Point of care testing of cardiac biomarkers: Intersection of evidence based medicine, guideline development and clinical practice

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Professor of Medical & Research Technology
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Evidence of a Major Health Problem

- 500,000 CHD deaths per year
- 250,000 sudden deaths per year
- 700,000 hospitalized MIs per year
- 1.25 million MIs per year
- 6 million patients with CHD
Atherosclerotic Plaque

Photos courtesy of Boehringer Ingleheim International GmbH, by Lennart Nilsson.
Plaque Rupture

Photos courtesy of Boehringer Ingleheim International GmbH, by Lennart Nilsson.
Platelet Activation

Photos courtesy of Boehringer Ingeheim International GmbH, by Lennart Nilsson.
Myocardial Ischemia

Photos courtesy of Boehringer Ingleheim International GmbH, by Lennart Nilsson.
Myocardial Infarction

Photos courtesy of Boehringer Ingleheim International GmbH, by Lennart Nilsson.
Acute Coronary Syndromes

No ST Elevation

Unstable Angina

NQW-MI

QW-MI

Cardiac Biomarkers
Relative Marker Increase after Myocardial Infarction

**Note:** Markers are expressed as multiples of the upper limit of the reference interval. Thus the relative increase will vary depending on the normal reference interval utilized.

**Note:** The time scale above (x-axis) is not linear.
Ischemia Markers: Potential Candidates

- Ischemia Modified Albumin
- Natriuretic peptides
- Myeloperoxidase
- Matrix metalloproteinases
- Placental Growth Factor
- Whole blood choline
- Nourin-1
- Soluble CD40L
- D-Dimer
- CRP, IL-1, IL-6
- Free fatty acid
- Troponin (fragments)
- Pregnancy Associated Plasma Protein A (PAPP-A)
- Cell adhesion molecules
- Glutathione peroxidase 1
- Glycogen phosphorylase-BB
- Antiplatelet Factor 4/heparin antibodies
- Thrombus precursor protein
- Lipoprotein associated Phospholipase A2
- Ox-LDL/MDA-modified LDL
# ACC/AHA Recommendation Classes

<table>
<thead>
<tr>
<th>I</th>
<th>IIa</th>
<th>IIb</th>
<th>III</th>
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</table>

- **Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.**
- Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. **Weight of evidence/opinion is in favor of usefulness/efficacy.**
- Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. **Usefulness/efficacy is less well established by evidence/opinion.**
- Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.
Weighing the Evidence

Weight of evidence grades

- **A** = Data from many large, randomized trials
- **B** = Data from fewer, smaller randomized trials, careful analyses of nonrandomized studies, observational registries
- **C** = Expert consensus
National Academy of Clinical Biochemistry—Laboratory Medicine Practice Guidelines

Biomarkers of Acute Coronary Syndrome: Point of Care Testing
**NACB POCT of Cardiac Markers**

- **Recommendation 1**: Early in the process, manufacturers are encouraged to seek assistance and provide support to professional organizations such as the AACC or IFCC to develop committees for the standardization of new analytes. These organizations will determine the need for analyte standardization based on the potential clinical importance of the marker and gather the necessary scientific expertise for the formation of a standardization committee.

- **Recommendation**: Class I
- **Level of Evidence**: B
cTnT and cTnI

Diagnosis of Acute Myocardial Infarction
When troponin is increased think heart

Cardiac isoforms in blood
“Definition of MI. Criteria for acute, evolving or recent MI.”

Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers for myocardial necrosis with at least one of the following:

- Ischemic symptoms
- Development of pathologic Q waves on ECG
- ECG changes indicative of ischemia (ST↑ or ST↓)

- Decision point (cutoff) for myocardial infarction is the 99th percentile of a reference control population.
- 10% total CV at the decision point
- Measurements should be performed at presentation, 6-9 hours, and >12 hours if earlier samples are negative and suspicion is high

NACB Draft Recommendations

Class I

Cardiac troponin is the preferred marker for the diagnosis of MI. CK-MB by mass assay is an acceptable alternative when cardiac troponin is not available (Level of Evidence: A).

