ABBOTT POINT OF CARE

i-STAT hs-TnI CARTRIDGE

# Clinical evaluation with i-STAT hs-TnI to aid in the diagnosis of Myocardial Infarction (MI)

This speaker program is sponsored by and on behalf of Abbott

ABBOTT POINT OF CARE

# i-STAT hs-TnI Cartridge

## INTENDED USE

The i-STAT hs-TnI cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of cardiac troponin I (cTnI) in whole blood or plasma samples in point of care or clinical laboratory settings. The i-STAT hs-TnI cartridge with the i-STAT 1 System is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

# Largest POC high-sensitivity Troponin Assay Study to date*

- A multicenter, prospective study was conducted at 28 clinical sites to evaluate the clinical performance of the *i-STAT hs-TnI* cartridge with *the i-STAT 1 System*.*
- Venous whole blood and plasma specimens were collected with lithium heparin anticoagulant from subjects presenting to the emergency department (ED) with signs and symptoms suggestive of acute coronary syndrome (ACS).


i-STAT 1 Wireless Analyzer


i-STAT hs-TnI Cartridge

**Note: i-STAT clinical study included 3,585 patients, Siemens included 1,089 and Quidel included 422*

*Sources:*

- *i-STAT hs-TnI Instructions for Use (US)*
- *Siemens Healthineers Atellica VTLi hs-cTnI Instructions for Use (OUS)*
- *Quidel TriageTrue High Sensitivity Troponin I Instructions for Use (OUS)*

ABBOTT POINT OF CARE

i-STAT hs-TnI CARTRIDGE WITH THE i-STAT 1 SYSTEM

# Clinical Performance Data

Abbott Point of Care Pivotal Study: CS-2020-0012

ABBOTT POINT OF CARE

CLINICAL PERFORMANCE | WHOLE BLOOD

# Sex-Specific Cut-off Analysis (Female: 13 ng/L | Male: 28 ng/L)

| SEX | TIME POINT (HOURS)* | N | MI | NON-MI | SENSITIVITY (%) | SPECIFICITY(%) | PPV(%) | NPV(%) |
|---|---|---|---|---|---|---|---|---|
| FEMALE | 0 to 1 | 1870 | 129 | 1741 | 91.47 | 83.23 | 28.78 | 99.25 |
| | >1 to 3 | 1799 | 119 | 1680 | 96.64 | 82.14 | 27.71 | 99.71 |
| | >3 to 6 | 724 | 70 | 654 | 97.14 | 77.83 | 31.92 | 99.61 |
| | >6 | 60 | 16 | 44 | 100.00 | 54.55 | 44.44 | 100.00 |
| MALE | 0 to 1 | 1090 | 130 | 960 | 79.23 | 84.17 | 40.39 | 96.77 |
| | >1 to 3 | 1025 | 118 | 907 | 90.68 | 83.90 | 42.29 | 98.58 |
| | >3 to 6 | 439 | 69 | 370 | 94.20 | 82.97 | 50.78 | 98.71 |
| | >6 | 47 | 12 | 35 | 91.67 | 57.14 | 42.31 | 95.24 |

*All timepoints are relative to ED presentation.

ABBOTT POINT OF CARE

CLINICAL PERFORMANCE | WHOLE BLOOD

# Overall Cut-off Analysis: (OVERALL: 21 ng/L)

| SEX | TIME POINT (HOURS)* | N | MI | NON-MI | SENSITIVITY (%) | SPECIFICITY(%) | PPV(%) | NPV(%) |
|---|---|---|---|---|---|---|---|---|
| FEMALE | 0 to 1 | 1870 | 129 | 1741 | 86.05 | 89.37 | 37.50 | 98.86 |
| | >1 to 3 | 1799 | 119 | 1680 | 92.44 | 89.70 | 38.87 | 99.41 |
| | >3 to 6 | 724 | 70 | 654 | 95.71 | 85.78 | 41.88 | 99.47 |
| | >6 | 60 | 16 | 44 | 93.75 | 65.91 | 50.00 | 96.67 |
| MALE | 0 to 1 | 1090 | 130 | 960 | 83.08 | 78.33 | 34.18 | 97.16 |
| | >1 to 3 | 1025 | 118 | 907 | 92.37 | 77.95 | 35.28 | 98.74 |
| | >3 to 6 | 439 | 69 | 370 | 95.65 | 74.32 | 40.99 | 98.92 |
| | >6 | 47 | 12 | 35 | 91.67 | 54.29 | 40.74 | 95.00 |

*All timepoints are relative to ED presentation.

Dr. Cullen is a researcher and practicing emergency medicine physician in Australia. Not all products discussed in this presentation are available for use in the United States.

The views expressed in this presentation belong to the speaker alone and do not necessarily reflect the views of Abbott or other organizations named in the speaker.

The *i-STAT hs-TnI* cartridge has not been evaluated or cleared by the FDA for use in any accelerated diagnostic protocol. The *i-STAT hs-TnI* cartridge is not cleared for use on i-STAT Alinity in the United States, but Dr. Cullen's study was done in Australia, where the *i-STAT hs-TnI cartridge* is cleared for use on the i-STAT Alinity. The *i-STAT hs-TnI cartridge* is only cleared for use on i-STAT 1 in the United States.



For U.S. audience only
For complete product information visit globalpointofcare.abbott
APOC-25002638.1

# HIGH SENSITIVITY POC TROPONIN TESTING

## and AMI diagnosis


**PROF LOUISE CULLEN**

MBBS PhD FACEM FESC

EMERGENCY PHYSICIAN


# Disclosures

The views expressed here are solely my own and do not reflect the opinions or positions of any affiliated employer, organization or entity.

**Representative roles:** National Heart Foundation, International Federation of Clinical Chemistry, ACVC Cardiac Biomarker Committee.

**Advisory board/Committee**: Abbott Diagnostics, Siemens Healthineers, Quidel/Ortho Diagnostics

**Consultant:** Abbott Diagnostics, Siemens Healthineers, Quidel/Ortho Diagnostics, Roche

**Institutional grant support**: Abbott Diagnostics, Siemens Healthineers, Beckman Coulter, Radiometer Pacific, Roche.

**IP/Patent**: None

**Stocks/Bonds:** None

# Learning Objectives

- Describe the clinical value of using point-of-care high-sensitivity troponin-I (hs-TnI) assays in the early assessment of patients with suspected acute myocardial infarction in rural institutions
- Identify key challenges in transitioning from contemporary troponin to high-sensitivity troponin assays
- Discuss how the implementation of hs-TnI testing at presentation can improve ED workflows and support timely clinical decision-making
- Discuss approaches to integrating hs-TnI point-of-care testing into existing chest pain pathways and protocols

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# OVERVIEW

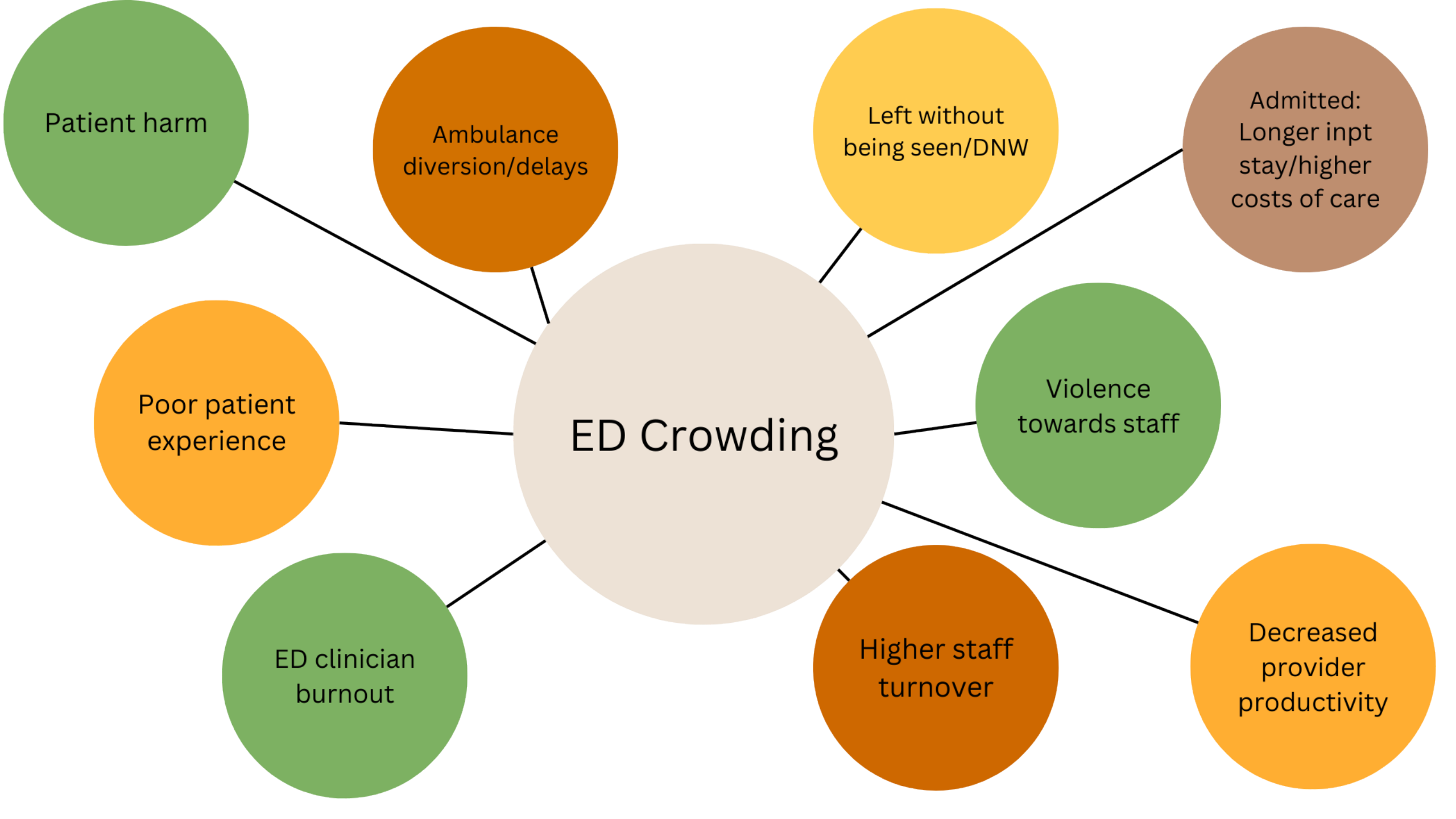
Emergency medicine and ACS

Rapid risk assessment strategies

Troponin assays

POC HS assays

Implementation of POC HS troponin assays


Patient harm
Ambulance diversion/delays
Left without being seen/DNW
Admitted: Longer inpt stay/higher costs of care
Poor patient experience
ED Crowding
Violence towards staff
ED clinician burnout
Higher staff turnover
Decreased provider productivity


