Troponin and version 5

New Requirements: Implementing the Guidelines

Ruth Cantu, BSN, RN, AACC

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Speaker Overview

Ruth Cantu, BSN, RN, AACC
Program Manager
Accreditation Review Specialist

There are no disclosures
Identify guideline-driven best practice recommendations on the use of biomarkers in the treatment of Acute Coronary Syndrome (ACS)

Review updates to the Myocardial Infarction (MI) Definition and Non-ST elevation Acute Coronary Syndromes (NSTE-ACS) guidelines

Discuss SCPC troponin turn-around-time (TAT) recommendations and documentation requirements

Share quality practices that optimize the care and outcomes of ACS patients
The Society does not promote or endorse lab based testing or point-of-care testing (POCT) rather focuses on processes and protocols for the identification and management of the Myocardial Infarction (MI) and Acute Coronary Syndrome (ACS) continuum.

The Society provides guidance and education with the position that each facility is responsible to determine the vendor partnerships that best align to their hospital-specific processes, protocols and goals.

Each hospital should be well versed in the latest guideline recommendations and ensure they have reviewed their protocols for Troponin, consistent with the assay(s) being used.
Acute Coronary Syndrome (ACS)

Per the 2014 guidelines…The new title, “Non–ST-Elevation Acute Coronary Syndromes” (NSTE-ACS) emphasizes the continuum between Unstable Angina (UA) and Non-ST Elevation Myocardial Infarction (NSTEMI). At presentation, patients with UA and NSTEMI can be indistinguishable and are therefore considered together in this Clinical Practice Guideline (CPG).

Estimated 5-8 million patients present to the ED annually for chest pain

20-25% diagnosed with Acute Coronary Syndrome

2,000,000

Low Risk/Observation Population: The other 6,000,000+ people

Source:

American Heart Association
Learn and Live
Definitions for Reperfusion

• **Percutaneous Coronary Intervention (PCI)** - most frequently used invasive method of treating the narrowing, or stenosis, of coronary arteries; performed in cardiac catheterization facilities (cath lab) at acute care hospitals

• **Primary PCI (PPCI)** - also known as (aka) emergency angioplasty, is a life-saving intervention performed during a heart attack (STEMI)

• **Non-primary PCI** - aka: elective angioplasty, scheduled intervention to relieve the narrowing of the artery; goal of preventing a heart attack from occurring in the future

Key Point: Facilities should ensure laboratorians are familiar with the protocols and facility diagnostic capabilities (cath lab, PPCI, thrombolytics, transfer) to address acute cardiac events.

Use explanations of the differences when working with Lab. Do not assume they know their role regarding the facility reperfusion strategy.
Guideline Updates:

“...As the field continues to absorb the guidelines, panelist and others advised laboratorians to take time to know the documents so they can have constructive discourse about them with physicians...”

Clinical Lab News, Feb 2014, vol 40, no 2
Updated MI Definition

Third Universal Definition of Myocardial Infarction (MI)
Kristian Thygesen, Joseph S. Alpert, Allan S. Jaffe, Maarten L. Simoons, Bernard R. Chaitman and Harvey D. White
*Circulation.* published online August 24, 2012

Key Points: First worldwide consensus document

- TROPONIN (I or T) - preferred biomarker overall
- Diagnosis of acute MI - detection of a rise and/or fall
- ...99th percentile is designated as the decision level for the diagnosis of MI and must be determined for each specific assay with appropriate quality control in each laboratory
  - Assays with CV >20% at the 99th percentile URL should not be used
  - Blood samples for the measurement of cTn should be drawn on first assessment and repeated 3-6 h later
  - Updated definitions for five different types of MI to include post-PCI and research
Clinical implications of the Third Universal Definition of Myocardial Infarction
White HD, Thygesen K, Alpert JS et al
*Heart* 2013;00:1-9. doi:10.1136/heartjnl-2012-302976

Summary:

- Comparative update from previous 2000 and 2007 Universal Definitions to the 2012 Third Universal Definition of MI
- Overview of the recommendations by category with a focus on clinical implications and practice considerations

“The new MI definition has important changes, which have been achieved by international consensus. It is hoped that they new definition will be embraced worldwide and be used to improve patient care.”
Coefficient of variation -
When the test is run multiple times on the same sample how frequently do you get the same result? The standard answer is rarely, if ever.