Blood should be obtained for testing at hospital presentation followed by serial sampling with timing of sampling based on the clinical circumstances. For most patients, blood should be obtained for testing at hospital presentation, at 6 to 9 hours, and again at 12 –24 hours if the earlier samples are negative and the clinical index of suspicion is intermediate or high (Level of Evidence: C).

Class Ila

For patients who present within 6 hours of the onset of symptoms, an early marker of myocardial necrosis may be considered in addition to a cardiac troponin. Myoglobin is the most extensively studies marker for this purpose. (Level of Evidence: B)
cTnT and cTnI

Risk stratification
Meta-Analysis: Troponin T or I and NSTE MI

*JACC 2001;38:478-85.*

<table>
<thead>
<tr>
<th>Troponin I</th>
<th>Less Risk</th>
<th>Odds Ratio</th>
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<td>Clinical Trials</td>
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<td>Hamm (10)</td>
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<td>Hamm (34)</td>
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<td>Ohman (13)</td>
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<tr>
<td>Summary</td>
<td>8.5 (3.5-21.1)</td>
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NACB Recommendation for Risk Stratification

Class I

A cardiac troponin is the preferred marker for risk stratification and, if available, should be measured in all patients with suspected ACS. In patients with a clinical syndrome consistent with ACS, a maximal (peak) concentration exceeding the 99\textsuperscript{th} percentile of values for a reference control group should be considered indicative of increased risk of death and recurrent ischemic events (Level of Evidence: A).
Commercial POCT Platforms

- Qualitative strips
- Strip devices with readers
- Small analyzers: Physician office (whole blood)
Spectral Diagnostics

Qualitative, 15 min assay.
Has connectivity docking station.
Has contract with Carnival cruise ships.
Response Biomedical

Emphasis on bioterrorism. Biological field tests for anthrax, West Nile virus, small pox, ricin, and botulinum toxin. Clinical menu: cTnI, troponin, CK-MB. Non-exclusive license from Roche granted 7/26/05 for NT-proBNP and cTnT.
Roche Diagnostics

Comments: Myoglobin, cTnT, d-dimer, NT-proBNP. High sample volume: 150 uL. 8 min for myoglobin, 12 min for cTnT and NT-proBNP.
iStat

iSTAT meters have wide distribution among hospitals. Only cTnI available now. 10 min assay. Very low sample volume: 16 uL. 10 min TAT.
Menu: myoglobin, CK-MB, cTnI, d-dimer, BNP. High Sample volume: 1.5 mL. 15 min TAT

Pioneering “panel” approach.

Have launched stroke panel in Europe (S100b, MMP-9, D-dimer, BNP).
Stratus CS

POL system
High analytical sensitivity.
Cleared for
Risk stratification.
High sample volume (3 ml).

Menu: cTnI, CK-MB, myoglobin, D-dimer, NTproBNP, hsCRP
bioMerieux

miniVidas is suited for Physician Office Laboratory or Satellite Labs. Only manufacturer to have FDA Clearance for d-dimer as a rule out Test for DVT and PE.
Innotrac Aio!

CK-MB, troponin I, myoglobin, d-dimer. 18 min TAT. Dry chemistry, time-resolved fluorometry.
Biomarkers and Samples (USA)
Arch Pathol Lab Med 2004;128:158-164

Cardiac markers performed in institution
Troponin 99.3%
CK-MB 92.1%

Biomarkers ordered on ED presentation with signs and symptoms of ACS
Troponin 98.7%
CK-MB 83.0%

Cardiac marker testing most commonly performed
Main Laboratory 92.8%
ED or Satellite 7.2%

Results of cardiac marker testing performed in lab are reported by
Telephone 1.4%
Computer 98.6%

Specimen most commonly collected for biomarker testing is
Fingerstick 0.6%
Serum 25.7%
Plasma 73.7%
### Imprecision Ratio at Low cTnl