Patient harm
dmitted:
Longer inpt
stay/higher
Decreased
provider
productivity
turnover
Patient
Morbidity and
Mortality

# Suspected ACS

Impact on the whole of ED

# Chest pain

Leading cause of
ED presentations

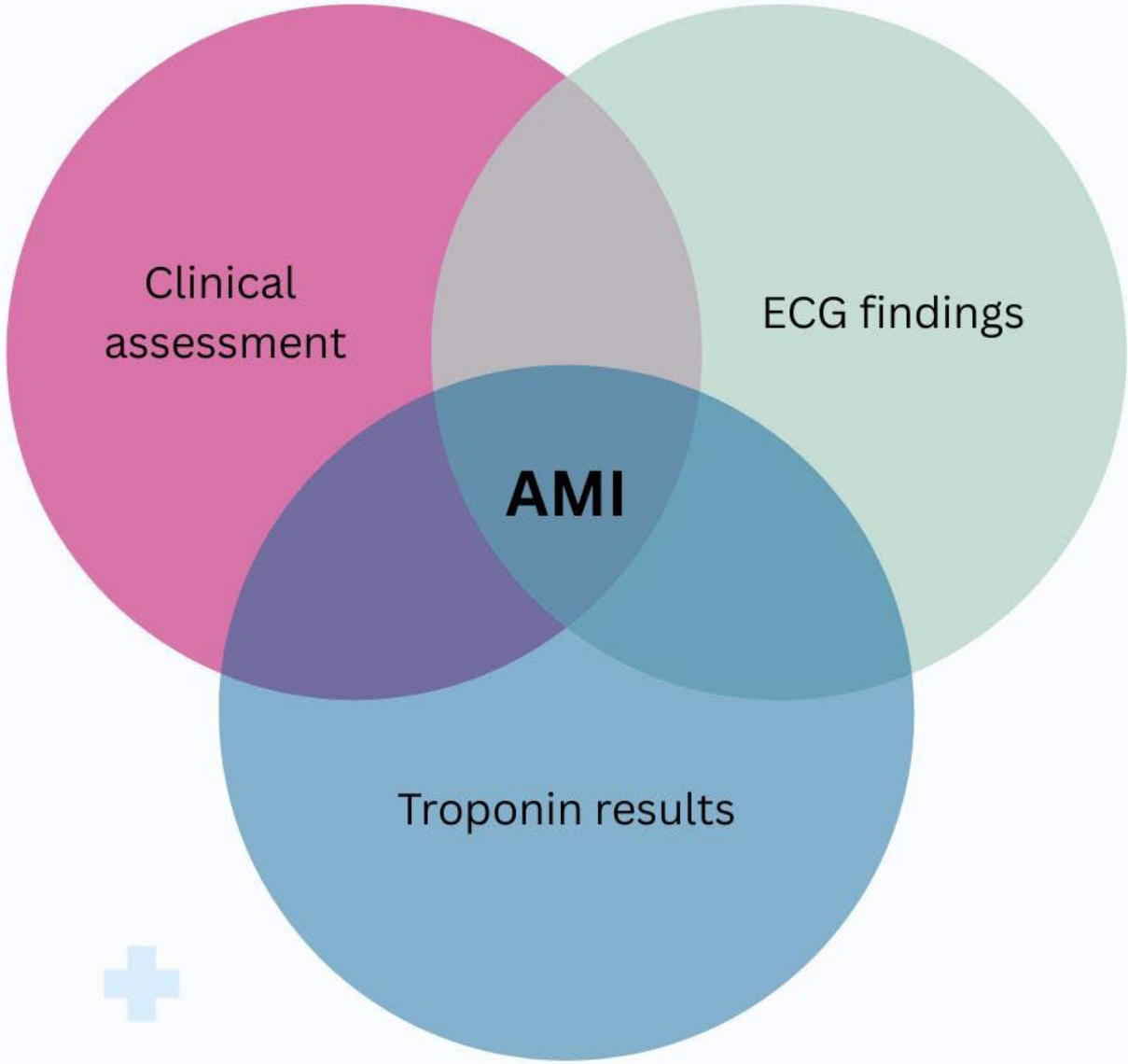
.
.
.

<15% with AMI

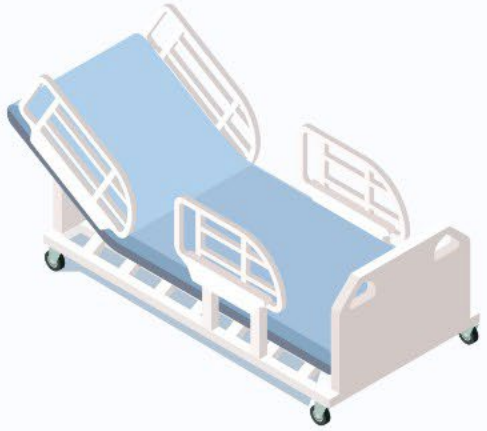
# AMI DIAGNOSIS

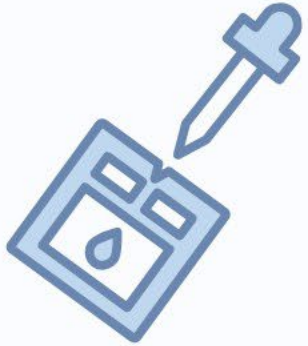
Combination of:

- Clinical assessment
- ECG
- Cardiac troponin (cTn) testing
- Other investigations