So in real world terms, this is measured by running the sample at least 20 times and identifying the % of variation within that set of results.

The 3rd Universal of MI allows from 10% to 20%

99th percentile -
Troponin is fairly unique as one of the few analytes where a 99% reference range is recommended.

The reason for this recommendation is that the goal of early prediction is to pick up that result as early in the elevation cycle as possible.

In the case of Analyzer X the published 99th % is 0-0.07 ug/ml, meaning that when 100 "normal" patients with heart disease were tested 99 of the results fell between 0 and 0.07. Results outside that range would then be considered "positive".
Troponin Definitions Made Easy

Coefficient of Variation

- When the test is run multiple times on the same sample, how frequently do you get the same result?
- In real-world terms, this is measured by running the sample at least 20 times and identifying the % of variation within that set of results.

The 3rd Universal of MI allows from 10% to 20%

High Accuracy, Different Precision

- 18% CV
- 10% CV

Contemporary Cardiac Troponin Assays are more precise

Courtesy of Dr. Robert Christenson, University of Maryland; SCPC Webinar 10/14/15
Dr. Fred Apple: Currently, the guidelines are predicated on the 99th percentile of cardiac troponin, and we use that 99th percentile first to say, any increase above that is indicative of myocardial injury, number one.

Secondly, we use that cutoff to say that in the clinical setting of myocardial ischemia and an increasing cardiac troponin above the 99th percentile, those two criteria are enough to make the call of a diagnosis of myocardial infarction.

Clinical Chemistry PODCAST - May 2009 with Dr. Fred Apple - Professor of Laboratory Medicine in the Department of Laboratory Medicine and Pathology at the University of Minnesota and Medical Director of Clinical Laboratories and the Clinical Chemistry and Toxicology Laboratories at Hennepin County Medical Center
"...in the clinical setting of myocardial ischemia an increasing Troponin above the 99th%ile...is enough to make the diagnosis of myocardial infarction..." Fred Apple

"...use the 99th% to say...any increase above that is indicative of myocardial injury..." Fred Apple

Thygesen K et al. Circulation 2012;126:2020-2035

Third Universal Definition of MI
Think “HEART” NOT “MI”!
Not all elevations are acute myocardial infarction

Explanation of the 99th Percentile

How to Interpret Elevated Cardiac Troponin Levels
Vinay S. Mahajan, and Petr Jarolim

Summary:

• “The use of the 99th percentile cutoff for cTn positivity does not imply that 1% of the population suffers from myocardial damage.

• Rather, this cutoff is useful only when applied to patients with a high pretest probability of ACS.

• The clinician must interpret cTn results in the context of clinical history, ECG findings, and possibly cardiac imaging to establish the correct diagnosis.

• A positive troponin in the setting of a low pretest probability for ACS may be suggestive but clearly is not indicative of a coronary event.”
2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes


- A full revision of the 2007 ACCF/AHA clinical practice guidelines (CPG) for the management of patients with unstable angina (UA) and non-ST-elevation myocardial infarction (NSTEMI) and the 2012 focused update.

- The new title, “Non-ST-Elevation Acute Coronary Syndromes,” emphasizes the continuum between UA and NSTEMI. At presentation, patients with UA and NSTEMI can be indistinguishable and are therefore considered together in this CPG.