**Clin Chem 2004:50;327-333.**

<table>
<thead>
<tr>
<th>Platform</th>
<th>99th percentile limit, $\mu$g/L</th>
<th>10% total CV concentration, $\mu$g/L</th>
<th>Ratio of 10% CV concentration to 99th percentile limit</th>
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<tr>
<td>AxSYM</td>
<td>0.30</td>
<td>1.22</td>
<td>4.1</td>
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<td>ACS: 180</td>
<td>0.10</td>
<td>0.37</td>
<td>3.7</td>
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<td>Centaur</td>
<td>0.10</td>
<td>0.33</td>
<td>3.3</td>
</tr>
<tr>
<td>Immun 1</td>
<td>0.10</td>
<td>0.34</td>
<td>3.4</td>
</tr>
<tr>
<td>Access</td>
<td>0.04</td>
<td>0.06</td>
<td>1.5</td>
</tr>
<tr>
<td>Access 2</td>
<td>0.04</td>
<td>0.09</td>
<td>2.3</td>
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<tr>
<td>Vidas</td>
<td>0.10</td>
<td>0.36</td>
<td>3.6</td>
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<tr>
<td>Liaison</td>
<td>0.03</td>
<td>0.065</td>
<td>2.2</td>
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<td>Dimension RxL</td>
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<td>Immulite One</td>
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<tr>
<td>Vitros ECI</td>
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<tr>
<td>E170</td>
<td>0.01</td>
<td>0.04</td>
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<td>Elecsys 1010</td>
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<td>0.04</td>
<td>4.0</td>
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<tr>
<td>AIA 21</td>
<td>0.06</td>
<td>0.09</td>
<td>1.5</td>
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</table>

$^a$ Data obtained from manufacturer’s package insert or through personal communications with manufacturers.

$^b$ ND, not determined.
Satisfaction with Accuracy

From Quantitative Central Lab Measurements to POCT

<table>
<thead>
<tr>
<th>Test</th>
<th>Before POCT (15 RNs, 36 MDs)</th>
<th>During POCT (13 RNs, 17 MDs)</th>
<th>Difference (During – Before)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis</td>
<td>4.0</td>
<td>4.6</td>
<td>0.6</td>
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<tr>
<td>Pregnancy testing</td>
<td>4.4</td>
<td>4.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Glucose</td>
<td>4.3</td>
<td>4.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>4.3</td>
<td>3.7</td>
<td>−0.6</td>
</tr>
<tr>
<td>Mean</td>
<td>4.25</td>
<td>4.53</td>
<td>0.28</td>
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NACB POCT of Cardiac Markers

- **Recommendation 5**: While it is recognized that qualitative systems do provide useful information, it is recommended that POC systems provide quantitative results.
  - **Recommendation: Class Ila**
  - **Evidence B**
Troponin is increased. Now what?
Acute Coronary Syndromes

No ST Elevation
Unstable Angina

ST Elevation
NQW-MI
QW-MI
Relationship between thrombus characteristics and therapeutic direction

Meta-Analysis of all Major Randomized Clinical Trials of GP IIb/IIIa Inhibitors

Lancet 2002;359:189-98
Meta-Analysis of all Major Randomized Clinical Trials of GP IIb/IIIa Inhibitors

• Baseline troponin available in 11,059 pts
• 45% had troponin positive baseline result
  – Compared to placebo or controls
  – 15% reduction in 30-day death/MI with GP IIb/IIIa treatment
  – 10.3% vs. 12.0%; Odds ratio: 0.85[0.71-1.03]

• 55% had troponin negative baseline result
  – Compared to placebo or controls
  – No risk reduction observed with GP IIb/IIIa treatment
  – 7.0% vs. 6.2%; Odds ratio: 1.17[0.94-1.44]

• Significant Differential Treatment effect: p=0.045
Meta-Analysis of all Major Randomized Clinical Trials of GP IIb/IIIa Inhibitors

“The available data confirmed that patients with raised troponin concentrations are at increased risk of adverse cardiac complications. Moreover, increased troponin concentrations identified a subgroup of patients in whom treatment with GP IIb/IIIa inhibitors was particularly beneficial. In fact, no benefit was apparent in patients with negative troponin value.”