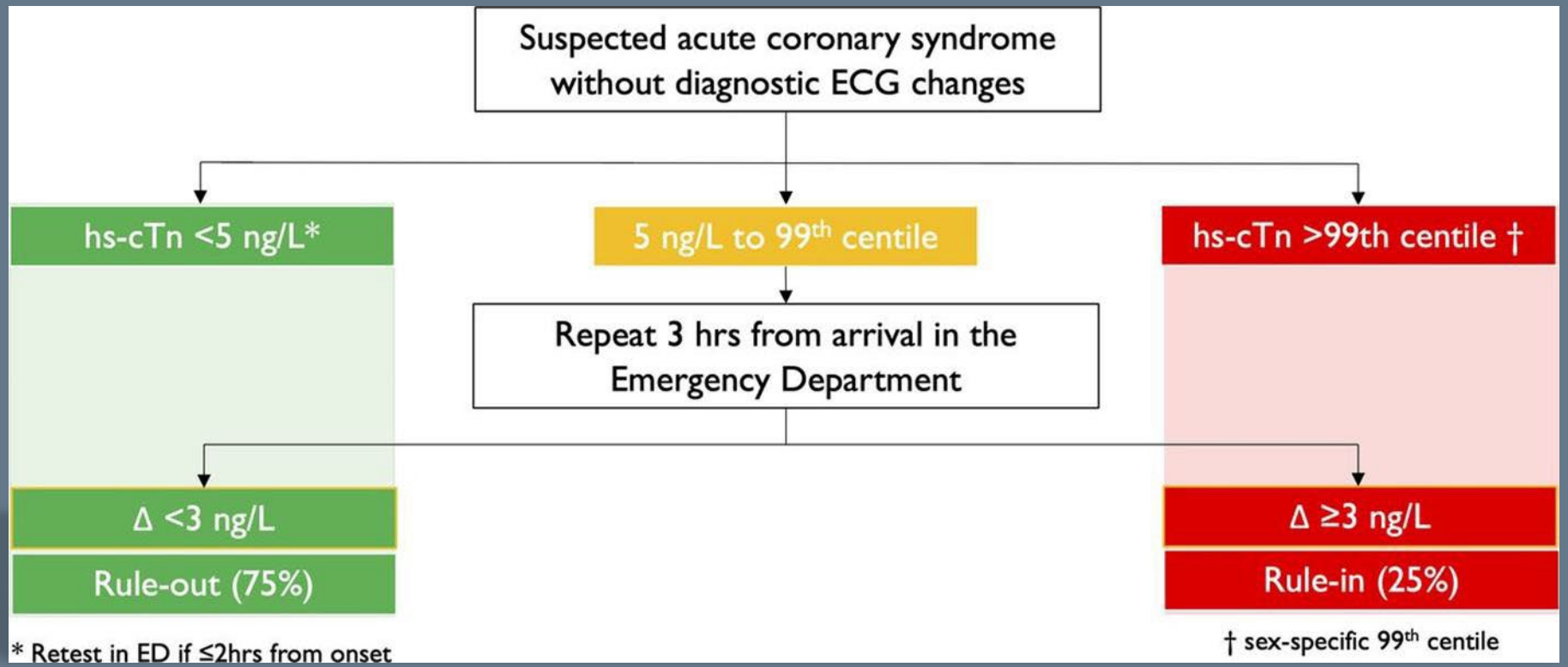


# RAPID SAFE RISK ASSESSMENT STRATEGIES



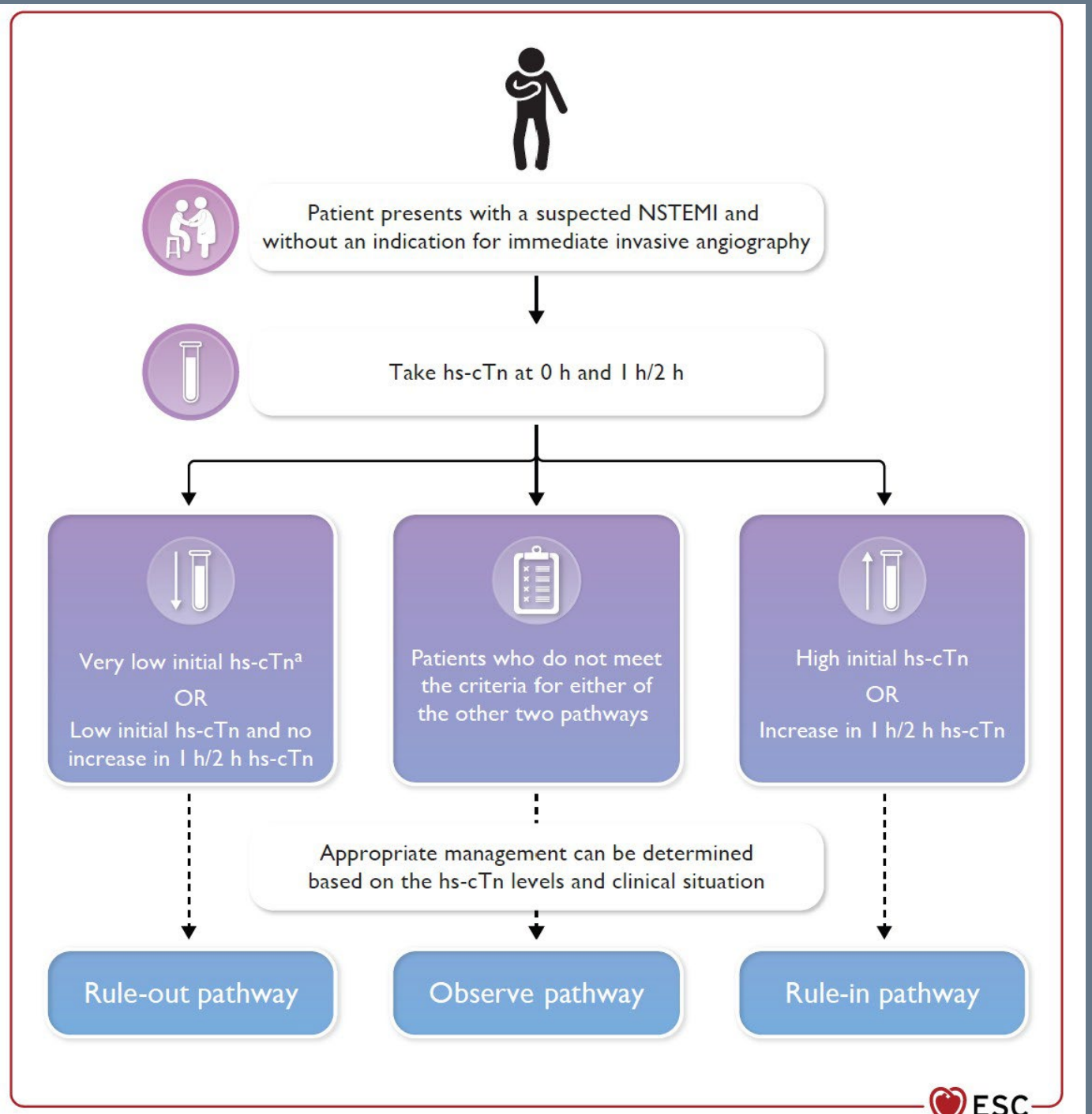


# High STEACS




Matthew T H Lowry et al. Heart 2021;107:1912-1919

# 0/1 and 0/2h strategies

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2023 **ESC** Guidelines for the management of acute coronary syndromes, EHJ (2023) 00, 1-107; https://doi.org/10.1093/eurheartj/ehad191

**Table S4** **Assay specific cut-off levels in ng/L within the 0 h/1 h and 0 h/2 h algorithms**

| 0 h/1 h algorithm | Very low | Low | No 1 hΔ | High | 1 hΔ |
|---|---|---|---|---|---|
| hs-cTnT (Elecsys; Roche) | <5 | <12 | <3 | ≥52 | ≥5 |
| hs-cTnI (Architect; Abbott) | <4 | <5 | <2 | ≥64 | ≥6 |
| hs-cTnI (Centaur; Siemens) | <3 | <6 | <3 | ≥120 | ≥12 |
| hs-cTnI (Access; Beckman Coulter) | <4 | <5 | <4 | ≥50 | ≥15 |
| hs-cTnI (Clarity; Singulex) | <1 | <2 | <1 | ≥30 | ≥6 |
| hs-cTnI (Vitros; Clinical Diagnostics) | <1 | <2 | <1 | ≥40 | ≥4 |
| hs-cTnI (Pathfast; LSI Medience) | <3 | <4 | <3 | ≥90 | ≥20 |
| hs-cTnI (TriageTrue; Quidel) | <4 | <5 | <3 | ≥60 | ≥8 |
| hs-cTnI (Dimension EXL; Siemens) | <9 | <9 | <5 | ≥160 | ≥100 |
| **0 h/2 h algorithm** | **Very low** | **Low** | **No 2 hΔ** | **High** | **2 hΔ** |
| hs-cTnT (Elecsys; Roche) | <5 | <14 | <4 | ≥52 | ≥10 |
| hs-cTnI (Architect; Abbott) | <4 | <6 | <2 | ≥64 | ≥15 |
| hs-cTnI (Centaur; Siemens) | <3 | <8 | <7 | ≥120 | ≥20 |
| hs-cTnI (Access; Beckman Coulter) | <4 | <5 | <5 | ≥50 | ≥20 |
| hs-cTnI (Clarity; Singulex) | <1 | TBD | TBD | ≥30 | TBD |
| hs-cTnI (Vitros; Clinical Diagnostics) | <1 | TBD | TBD | ≥40 | TBD |
| hs-cTnI (Pathfast; LSI Medience) | <3 | TBD | TBD | ≥90 | TBD |
| hs-cTnI (TriageTrue; Quidel) | <4 | TBD | TBD | ≥60 | TBD |



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| hs-cTnI (TriageTrue; Quidel) | <4 | <5 | <3 | ≥60 | ≥8 |
| hs-cTnI (Dimension EXL; Siemens) | <9 | <9 | <5 | ≥160 | ≥100 |
| **0 h/2 h algorithm** | **Very low** | **Low** | **No 2 hΔ** | **High** | **2 hΔ** |
| hs-cTnT (Elecsys; Roche) | <5 | <14 | <4 | ≥52 | ≥10 |
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ESC European Society of Cardiology
European Heart Journal (2021) 42, 1289–1367
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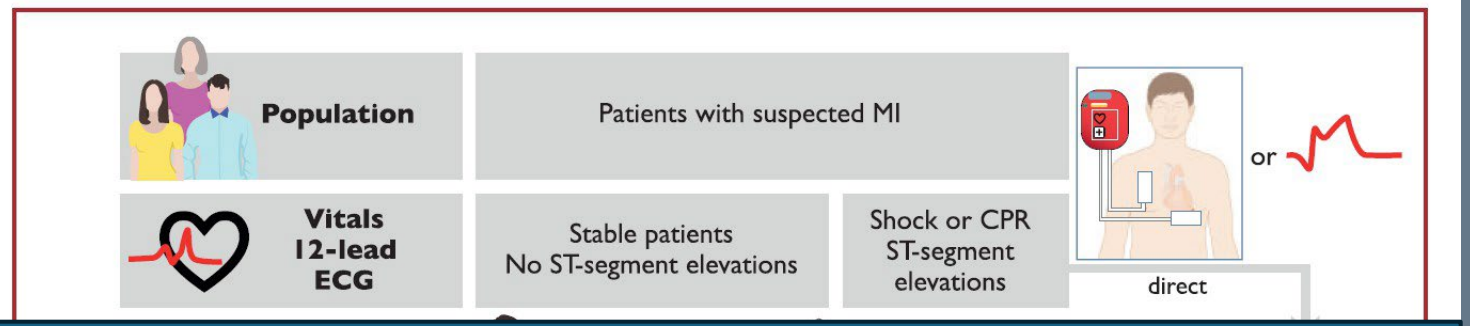