- Supports the Third Universal Definition of MI for Troponin and Serial Testing
Class I

• Cardiac-specific troponin (troponin I or T when a contemporary assay is used) levels should be measured at presentation and 3 to 6 hours after symptom onset in all patients with symptoms consistent with ACS to identify a rising and/or falling pattern. (Level of Evidence: A)

• Additional troponin levels should be obtained beyond 6 hours after symptom onset in patients with normal troponins on serial examination when electrocardiographic changes and/or clinical presentation confer an intermediate or high index of suspicion for ACS. (Level of Evidence: A)

• If the time of symptom onset is ambiguous, the time of presentation should be considered the time of onset for assessing troponin values. (Level of Evidence: A)

Class III: No Benefit

• With contemporary troponin assays, creatinine kinase myocardial isoenzyme (CK-MB) and myoglobin are not useful for diagnosis of ACS. (Level of Evidence: A)
Examples: Orders

No pre-checked panel: Serial strategy and use of 99th percentile consistent with guideline recommendations

| Diagnostic: | ECG: [ ] Repeat ECG at 3 hours and 6 hours after initial ECG, then ECG in am.  
|            | [ ] ECG at the following times: ______, ______, ______.  
|            | Repeat ECG pm for symptoms suggestive of new, ongoing, or worsening chest pain or S/S of Acute Coronary Syndrome. *Notify physician.  
|            | [ ] CXR-PA and Lat  
|            | [ ] Other: ____________________________  
| Labs:      | Repeat Troponin-I at 3 hours and 6 hours after initial Troponin,  
|           | Notify MD if Troponin greater than 0.06.  
|           | [ ] CK  [ ] CKMB  
|           | [ ] BMP in am   [ ] CBC in am   [ ] Fasting Lipid Panel in am [ ] HgA1c in am  [ ] TSH in am  
|           | [ ] Other: ____________________________ |
Discontinuation of AMI Profile

There is a general consensus that cardiac troponin is the biomarker of choice for myocardial necrosis and that CK-MB has little role to play in the primary diagnosis of non-ST elevation myocardial infarction (NSTEMI). When we instituted our current “extra-sensitive” central lab troponin assay in February 2008, we retained CK-MB as a no-charge component of what we were then designating “AMI profile.” We think this is no longer indicated and are discontinuing the order “AMI profile” in favor of individual test orders. In other words, CK-MB and other more historic markers will still be available but should be ordered on an individual case basis, consistent with clinical judgment and specific indications.
How to Use **High-Sensitivity*** Cardiac Troponins in Acute Cardiac Care
Kristian Thygesen et al
*European Heart Journal* doi:10.1093/eurheart/ehs154 PDF online 2012

Summary Regarding Use of hsCardiac Troponin in Clinical Routine:

- **Use 99th%ile concentration**
- **Serial testing**...a minimum change of >20% in follow-up testing is required
- Blood sampling ...admission and 3 h later...repeated 6 h after admission in patients of whom the 3 h values are unchanged but...clinical suspicion of AMI is still high
- Other markers, such as myoglobin or creatine kinase MB no longer needed

* High-Sensitive Troponin are not approved in the U.S.
Changing Perspectives of Turn-Around-Time (TAT) Tracking: Accountability and Accreditation requirements
TAT Tracking: Healthcare Implications

July 2014 Clinical Laboratory News: Volume 40, Number 7

What Does Turnaround Time Say About Your Lab?

Key Quotes:

- “Every laboratorian knows that their colleagues in medicine see TAT as something almost as important as the quality of test results themselves.”

- “In fact, surveys have found that 80% of labs get complaints about TAT.”
Studies and research support the following:

• Assessing the “whole process” (i.e.: arrival)

• Standardizing the definitions of turn-around-time (TAT)

• Assessing TAT with patient outcomes and length of stay
TAT Tracking: Healthcare Implications


Proposed new concepts for TAT in the diagnostic process:

As a “Patient-oriented” view or the “whole process”

- Diagnostic TAT - arrival to reporting of results
  - outcomes median 122 min
- Clinical TAT - arrival to order
- Laboratory TAT - order to report/resulted
In *Academic Emergency Medicine, 2010:17*, Hwang et al noted:

“Guidelines do not exist delineating times frames for when a troponin test should optimally be resulted in association with improved patient outcomes.”

“Prolonged laboratory TAT may delay recognition of conditions in the acutely ill, potentially affecting clinician decision-making and the initiation of timely treatment.”

