST)
  - Stability:
    » 24 hours at 2-8 °C
    » 12 months at -20 °C
    » Freeze only once
Roche Gen 5 cTnT

• Measuring range (Analytic Measuring Range, AMR): 6-10,000 ng/L
  - Values below 6 ng/L are reported as <6
  - Values above 10,000 ng/L are reported as >10,000

• Limit of Quantitation: 6 ng/L
  - The lowest analyte concentration that can be reproducibly measured with an intermediate precision
    » CV of ≤ 20% (%CV; coefficient of variation)
Diagnosis of AMI

• Universal Definition of MI:
  1. cTn serial sampling to detect a rise and/or fall above the 99th percentile upper reference limit
  2. Consistent with clinical assessment (ischemic symptoms and EKG changes)

• The 99th percentile upper reference limit is derived from a reference control group of normal, non-diseased individuals

• ...recommends using a cTn that can measure the 99th percentile upper reference limit with an analytical imprecision of CV ≤10%
Roche Gen 5 cTnT

Roche Data:

- 99th percentile upper reference limit of a normal US population (age range 21 to 89 years)
  - 19 ng/L for both sexes
  - 14 ng/L for females
  - 22 ng/L for males

- The 10% CV (total imprecision) for this assay: 11 ng/L
Our Gen 5 Cut-Points - Rule-out cut-points

• <11 ng/L (females, sex unidentified)
• <14 ng/L (males)

Rationale

- Published data: A lot!
  » Apple et al; Clinical Chemistry(Vol. 66, Issue 3); Mar. 2020:
    ▪ Female: 10-14
    ▪ Male: 16-19
- Our own validation performed at MMC and Brighton:
  » Current Gen 4 cut-point of 0.01 ng/mL is equal to <6-32 ng/L
- 11 ng/L is the "magic number" where the assay is at an acceptable imprecision (CV of 10%)
- Very convincing evidence that male's cut-point is higher than female's
- MGH's: 10 (F) and 12 (M)
- Mayo's: 11 (F) and 16 (M)
- Sensitivity, especially initially in the implementation
Our Gen 5 Cut-Points - Rule-in cut-point

- >50 ng/L

- Rationale
  - Published data:
    » Current Gen 4 cut-point of 0.03 ng/mL is equal to 52-54 ng/L
  - Our own validation performed at MMC and Brighton:
    » Range of 45-60 ng/L
  - Sensitivity, especially initially in the implementation
Importance of Delta (Rise and/or Fall)

• Insignificant delta defined as less than 4 ng/L
  - Combined with a Normal baseline value: Rule-out AMI
    » Provided >3 hours after symptoms onset

• Abnormally significant delta defined as more than 10 ng/L
  - Flagged as Abnormal
  - Rule-in equivalent

• Indeterminate delta with values 4 - 10 ng/L
  - Corresponds to Observation Zone; however
    » Consider baseline: >50 ng/L is rule-in (if no reason for chronic myocardial injury)
    » Consider 4-hour delta
Essential Knowledge

• Use troponin in context of other components required for diagnosis of acute MI (i.e. chest pain, clinical presentation, ECG)

• Roche limit of quantitation is 6 ng/L

• Know our 99th percentile upper limits of normal - Our Data:
  - 11 ng/L (Female, Sex Unidentified)
  - 14 ng/L (Male)

• Timing of sample is important
  - Must be greater than 3hrs after onset of symptoms
  - Late sampling can be problematic
Essential Knowledge

• Female and Male specific values for negative test/rule-out - same as our 99\textsuperscript{th} percentile upper limits of normal
  - Females, Sex Unidentified: <11 ng/L
  - Males: <14 ng/L

• Importance of the \textbf{Delta} between successive samples (RISING or FALLING):
  - Insignificant Delta: <4 ng/L
  - Abnormal Delta: >10 ng/L

• Single value for rule-in: >50 ng/L

• Understand the distinction between acute and chronic myocardial injury
• Understand differential diagnosis of abnormal hs-cTnT concentration
Lab Results

- Absolute troponin value (ng/L)
  - Baseline, 2-hour, 4-hour (if needed)
  - Interpretation Message (Comment)
    - **NORMAL** (no flag)
      - <11 ng/L (female/unidentified)
      - <14 ng/L (male)
    - **INDETERMINATE** (Indeterminate for Myocardial Injury) (flagged as “high”)
      - 11-50 ng/L (female/unidentified)
      - 14-50 ng/L (male)
      - Consider Delta: e.g. If delta >10 ng/L → Rule-in
    - **ABNORMAL** (Highly Suggestive of Myocardial Injury) (flagged as “critical”)
      - >50 ng/L

- Delta (Insignificant <4, Abnormal >10)
  - Baseline to 2-hour change
  - Baseline to 4-hour change (if needed)
Lab Results

### GENERATION 5 HIGH SENSITIVITY CARDIAC TROPONIN T, STAND ALONE

**Status:** Final result  
**Visible to patient:** No (inaccessible in MyChart)  
**Next appt:** None

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0 - 10 ng/L

**Comment:** NORMAL

*Access the MaineHealth Chest Pain Algorithm via the NorDx Test Catalog.*

https://nordx.testcatalog.org/show/G5INT-1

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**Click here**
Lab Results

Normal: Baseline, 2hr and 4hr (unnecessary)
Canceling the 4hr order if unnecessary

If the baseline and 2hr results are both normal, then the 4hr order is unnecessary.

In this instance, a BPA will fire to cancel the 4 hour troponin order.
Lab Results

Indeterminate: 2hr

Abnormal: 4hr
Hemolyzed Results

Baseline result could not be reported due to Hemolysis.
Canceling Orders

Hemolyzed specimen or unnecessary 4hr draw

Signing a new order for the panel will trigger a BPA to discontinue the remaining pending 2 hour and 4 hour specimens.