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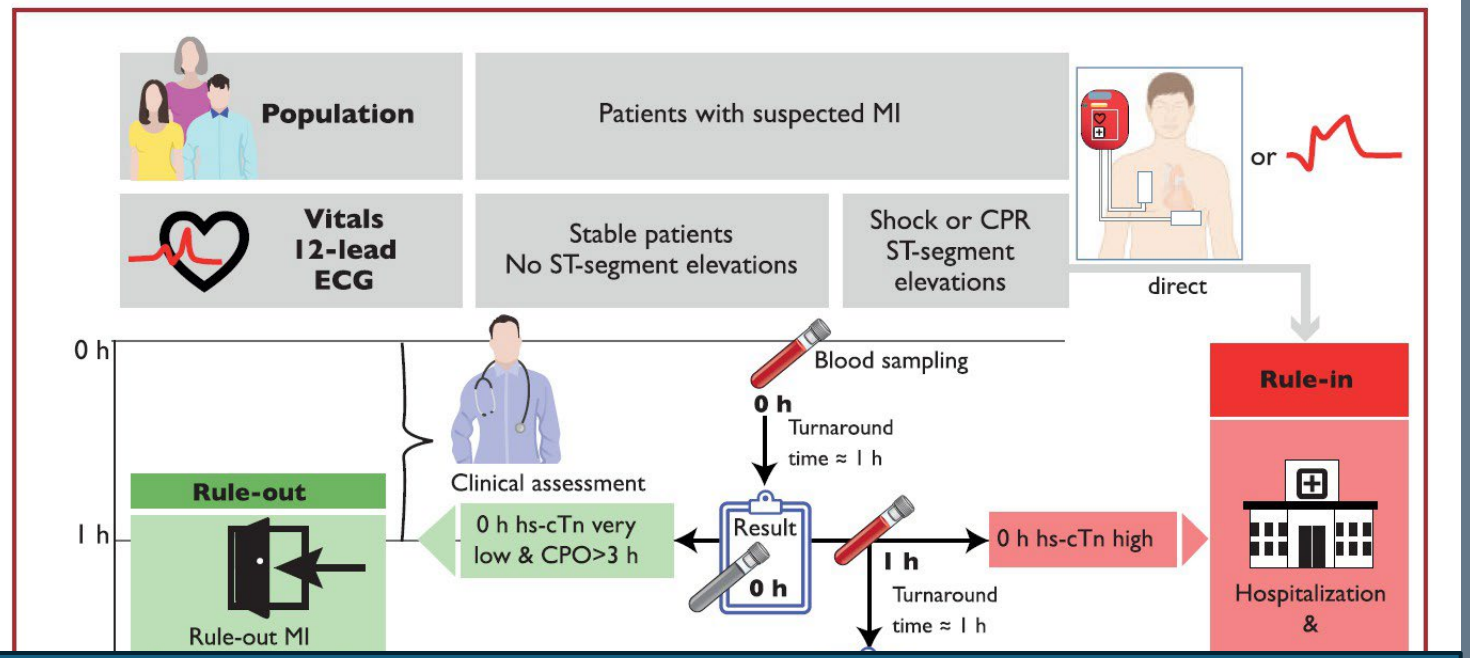

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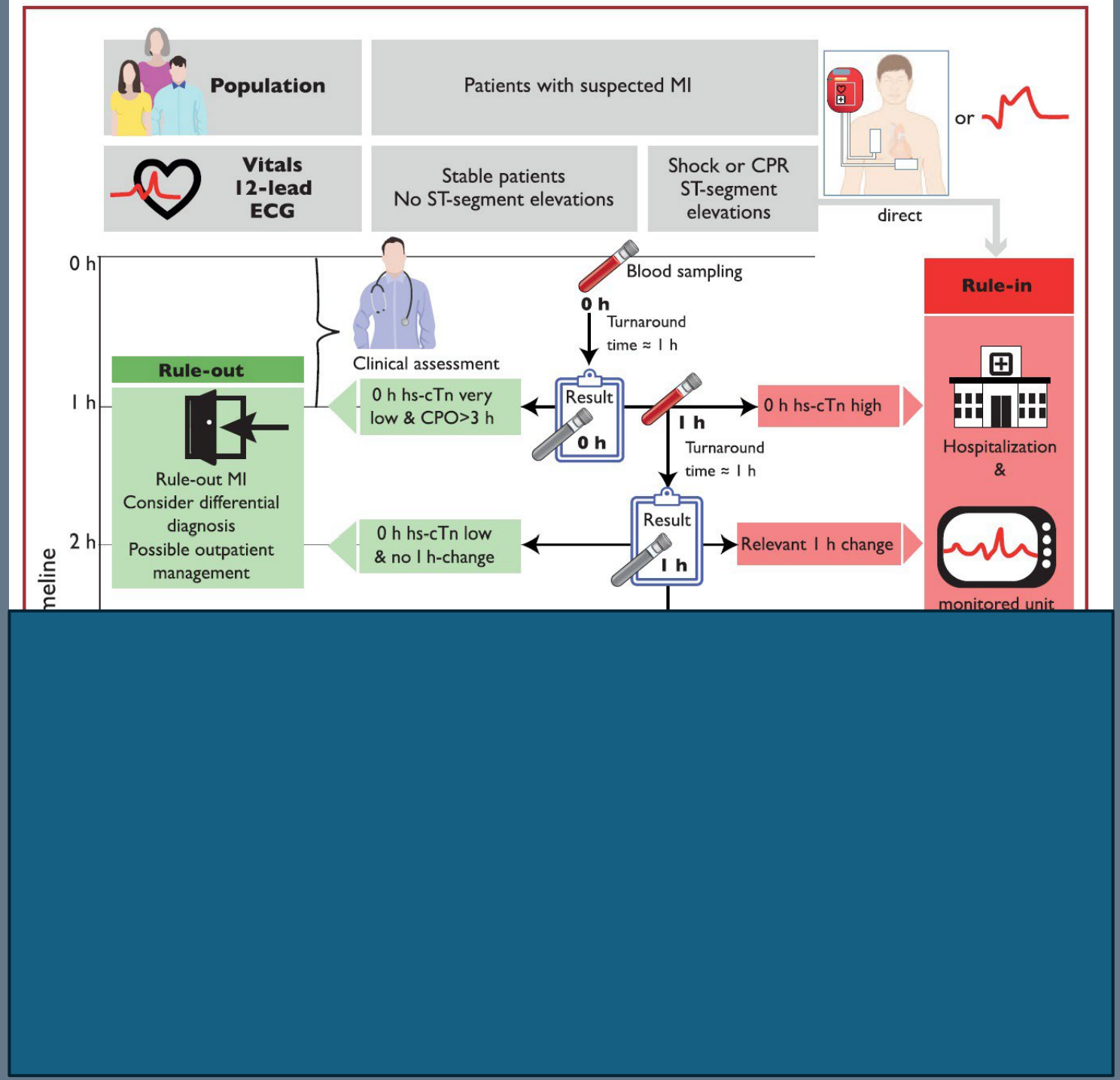

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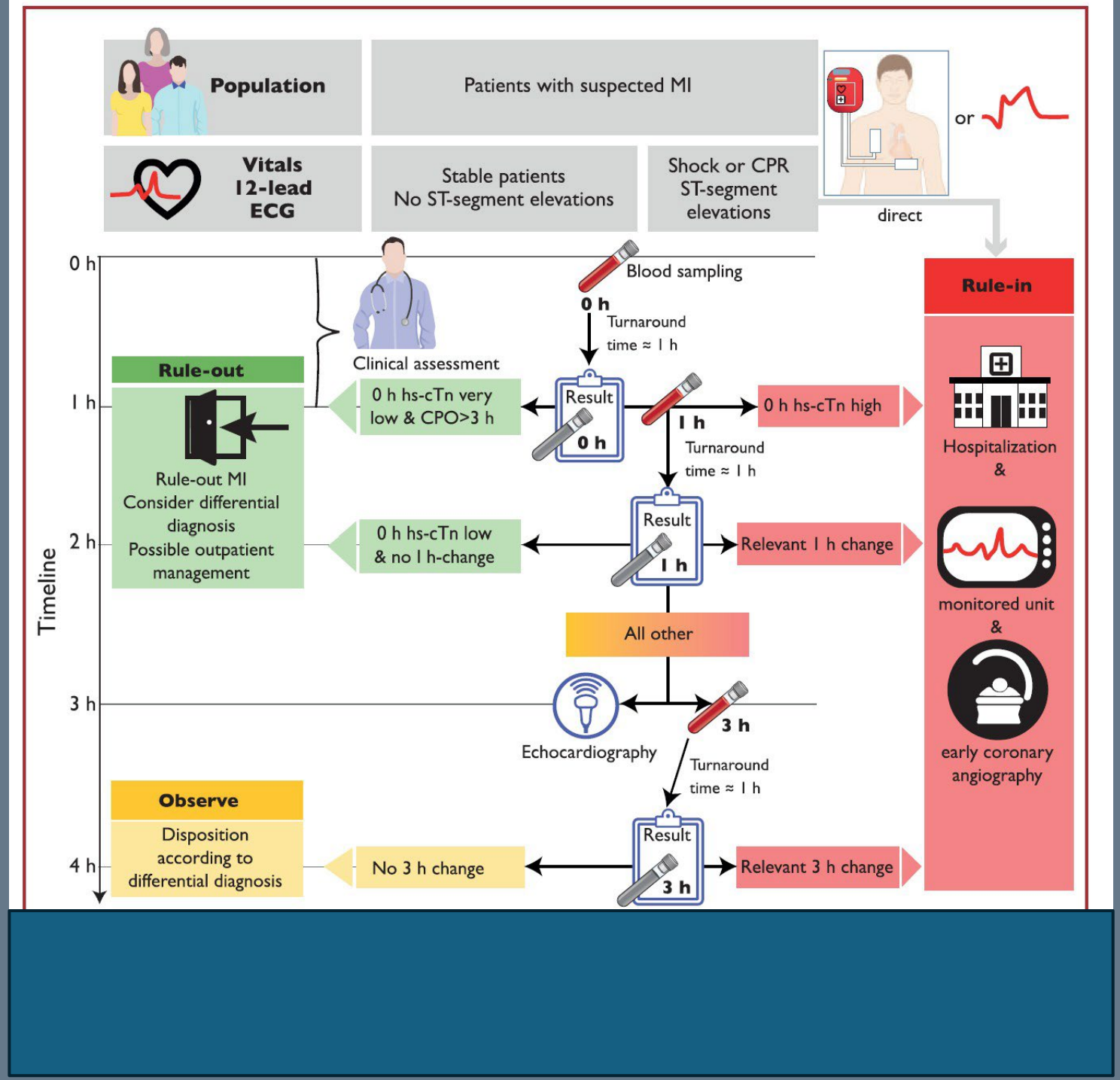