– Outcomes median 107 minutes; “ordered to resulted”
SCPC Cardiac Biomarker Requirements

- Measuring TAT is and has been a guideline driven recommendation for many years
- No previous TAT requirements from any organization until...
  - 2012: CMS OP 16 requiring compliance for “Door-to-Result in 60 minutes”
    - initiated and then revoked
    - not reinstated to date
- SCPC requirement started in 2012
  - CPC to track and demonstrate improvements
- SCPC requirements continue to date
  - Review guideline compliance; patient-level data reviewed
**Time is muscle - think HEART!**

<table>
<thead>
<tr>
<th>OLD</th>
<th>NEW</th>
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<tbody>
<tr>
<td>Door to ECG = 10 minutes</td>
<td>Door to ECG READ within 10 minutes</td>
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<tr>
<td>Door to Reperfusion = 90 minutes</td>
<td>Door to Reperfusion &quot;as soon as possible&quot;</td>
</tr>
<tr>
<td>First Medical Contact (FMC) to Reperfusion &lt; 90 minutes</td>
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<tr>
<td>TRANSFER: Door in - Door out = 30 minutes</td>
<td>Door in - Door Ready = 25 minutes</td>
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<tr>
<td>Door to Thrombolytics = 30 minutes</td>
<td>Same consideration; low utilization</td>
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<tr>
<td>Lab received to results = 60 minutes</td>
<td>Door to Troponin Results in 60 minutes (facility sets % compliance - recommend setting at 75%)</td>
</tr>
<tr>
<td>Order/Collect to results = 60 minutes</td>
<td>% compliance = 90%</td>
</tr>
</tbody>
</table>

**NEW CONCEPTS: GOLDEN HOUR for the HEART**

STEMI is a heart trauma: think 60 minutes from "door"

NEW GOAL: Door to Reperfusion in 60 minutes (60%)

Troponin decision: think 60 minutes from "door"
CPC: Patient Population Focus

Dual Challenge with Managing Chest Pain Patient Populations

Vague Symptomology

Combining ‘Rule Out’ Process with ‘Diagnosis’ Process
(treat as ACS until proven otherwise)

RISK STRATIFICATION IS THE KEY

LOW-RISK/Observation

NSTE-ACS

STEMI

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Emergent Risk Assessment Must Include:

1. Symptomology Evaluation
2. ECG Completed and Read within 10 Minutes
3. Troponin: Turn Around Time (TAT)*
4. Risk Scoring Mechanism: ex. TIMI, GRACE, or other form founded in science

1. Facility Defined Evidence-Based Risk Stratification Model
2. Consistently Utilized and Documented by Facility’s Providers (order-set, flowcharts, patient’s chart)

*Turn-around time requirements are explained in the appropriate accreditation tools
Emergent Risk Assessment Must Include:

- **Entry into the Bucket**
  - Chief Complaint Suggestive of ACS
  - EKG Read in <10 Minutes
  - Troponin Resulted* in <1 hour
  - Facility Defined Risk Score

**THE LOW RISK BUCKET**

- **THE BUCKET**
- **STEMI + EKG**
- **Troponin Positive for NSTE-ACS**

80% of patients remain LOW RISK

= 6,000,000 Annual Population

*Turn-around time requirements are explained in the appropriate accreditation tools
Laboratory participation for assistance with TAT tracking to assess PROCESSES; now begins at the “door” for both POCT and Central Lab and measured through “results”
Laboratory engagement in the LOW-RISK and NSTE-ACS processes of care for serial Troponin strategies is vital in multiple areas to include the entire ACS continuum for ED, Observation and In-Patient.
Laboratory engagement in Risk Stratification strategies will be assessed to include adherence to the guidelines for standardization in timing, use of 99th percentile; eliminating outdated markers and “gray-zone”; providing interpretive results.
“To the extent that laboratory test TAT is only one factor impacting ED length of stay and patient outcomes, it is unlikely that POCT alone, in the absence of an interdepartmental approach to ED operations, will produce measurable improvements in outcomes.”