Lancet 2002;359:189-98
ACC/AHA Guidelines: Recommendations for Acute Therapies

High risk: ST-segment depression, **positive cardiac markers**, transient ST Segment elevation, deep T-wave inversion, and recurrent/continuing ischemia.

* Circulation 2000;102:1193-1209
Acute Coronary Syndromes

Is Time Muscle?

No ST Elevation

Unstable Angina

Cardiac Biomarkers

NQW-MI

QW-MI

70% of patients

30% of patients

?
EARLY Pilot Trial

Eptifibatide for Acute Coronary Syndromes: Rapid vs. Late Administration - Therapeutic Yield

Duke Clinical Research Institute
Non-ST-Elevation ACS
Chest Pain > 10 mins

Immediate Cardiac Catheterization Discouraged
Aspirin + IV Heparin Required

Randomization

Eptifibatide (Integrilin®)
Bolus + Infusion

Placebo
Bolus + Infusion

12 – 24 hours of Double Blinded Therapy

Second Bolus Placebo
Between 12–24 hrs.

Second Bolus (Crossover) Eptifibatide
Between 12–24 hrs.

Following 2nd Bolus,
Place All Patients on Open-Label Eptifibatide Infusion

Cardiac Catheterization Encouraged
### Core Lab Analyses - All Patients

<table>
<thead>
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<th>Early Treatment (n=153)</th>
<th>Late Treatment (n=158)</th>
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</thead>
<tbody>
<tr>
<td><strong>Actual Peak CK-MB (ng/ml)</strong></td>
<td>7.4 (2.1, 51.5)</td>
<td>9.1 (1.9, 34.6) *</td>
</tr>
<tr>
<td>Peak CK-MB &lt; 2X ULN (%)</td>
<td>60.8</td>
<td>60.8</td>
</tr>
<tr>
<td>Peak CK-MB 2-5X ULN (%)</td>
<td>10.1</td>
<td>15.2</td>
</tr>
<tr>
<td>Peak CK-MB &gt; 5X ULN (%)</td>
<td>29.1</td>
<td>24.1</td>
</tr>
<tr>
<td>Time to Peak CK-MB (hrs)</td>
<td>5.1 (3.1, 8.3)</td>
<td>4.5 (3.0, 9.6)</td>
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<tr>
<td>Actual Peak TnT (ng/ml)</td>
<td>0.2 (0.0, 1.2)</td>
<td>0.3 (0.0, 1.3)</td>
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</table>

* *p-value = 0.75*
“We demonstrated no difference in serological measurements of infarct size in patients with NSTE ACS with early versus late administration of eptifibatide.”

Time is Muscle?

Acute Coronary Syndromes

No ST Elevation

- Unstable Angina: 70% of patients

ST Elevation

- NQW-MI
- QW-MI: 30% of patients

No evidence of treatment benefit in first 24 h after onset of symptoms.

Time to Treatment Definitely Has impact on Outcome <6-12 hours
Impact of a POC Satellite Lab in the ED

• Physician satisfaction
  – Test TAT
  – Testing Accuracy
• Turnaround time difference
• ED Length of stay before and after implementation of a satellite lab

NOTE: Qualitative assay used for cardiac biomarkers
### In-lab TAT for Markers

<table>
<thead>
<tr>
<th>Test</th>
<th>Turnaround Time Before POCT, min</th>
<th>Turnaround Time During POCT, min</th>
<th>Change in Turnaround Time After Initiation of POCT, min</th>
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<tr>
<td>Urinalysis</td>
<td>40 (n = 37)</td>
<td>4 (n = 106)</td>
<td>-36 (90%)</td>
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<td>Pregnancy testing</td>
<td>78 (n = 44)</td>
<td>5 (n = 54)</td>
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<td>Glucose</td>
<td>18 (n = 128)</td>
<td>6 (n = 38)</td>
<td>-12 (69%)</td>
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<td>Cardiac markers</td>
<td>110 (n = 62)</td>
<td>17 (n = 128)</td>
<td>-93 (84.5%)</td>
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<tr>
<td>Mean</td>
<td>59.5</td>
<td>8</td>
<td>-51.3 (86.6%)</td>
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### ED Length of Stay