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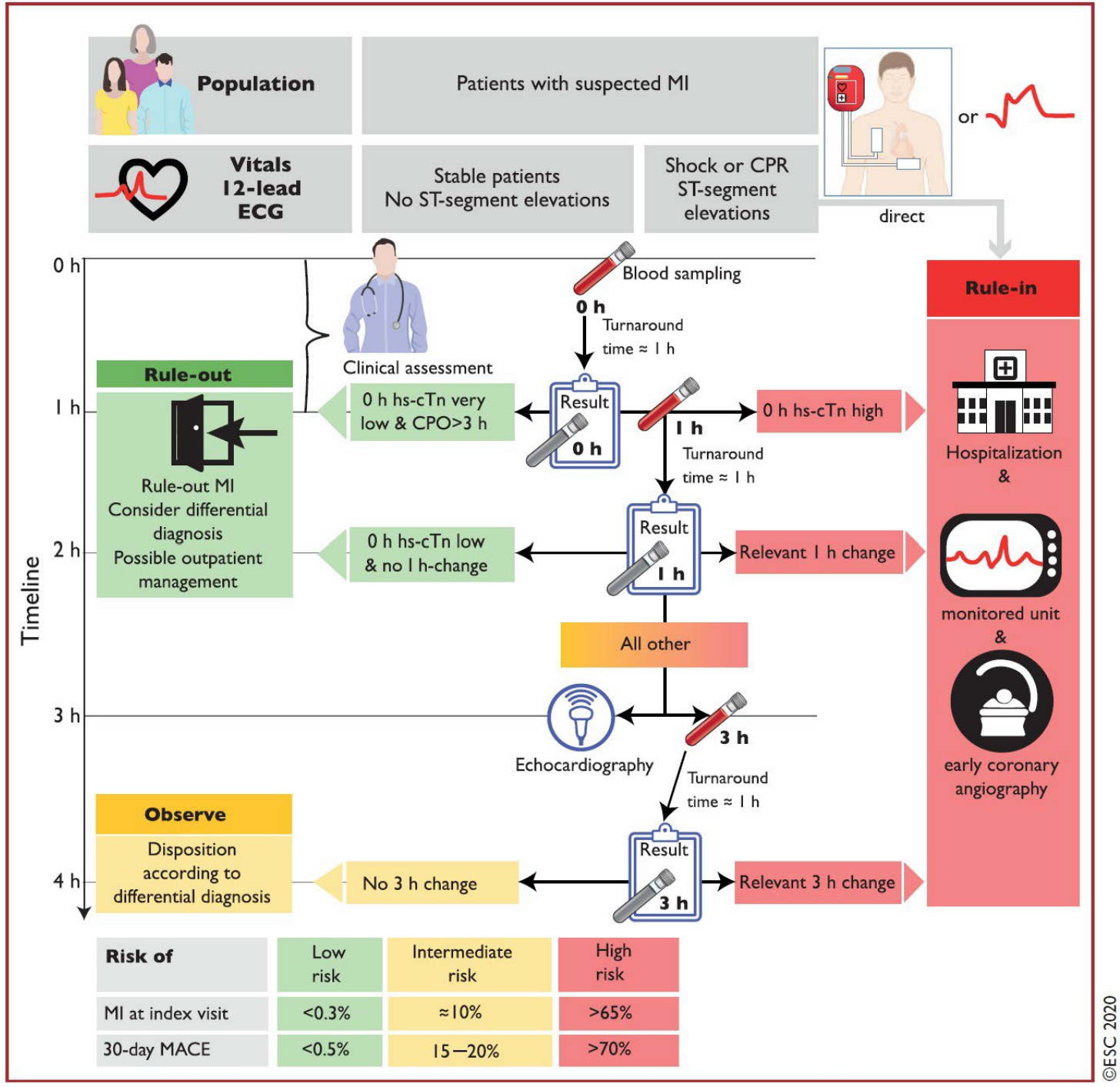

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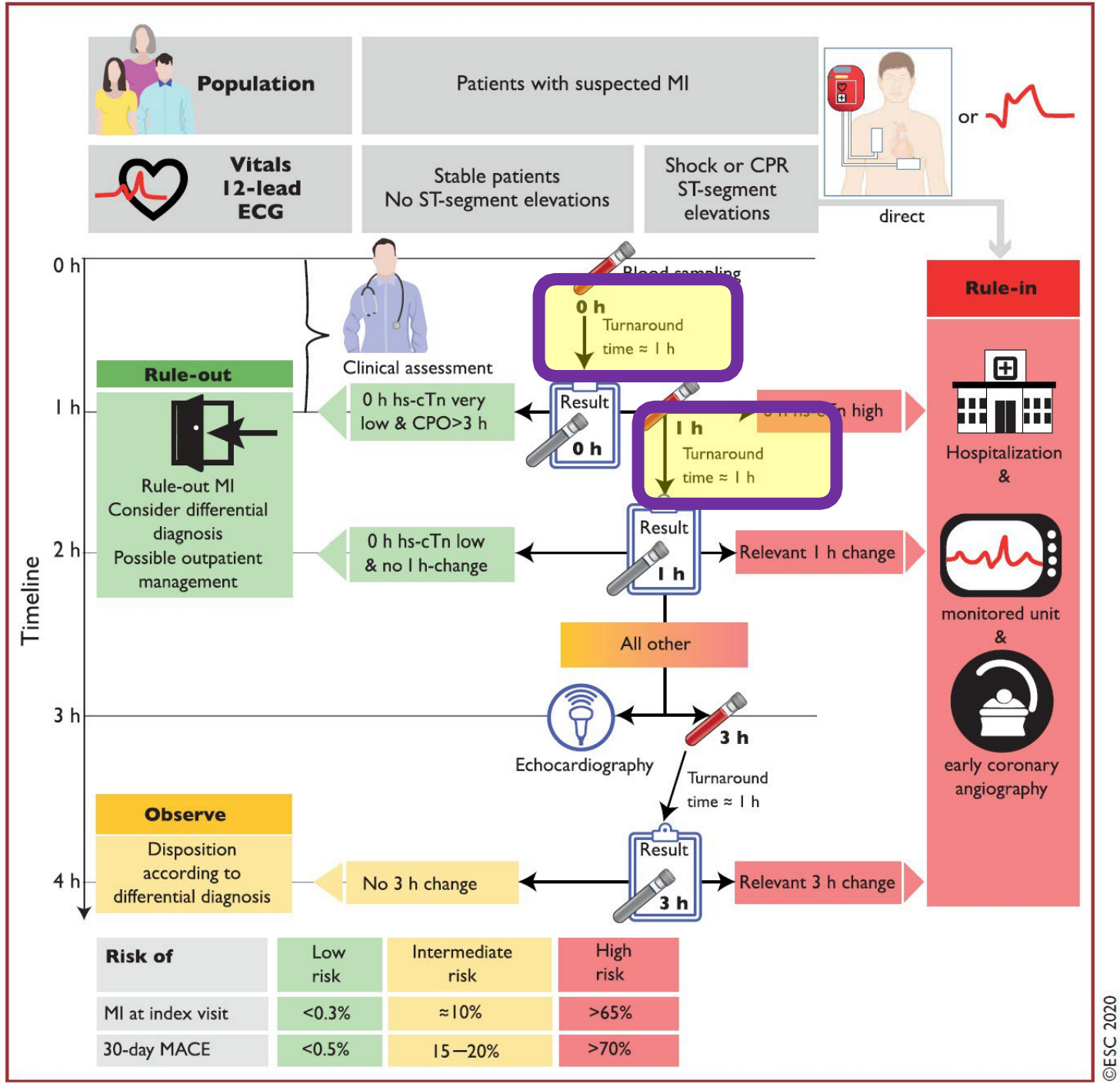
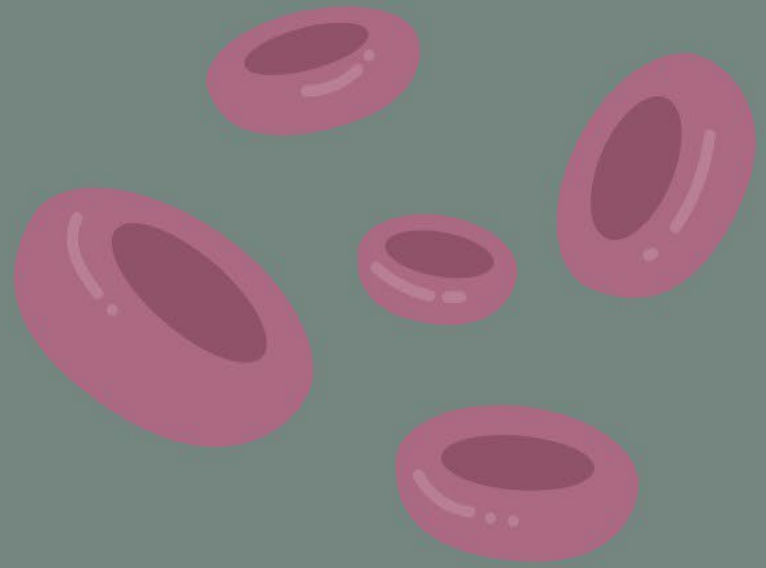