CYLE III & IV: SCPC GENERAL FINDING
(results for discussion purposes only)

- Cycle III FIB data: n=700
  - 65% using the 99th percentile
  - 50% using POCT

- Cycle IV FIB data YTD: n=629
  - 77% using the 99th percentile
  - Of those, 87% using manufacturer recommendations
  - 40% using POCT
  - Of those, 78% using Troponin only (no other markers)

No previous validation of accuracy
Per Amsterdam et al in a Circulation 2010 article:

“Testing of Low Risk Patients Presenting to the ED with Chest Pain”

“...current studies have confirmed that contemporary troponin assays can identify the majority of MI’s within 3 hours of ED arrival...”
The International Federation of Clinical Chemistry (IFCC)

Supporting documentation on all assays specifications

Last update: Nov 2014

Website:

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<th>Commercially available assays - Company/ platform(s)/ assay</th>
<th>LoB</th>
<th>LoD</th>
<th>99th %</th>
<th>% CV at 99th %</th>
<th>10% CV</th>
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<td>NA</td>
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<td>8.5</td>
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</table>
**CPC v5: Framework**

**EC4.M1d:** Serial troponin strategy is defined in an evidenced-based standardized protocol that is consistent with the assay used. Supporting documentation must include:

<table>
<thead>
<tr>
<th>EC4.M1d1</th>
<th>Manufacturer and assay used in central lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC4.M1d2</td>
<td>Manufacturer and assay used for POC testing</td>
</tr>
<tr>
<td>EC4.M1d3</td>
<td>Decision cut point for positive test for both central lab and POC <em>(where applicable)</em></td>
</tr>
<tr>
<td>EC4.M1d4</td>
<td>Decision cut point for negative test for both central lab and POC <em>(where applicable)</em></td>
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<tr>
<td>EC4.M1d5</td>
<td>99th percentile for both central lab and POC <em>(where applicable)</em></td>
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<tr>
<td>EC4.M1d6</td>
<td>Coefficient of variation at the 99th percentile for both central lab and POC <em>(where applicable)</em></td>
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<tr>
<td>EC4.M1d7</td>
<td>Protocol and policies define the standardized timing used</td>
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</tbody>
</table>
Lab specific assessments are now part of the tool
For both CENTRAL LAB and POC Troponin

Troponin assessment:
- Manufacturer
- Analyzer
- 99\textsuperscript{th} Percentile
- Coefficient of Variation at 99\textsuperscript{th}%
- Review use of outdated assays

- Reviewing *Interpretive Comments* to ensure they are current to the guidelines
- Reviewing *Instructions for Use IFU* to validate Troponin precision
  - IFU document language are rarely updated due to FDA rules
  - Ensuring facilities are not using or referencing outdated WHO criteria from IFU
  - More current assays include current guideline language in IFU
For both CENTRAL LAB and POC Troponin

- Participation requirement by Lab personnel in CPC meetings

- Definition of baseline timing for serial strategy (i.e., ED arrival versus 1st lab draw)

- Nursing staff whose focus is on the ACS patient (STEMI/NSTE-ACS/LOW-RISK) must receive annual education on cardiac biomarkers (CBM)

- **NEW-MANDATORY** Requirement = 50% participation in CPC (or appropriate) committee meetings

- Defined protocols & policies of serial strategy throughout the hospital stay continuum

- **NEW**-Educational requirement for CBM – Lab assistance to create education to show hospital compliance of guidelines
Lab specific assessments are now part of the tool to ensure communication and evaluation takes place

For both CENTRAL LAB and POC Troponin

- Metrics of trends for Troponin TAT - arrival to result (ACS patients beyond STEMI)
- % compliance TAT arrival to result in 60 minutes
- SCPC ACD and hospital metrics
- More stringent than the current guideline requirements
- No compliance standard set at this time; no industry compliance standards set however the process is assessed from “door to result”
Follow-up Article: MI and Serial Strategy

Cardiac Troponin Serial Ordering Recommendations: For Today and Tomorrow
Sara Love, PhD and Fred Apple, PhD
Clinical Lab News, May 2014, vol 40, no. 5

Summary:

• Implementation practices by facility addressing updated 2012 MI definition and the use of the 99th percentile and serial strategies