When the panel is reordered while specimens remain pending, this BPA prevents the order from being signed until the duplicate orders are resolved.

Or cancel the specimen from the new request by hovering over the respective order and clicking the X.
Patient Summary Report

High-Sensitivity Cardiac Troponin T Report

Go to now 2/13/2023

Monday 0100 - Monday 2259

Detailed information - High-Sensitivity Cardiac Troponin T

Important Details

- Use troponin in context of other components required for diagnosis of acute MI (i.e. chest pain, clinical presentation, ECG).
- Understand the distinction between acute and chronic myocardial injury.
- First troponin sample must be greater than 3 hrs. after onset of symptoms, late sampling can be problematic.
- Understand differential diagnosis of abnormal hs-cTnT concentration (see bottom of algorithm).
- Roche limit of quantitation is 6 ng/L.
- Lab results
  - Normal test/rule-out values (99th percentile upper limits of normal)
    - 11 ng/L (Female, Sex: Unidentified)
    - 14 ng/L (Male)
  - Abnormal test/rule-in value: >50 ng/L
  - Importance of the Delta between successive samples (RISING or FALLING)
    - Insignificant Delta: <4 ng/L
    - Abnormal Delta: >10 ng/L

**New collection needed for hemolyzed specimens**

Chest Pain Algorithm

MaineHealth

Patient arrives with chest pain or anginal equivalent.

- Order the high-sensitivity troponin (hs-cTnT) panel upon presentation.
  - Observation of hs-cTnT and high-sensitivity cardiac troponin T elevation.

ANY hs-cTnT >90 ng/L OR
  ▲ >10 ng/L

Indeterminate lab result

ALL hs-cTnT =11 ng/L (female/undetermined) or =14 ng/L (male) with ▲ =4 ng/L or 3 hours after symptom onset.
Summary
MaineHealth go-live: February 28, 2023

- Order hs-cTnT upon presentation of chest pain
  - Order set: at baseline, 2 hour and 4 hours (as needed)
  - Single order: rule-out at baseline

- Results
  - **Rule-in** (abnormal) >50 ng/L OR Δ >10 ng/L → Admit to Cardiology or Medicine (see table 1)
  - **Rule-out** (normal) <11 ng/L (female/unidentified)/<14 ng/L (male) AND Δ <4 ng/L → discharge or observe
  - **Observation** (indeterminate) → admit/consult Cardiology or observe

More Information

Slides and algorithm available here: [Emergency Department Clinical Guidelines | MaineHealth](#)

Informational Video: [Cardiac Services Didactics (instructure.com)](#)
Frequently Asked Questions

- **What is the High-Sensitivity Cardiac Troponin T Assay?**
  - Troponin T is a cardiac-specific protein and a marker of myocardial injury. Troponin T aids in the diagnosis of acute coronary syndrome (ACS).
  - The assay will be reported as NORMAL (<11(F/NB)/<14(M) ng/L), INDETERMINATE and ABNORMAL (>50 ng/L).

- **What is the MMC telemetry bed policy regarding transfers to Cardiology?**
  - MMC transfers to telemetry capable beds should follow the established MMC ECG Monitoring Policy.
  - MMC orders for a single or troponin panel in-and-of-itself should not be used as criteria to initiate a transfer.
  - MMC transfers to telemetry should be based off of a high-risk clinical presentation concerning for ACS or arrhythmia with instability.
  - Other MH sites are to follow their respective institutional policies, as applicable.

- **The Cancel 4-hour Troponin BPA fired, how do I cancel the 4hr order?**
  - In the cancel 4-hour Troponin BPA, click the link “Recommended: ED Provider Cancel Troponin 4 hour lab,” this takes you to the Active Orders tab located next to the ED Quick List tab.
  - Find the active TroponinT 4-Hour order and click the Discontinue button. Click Sign to discontinue the order.

- **Is there a way to easily view all troponin orders?**
  - The “High-Sensitivity Cardiac Troponin T Report” is available in Epic under the Summary or Snapshot tab and includes all troponin order results along with important information and the algorithm.
  - Add report: in the Summary or Snapshot activity search “troponin,” use the wrench icon to add the report. This is also available in the ED Trackboard reports.

- **How do I reorder when the specimen is hemolyzed?**
  - If the baseline Troponin T is hemolyzed, a new panel needs to be re-ordered with a new collection; the baseline will be reported as hemolyzed, and the original pending 2-hour and 4-hour collections will have to be cancelled before a new panel is ordered.
  - If the 2-hour Troponin T is hemolyzed, you can either order a standalone Troponin T to fill in or wait for the 4-hour collection.
  - If the 4-hour Troponin T is hemolyzed, a re-collection may be needed based on the algorithm and clinical relevance.

- **What if I need to change the timing of panel orders?**
  - It’s not recommended to adjust the panel order times. If one of the panel three order collection times is adjusted, all proceeding order times need to be adjusted accordingly (every 2 hours).
  - The delta will not apply if the orders (2-hour vs. baseline, or 4-hour vs. baseline) are more than 5hrs apart.

- **What is a screening troponin?**
  - We recommend the use of the Troponin T panel. We currently, in general, don’t recommend the use of single Troponin T sampling. In order for this to be considered “negative” the patients lab value must be <6 and a delta <4.

- **How is this new test different than what we used to do?**
  - In many ways. Please refer to video recording of steering committee presentation HERE.

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Click HERE for detailed information and the hs-cTnT algorithm

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Selected References