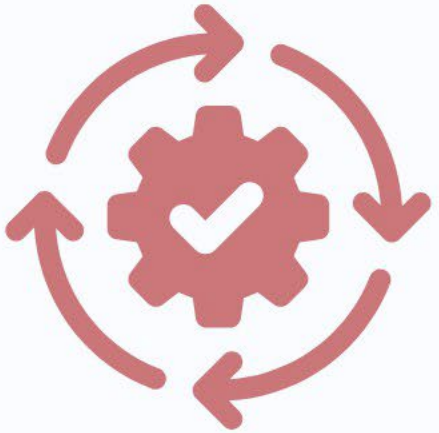
# TROPONIN ASSAYS

# TROPONIN ASSAYS

## HS troponin assays:

- Superior analytical performance
- Defined by two key criteria:
  - Coefficient of Variation (CV) at the 99th percentile upper reference limit (URL) of <=10%
  - ability to measure concentrations above the limit of detection (LoD) but below the 99th percentile in more than 50% of healthy individuals

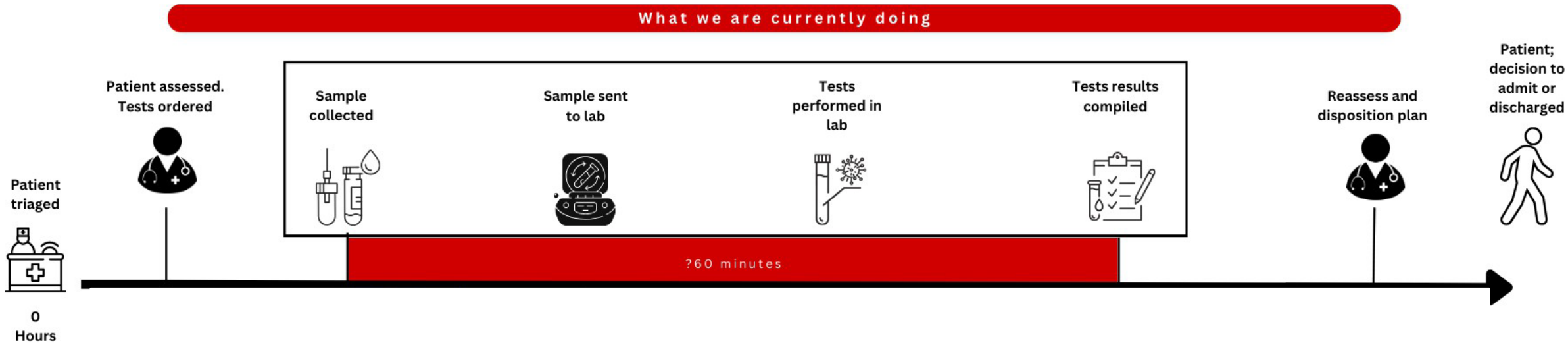
# HS TROPONIN ASSAYS

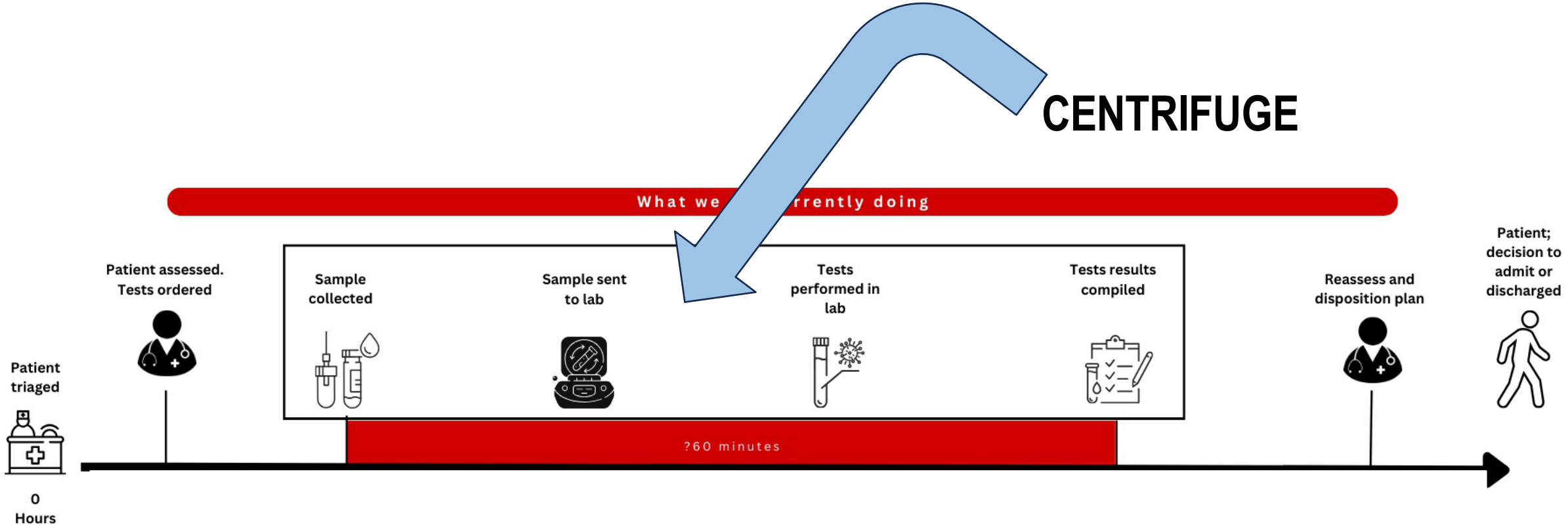


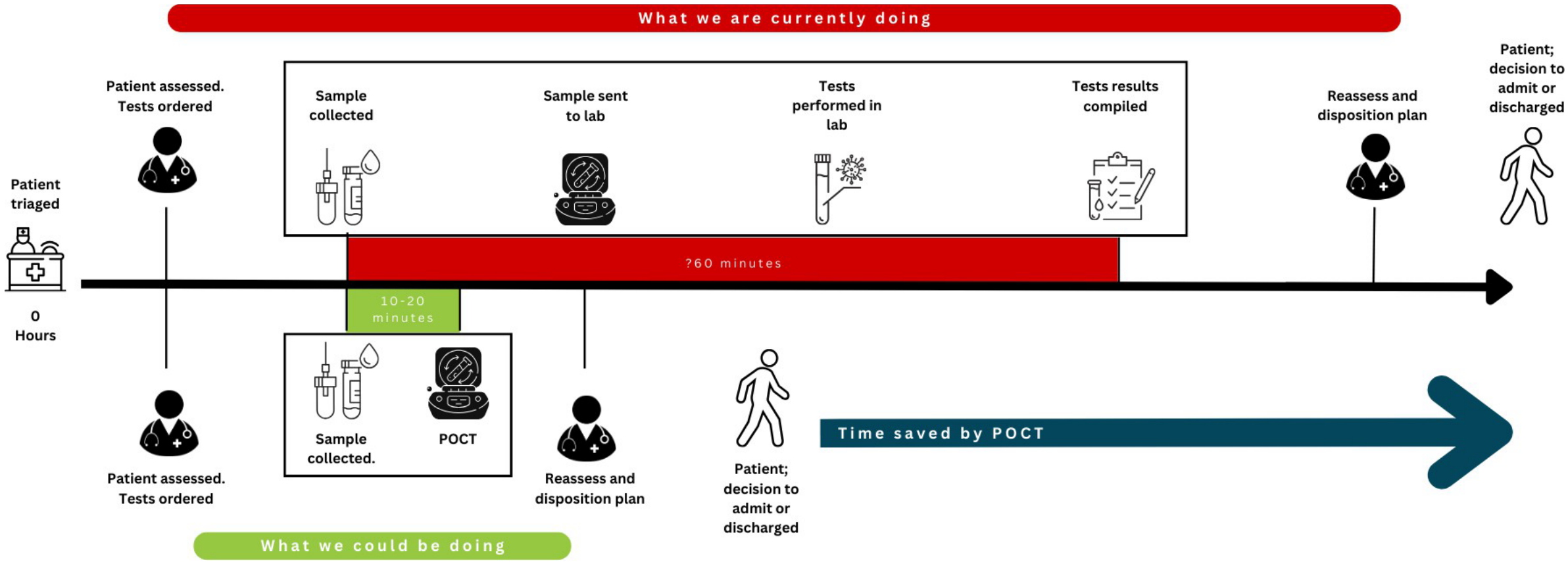
- Earlier and more accurate diagnosis of AMI[1]
- Lower 1-year mortality[2]
- Efficient risk stratification[3]
- Operational and Health system advantages
  - single blood draws, reduced serial testing
  - decrease ED LoS (1.5 - 3 hour reductions)[3]
- Patient benefits - reduced anxiety, earlier DC
- Personalised medicine capabilities - Sex-specific ranges[4], machine learning tech.
- Cost effective - higher test cost, early DC and reduced downstream heath care utilisation[5]

1. Twerenbold, R et al. JACC. 2017. https://doi.org/10.1016/j.jacc.2017.07.718; 2. Hickling S, et al. Heart. 2025. https://doi: 10.1136/heartjnl-2024-324959; 3. Anand A, et al. Circulation. 2021. https://doi.org/10.1161/CIRCULATIONAHA.120.052380; 4. Sandoval Y et al. Circulation. 2022. https://doi.org/10.1161/CIRCULATIONAHA.122.059678; 5. Pincombe A et al. Am Heart J. 2025. https://doi: 10.1016/j.ahj.2025.03.022