“....serial cTn ordering is a critical component of acute MI diagnosis readily understood in terms of timing, frequency and duration of cTn measurements...”
Facilities may still use a 0-6-12 strategy however it will most likely be listed as an “opportunity” for review and consideration to accelerate the diagnostic protocol per the updated guideline recommendations and impact on length-of-stay (LOS).

| EC4.M1d7 | Policies, protocols or orders for Troponin testing demonstrating the facility serial strategy. Facilities cannot use a serial strategy that is q8x3 as this is no longer the recommendation in the guidelines. The serial strategy must be standardized as demonstrated on the order-sets and flowcharts. Also refer to EC4M4a2. |
| EC4.M4a2 | Timing between serial troponins are standardized throughout the facility. *(Examples of timing strategy may include: 0, 2, 6 - 0, 3, 6 - 0, 3, etc. Duration of serial strategy may also be as short as three 3 hours using sensitive troponins, or troponin deltas if provocative cardiac testing or imaging takes place)* |
## Serial Troponin Line Item Evaluation

### Serial Strategy (applies to LOW-RISK and NSTEMI)

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Time of Draw</th>
<th>Time of Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin #1</td>
<td>0</td>
<td>MM/DD/YYYY</td>
<td>MM/DD/YYYY</td>
</tr>
<tr>
<td>Troponin #2</td>
<td></td>
<td>MM/DD/YYYY</td>
<td>MM/DD/YYYY</td>
</tr>
<tr>
<td>Troponin #3</td>
<td></td>
<td>MM/DD/YYYY</td>
<td>MM/DD/YYYY</td>
</tr>
<tr>
<td>Troponin #4</td>
<td></td>
<td>MM/DD/YYYY</td>
<td>MM/DD/YYYY</td>
</tr>
<tr>
<td>Troponin #5</td>
<td></td>
<td>MM/DD/YYYY</td>
<td>MM/DD/YYYY</td>
</tr>
</tbody>
</table>
### CPCv5: TROPONIN Case Study

#### Serial Troponins

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Time of Draw</th>
<th>Time of Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin #1</td>
<td>0.04</td>
<td>14:50:00</td>
<td>17:24:00</td>
</tr>
<tr>
<td>Troponin #2</td>
<td>0.18</td>
<td>20:13:00</td>
<td>20:13:00</td>
</tr>
<tr>
<td>Troponin #3</td>
<td>1.01</td>
<td>21:20:00</td>
<td>22:00:00</td>
</tr>
<tr>
<td>Troponin #4</td>
<td>1.33</td>
<td>8/25/2015 13:40:00</td>
<td>8/25/2015 14:39:00</td>
</tr>
<tr>
<td>Troponin #5</td>
<td>1.3</td>
<td>8/25/2015 13:40:00</td>
<td>8/25/2015 14:39:00</td>
</tr>
</tbody>
</table>

#### Serial ECG

<table>
<thead>
<tr>
<th>ECG #1</th>
<th>Completed On</th>
<th>Read On</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/24/2015</td>
<td>14:33:00</td>
<td>8/24/2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ECG #2</th>
<th>Completed On</th>
<th>Read On</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/26/2015</td>
<td>09:56:00</td>
<td>8/28/2015</td>
</tr>
</tbody>
</table>

#### Assay Details

- **Troponin I ED POC**
  - Negative: ≤ 0.08 / Positive: ≥ 0.09
- **Troponin I Central Lab**
  - Negative: ≤ 0.045 / Positive: ≥ 0.05

#### Facility Serial Strategy

0-3-6

#### EMS Details

- CP/SOB - Arrival at 14:28
- ED Disposition to In-Pt at 22:27

#### Additional Information

- ER LOS = 7.59
- From TnI draw = 7.37
- = 2.44
  - (POC)
- = 5.23
- = 1.07
The infamous “Gray Zone” of Troponin Testing
cTn History—A Moving Target

In early studies, first-generation assays did not consistently outperform the then-gold standard CK-MB in sensitivity or analytical precision NACB guidelines for cardiac biomarkers, published in 1999

- Two cutoffpoints,
  - ROC curve used to establish acute MI decision limits.
  - They “Gray Zone” was born
  - Elevations below AMI curve were mainly labeled as false positives or ignored.
  - Risk Stratification was a concept few were believing in at this point.