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<th>Test</th>
<th>ED Length of Stay Before POCT, min</th>
<th>ED Length of Stay During POCT, min</th>
<th>Change in ED Length of Stay After Initiation of POCT†</th>
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<td>Urinalysis</td>
<td>395 (n = 37)</td>
<td>358 (n = 106)</td>
<td>37 (P = .25)</td>
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<td>Pregnancy testing</td>
<td>386 (n = 44)</td>
<td>346 (n = 54)</td>
<td>40 (P = .22)</td>
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<td>Glucose</td>
<td>380 (n = 128)</td>
<td>404 (n = 56)</td>
<td>24 (P = 0.03 see text)</td>
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<tr>
<td>Cardiac markers</td>
<td>386 (n = 62)</td>
<td>338 (n = 128)</td>
<td>47 (P = .06)</td>
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<tr>
<td>Mean†</td>
<td>389</td>
<td>347</td>
<td>41 (P = .006)</td>
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### Clinician Satisfaction

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<td>4.5</td>
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<td>Pregnancy testing</td>
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<tr>
<td>Mean</td>
<td>1.95</td>
<td>4.3</td>
<td>2.35 (P &lt; .001)</td>
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*Arch Pathol Lab Med 2003;127:456-460.*
Biomarkers Turnaround Time

Arch Pathol Lab Med 2004;128:158-164

• Determine normative rates of TAT and examine hospital and lab practices associated with faster TATs
• 159 hospitals participating in CAP Q-probes
• Disconnected impression of reasonable vein-to-brain times
  – 82% of Laboratorians, order to report time 60 minutes
  – 75% of ED physicians, vein to brain time 45 minutes
• 7020 troponin and 4368 CK-MB measurements
Biomarkers Turnaround Time

Arch Pathol Lab Med 2004;128:158-164

- TAT expectations of clinicians exceed those lab personnel producing the results.
- Actual TAT meet expectations of neither the lab nor the clinical groups
- Improving TAT performance will require that clinicians and laboratorians work together to develop standards that meet the needs of the medical staff and that are achievable by laboratory personnel.
Biochemical Markers required for diagnosis of NSTEMI

- “When the central lab is used, results should be available within 60 minutes, preferably within 30 minutes…

- …POC Systems…have the advantage of reducing delays in transportation and processing…and can reduce delays at all hours…

- “Portable devices… That allow simultaneous, rapid measurement of myoglobin, CK-MB, and troponin at the bedside are likely to be useful in the assessment of patients with ACS”

NACB POCT of Cardiac Markers

• **Recommendation**: The laboratory should perform cardiac marker testing with a turnaround time (TAT) of 1 hour, optimally 30 minutes, or less. The TAT is defined as the time from blood collection to the reporting of results.

• **Strength/consensus of recommendation**: Ila

• **Level of Evidence**: B
NACB POCT of Cardiac Markers

- **Recommendation:** Institutions that cannot consistently deliver cardiac marker turnaround times of approximately 1 hour should implement point-of-care (POC) testing devices.

- **Recommendation: Class IIb**

- **Evidence C**
Cardiac Biomarkers POCT Summary

- Cardiac troponin T or I is cornerstone
  - Serial sampling: presentation, 6-9 hrs, >12 hrs
- No evidence that decreasing time from symptoms onset to treatment within 24 hours is associated with better patient outcomes.
- POCT measurements can expedite patient flow through healthcare systems.
- POCT cardiac biomarkers have same specifications as central lab measurements.
- 30 min to 1 hr TAT is consensus
Adherence to Guidelines Is Important!
Link Between Overall Guidelines Adherence and Mortality

Every 10% ↑ in guidelines adherence → 11% ↓ in mortality (OR=0.89, 95% CI: 0.81-0.98)

Peterson et al, ACC 2004
Thank you!
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