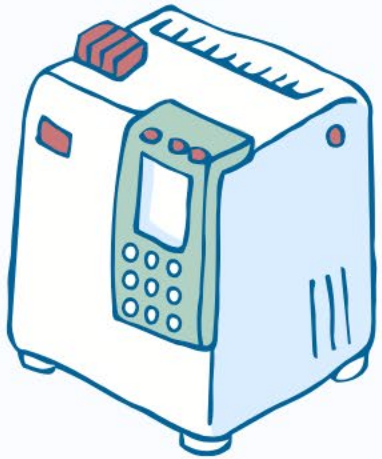
# HS Troponin POC assays


What we are currently doing
Patient triaged
0 Hours
Patient assessed. Tests ordered
Sample collected
Sample sent to lab
Tests performed in lab
Tests results compiled
?60 minutes
Reassess and disposition plan
Patient; decision to admit or discharged


CENTRIFUGE
What we rrently doing
Patient triaged
0
Hours
Patient assessed.
Tests ordered
Sample
collected
Sample sent
to lab
Tests
performed in
lab
Tests results
compiled
?60 minutes
Reassess and
disposition plan
Patient;
decision to
admit or
discharged


What we are currently doing
Patient assessed. Tests ordered
Sample collected
Sample sent to lab
Tests performed in lab
Tests results compiled
Reassess and disposition plan
Patient; decision to admit or discharged
Patient triaged
?60 minutes
0 Hours
10-20 minutes
Sample collected.
POCT
Patient assessed. Tests ordered
Reassess and disposition plan
Patient; decision to admit or discharged
Time saved by POCT
What we could be doing

# POC DEVICES WITH HS ASSAYS

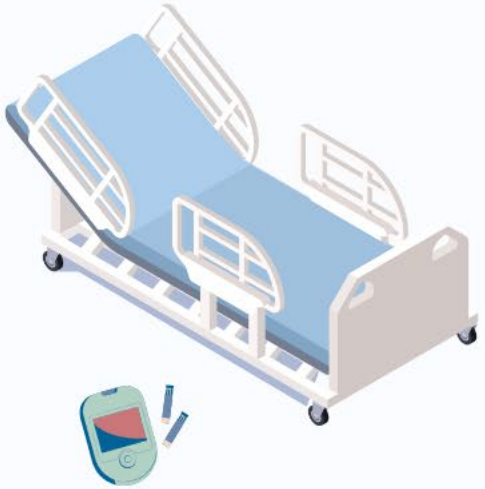


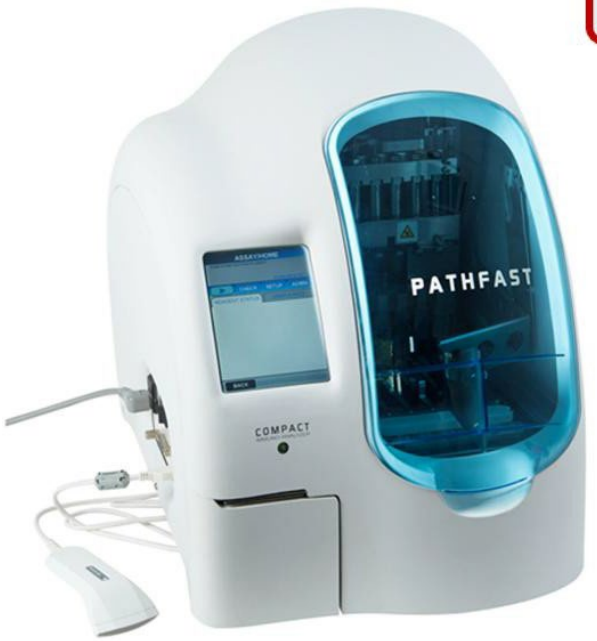
## BENCHTOP PLATFORMS

- PATHFAST
- SPINCHIP
- PYLON

## PORTABLE HAND HELD PLATFORMS

- TRIAGE TRUE
- i-STAT ALINITY
- ATELLICA VTLI




| 0 h/1 h algorithm | Very low | Low | No 1 hΔ | High | 1 hΔ |
|---|---|---|---|---|---|
| hs-cTnT (Elecsys; Roche) | <5 | <12 | <3 | ≥52 | ≥5 |
| hs-cTnI (Architect; Abbott) | <4 | <5 | <2 | ≥64 | ≥6 |
| hs-cTnI (Centaur; Siemens) | <3 | <6 | <3 | ≥120 | ≥12 |
| hs-cTnI (Access; Beckman Coulter) | <4 | <5 | <4 | ≥50 | ≥15 |
| hs-cTnI (Clarity; Singulex) | <1 | <2 | <1 | ≥30 | ≥6 |
| hs-cTnI (Vitros; Clinical Diagnostics) | <1 | <2 | <1 | ≥40 | ≥4 |
| hs-cTnI (Pathfast; LSI Medience) | <3 | <4 | <3 | ≥90 | ≥20 |
| hs-cTnI (TriageTrue; Quidel) | <4 | <5 | <3 | ≥60 | ≥8 |
| hs-cTnI (Dimension EXL; Siemens) | <9 | <9 | <5 | ≥160 | ≥100 |
| **0 h/2 h algorithm** | **Very low** | **Low** | **No 2 hΔ** | **High** | **2 hΔ** |
| hs-cTnT (Elecsys; Roche) | <5 | <14 | <4 | ≥52 | ≥10 |
| hs-cTnI (Architect; Abbott) | <4 | <6 | <2 | ≥64 | ≥15 |
| hs-cTnI (Centaur; Siemens) | <3 | <8 | <7 | ≥120 | ≥20 |
| hs-cTnI (Access; Beckman Coulter) | <4 | <5 | <5 | ≥50 | ≥20 |
| hs-cTnI (Clarity; Singulex) | <1 | TBD | TBD | ≥30 | TBD |
| hs-cTnI (Vitros; Clinical Diagnostics) | <1 | TBD | TBD | ≥40 | TBD |
| hs-cTnI (Pathfast; LSI Medience) | <3 | TBD | TBD | ≥90 | TBD |
| hs-cTnI (TriageTrue; Quidel) | <4 | TBD | TBD | ≥60 | TBD |

2023 **ESC** Guidelines for the management of acute coronary syndromes, EHJ (2023) 00, 1-107; https://doi.org/10.1093/eurheartj/ehad191

# HS POINT OF CARE ASSAYS

| Platform | LoD (ng/L) | 10%CV (ng/L) | URL Male | URL female | Detectable % healthy reference population | Time to results | Clinical performance studies |
|---|---|---|---|---|---|---|---|
| **i-STAT Alinity (Abbott)** | 1.6 (whole blood) | 6.9 | 28 | 13 | | | |
| **TriageTrue (Quidel/Ortho)** | 1.6 (plasma) 1.9 (whole blood) | 8.4 (plasma), 6.2 (wh | | | | | |
| **Atellica VTLi (Siemens)** | | | | | | 8min | yes |
| | | | | 21 | >52% | <17min | yes |
| **(Spin** | | 3.7 | 36.9 | 27.3 | >62% | ~10min | yes |
| **(ET Healthcare)** | 1.2-1.4 | 10 (whole blood) 5 (plasma) | 27 | 21 | >89% | <20min | no |

i-STAT hs-TnI is not cleared for use on the i-STAT Alinity in the U.S. Dr. Cullen's study was done in Australia where she is a practicing physician and where i-STAT hs-TnI is cleared for use on the i-STAT Alinity. i-STAT hs-TnI is only cleared for use in on i-STAT 1 in the U.S.

# HS POINT OF CARE ASSAYS

| Platform | LoD (ng/L) | 10%CV (ng/L) | URL Male | URL female | Detectable % healthy reference population | Time to results | Clinical performance studies |
|---|---|---|---|---|---|---|---|
| **i-STAT Alinity (Abbott)** | 1.6 (whole blood) | 6.9 | 28 | 13 | >50% | ~15min | yes |
| **TriageTrue (Quidel/Ortho)** | 1.6 (plasma)<br>1.9 (whole blood) | 8.4 (plasma),<br>6.2 (whole blood) | 25.7 | 14.4 | >=50% | <20min | yes |
| **Atellica VTLi (Siemens)** | 1.2 (plasma)<br>1.6 (whole blood) | 6.7 (plasma)<br>8.9 (whole blood) | 27 | 18 | >=80% | ~8min | yes |
| **Pathfast (LSI Medience)** | 2.3 | 15 | 30 | 21 | >52% | <17min | yes |
| **SpinChip (SpinChip Diagnostics)** | 1. (plasma)<br>2. (whole blood) | 3.7 | 36.9 | 27.3 | >62% | ~10min | yes |
| **Pylon (ET Healthcare)** | 1.2-1.4 | 10 (whole blood)<br>5 (plasma) | 27 | 21 | >89% | <20min | no |

# CLINICAL STUDIES

| Study | Assay | Study type | Sample type |
|---|---|---|---|
| Sorensen NA et al. Clin Chem 2019; 65:1592–601 | PATHFAST; LSI Medience | Retrospective derivation | Stored plasma |
| Boeddinghaus J, et al. JACC 2020; 75:1111–24; Dakshi AA, et al. EHJ 2023;44. | TriageTrue; Quidel/Ortho Diagnostics | Retrospective derivation<br>Prospective validation | Stored plasma<br>Whole blood (WB) |
| Apple FS, et al. Circulation 2022; 146:1918–29; Cullen L, et al. EHJ 2024; 45 (28):2508-2515 | Atellica VTLi; Siemens | Prospective derivation/validation | Fresh WB/Stored plasma |
| *Greenslade JH, et al. EHJ. ACC. 2025. doi: 10.1093/ehjacc/zuaf068. Epub. | i-STAT; Abbott | Retrospective derivation/validation | Stored plasma |
| Koechlin L, et al. JACC 2024;84:726-740. | SpinChip; SpinChip Diagnostics | Retrospective derivation/validation | Stored plasma |