“...That set the stage for using whatever cutoff you want, and the field has never recovered from it,”

Jaffe et al, Clinical Chemistry 2008

2005

- Introduced the concept of elevations greater than the 99%tile (of a well patient population) with a Coefficient of variation [CV] of 10% or <.
  - Only one or two assays could meet this requirement at that time.
- It did however force the diagnostic industry to a goal of assay performance (moving closer to standardization [harmonization?])

NACB Guidelines Published In 2007

- Represented the first attempt to get all cardiac testing standardized.

Excerpt from internet presentation n.d. “Cardiac Markers: Why all the Confusion?” by R. Heitsman, Radiometer, National Accounts Manager

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Guidance Statement

The Lab must be consulted for these items. The facility must provide a policy, procedure or protocol to show the decision point for a positive test. The facility may also provide the Interpretive Comments for Troponin results. Troponin test interpretive comments are what the clinicians see once the Troponin test is resulted. If the facility is using both central lab and a Point-of-Care (POC) analyzer, information for both assays is required.

**Decision cut points must be clearly documented by the facility and not open to interpretation.**

(These items are a progression from the CIV Facility Information Booklet (FIB) into the actual body of the tool and requires documentation, where the FIB did not.)
Interpretive Comments – Assessment of “Gray Zone”
(from actual hospital reporting of results)

- **TROPONIN T (TnT) 0.01 – 0.05 mg/L**
  - Indicates minimal myocardial damage which with the appropriate clinical and ECG findings may be of prognostic significance in patients with ACS. However levels within this range may also be due to non-ACS causes e.g. pulmonary embolus, heart failure, CRF, severe sepsis etc.

- In ACS TnT starts to rise at 3-4h and reaches maximum sensitivity at 12-18h post symptoms and can remain elevated for up to 7-8 days. For exclusion of ACS levels should not be taken before 12h post symptoms.

- **TnT >0.05 mg/L would support a diagnosis of AMI**

Using the 99\(^{th}\)% ile for decision point? **Need more information** (see IFCC or other document)

Using a “Gray Zone”? **No, there is a negative and a positive**
### TROPONIN I

<table>
<thead>
<tr>
<th>Value</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.04</td>
<td>No evidence of myocardial damage provided sample is at least 12h post symptoms (event).</td>
</tr>
<tr>
<td>0.04 – 0.48</td>
<td>Suggest minor myocardial damage provided at least 12h post event</td>
</tr>
<tr>
<td>&gt;0.49</td>
<td>Indicates major myocardial damage</td>
</tr>
</tbody>
</table>

- **Using the 99th% ile for decision point?** Need more information (see IFCC or other document)
- **Using a “Gray Zone”?** YES
TROPONIN I

- <0.04: Troponin appears normal or minor myocardial damage or other cause
- >0.04: Consistent with Myocardial Infarction

This information is based on the recommendations of the 2012 Third Universal Definition of Myocardial Infarction for Troponin to be at least one value above the 99th percentile upper reference limit.

- Using the 99th% ile for decision point? Probably (see IFCC or other document) – also cite the source (may see website links or PDF links)

- Using a “Gray Zone”? No, there is a negative and a positive
SCPC Website: GUIDELINES

Guidelines

SCPC provides the following links, which are known to be the current guidelines and recommendations for the care of patients with ACS.

Guidelines

- ACC/AHA 2014 Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes
- ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Intervventional Procedures
- 2013 ACCF-AHA Guideline for the Management of STEMI
- 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction
- 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction
- Comprehensive listing of all ACCF/AHA current guidelines
RESOURCES: www.acc.org

Third Universal Definition of Myocardial Infarction

Oct 16, 2012

Journal of the American College of Cardiology


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Science tells us what we can do

Guidelines tell us what we should do

Accreditation is the roadmap to implement the “should do”

Registries measure performance on the “should do”

Quality Initiatives & Education are the levers to improvement
Thank you!
Ruth Cantu, BSN, RN
rcantu@acc.org