*Greenslade JH, et al relates to off-label use of the i-STAT hs-tnI cartridge. For on-label use please see the i-STAT hs-TnI cartridge IFU available at https://www.globalpointofcare.abbott/content/dam/ardx/globalpointofcare/apoc/support/i-stat-1/cti-ifu/english-uk/ifu/798049-01A.pdf

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 75, NO. 10, 2020


# Early Diagnosis of Myocardial Infarction With Point-of-Care High-Sensitivity Cardiac Troponin I

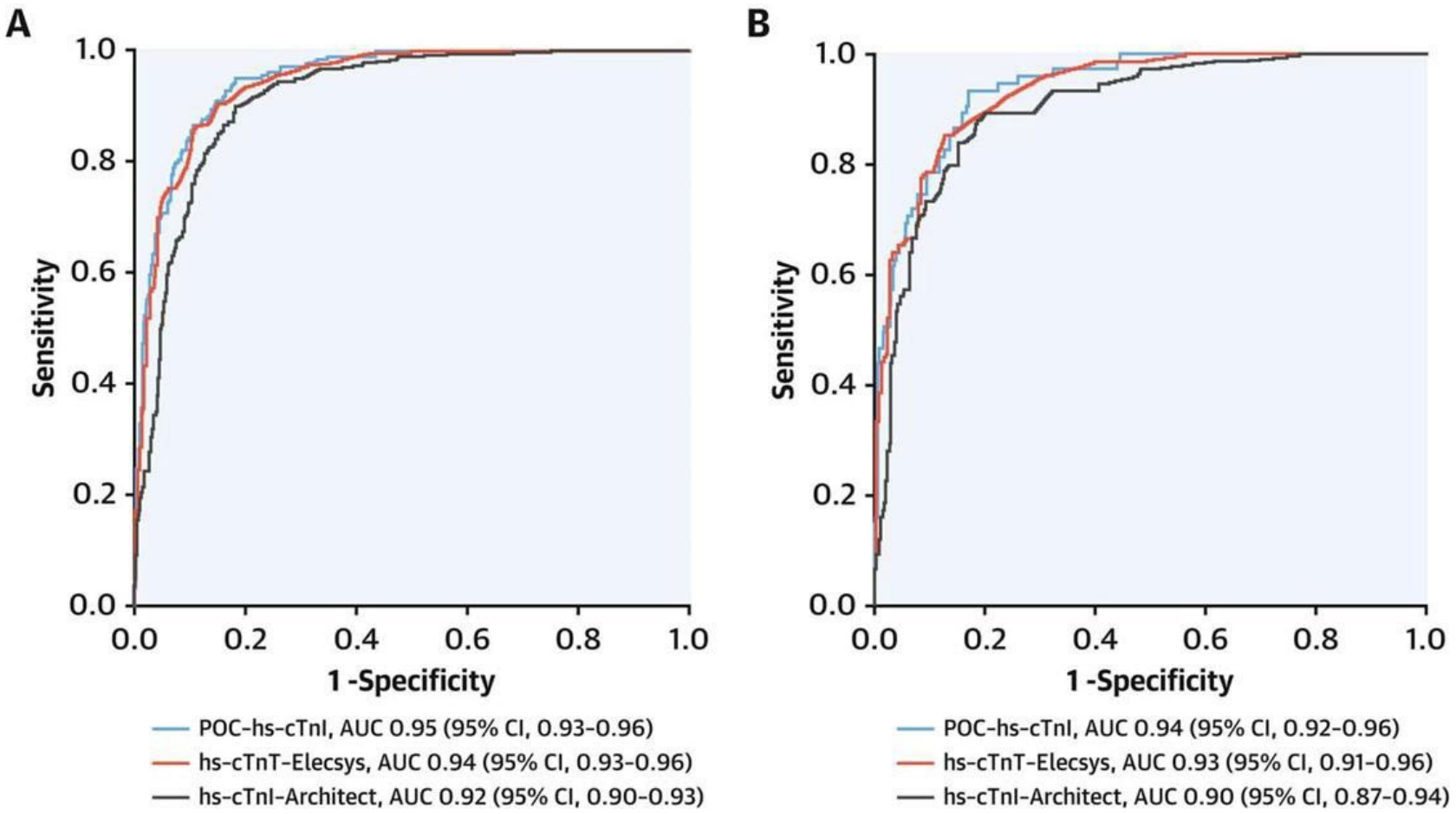
Jasper Boeddinghaus, MD,[a,b,*] Thomas Nestelberger, MD,[a,b,*] Luca Koechlin, MD,[a,b,c] Desiree Wussler, MD,[a,b,d] Pedro Lopez-Ayala, MD,[a,b] Joan Elias Walter, MD,[a,b,d] Valentina Troester, MD,[a,b] Paul David Ratmann, MD,[a,b] Funda Seidel, MD,[a,b] Tobias Zimmermann, MD,[a,b,d] Patrick Badertscher, MD,[a,b,e] Karin Wildi, MD,[a,b,f] Maria Rubini Giménez, MD,[a,b,g] Eliska Potlukova, MD,[a,b,d] Ivo Strebel, MSc,[a,b] Michael Freese, RN,[a,b] Òscar Miró, MD,[b,h] F. Javier Martin-Sanchez, MD,[b,i] Damian Kawecki, MD,[b,j] Dagmar I. Keller, MD,[k] Danielle M. Gualandro, MD,[a,b,l] Michael Christ, MD,[b,m] Raphael Twerenbold, MD,[a,b] Christian Mueller, MD,[a,b] for the APACE Investigators

## **Primary Objective**:

- Directly compare the diagnostic accuracy of POC-hs-cTnI-TriageTrue versus two central laboratory assays (Roche Elecsys hs-cTnT and Abbott Architect hs-cTnI)

## **Secondary Objective**:

- The derivation and validation of a POC-hs-cTnI-TriageTrue specific 0/1-h algorithm

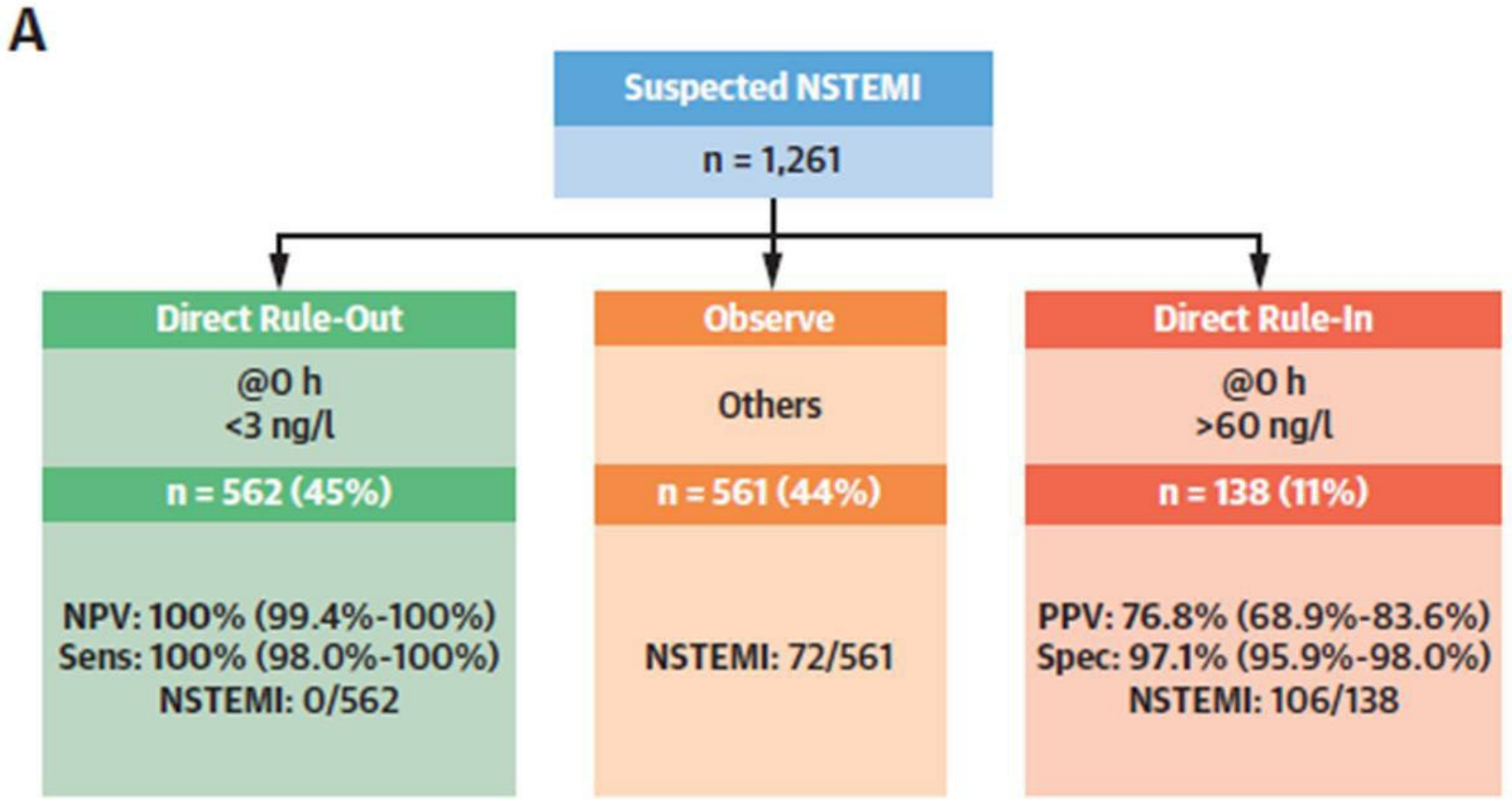



The diagnostic accuracy of TriageTrue was high.

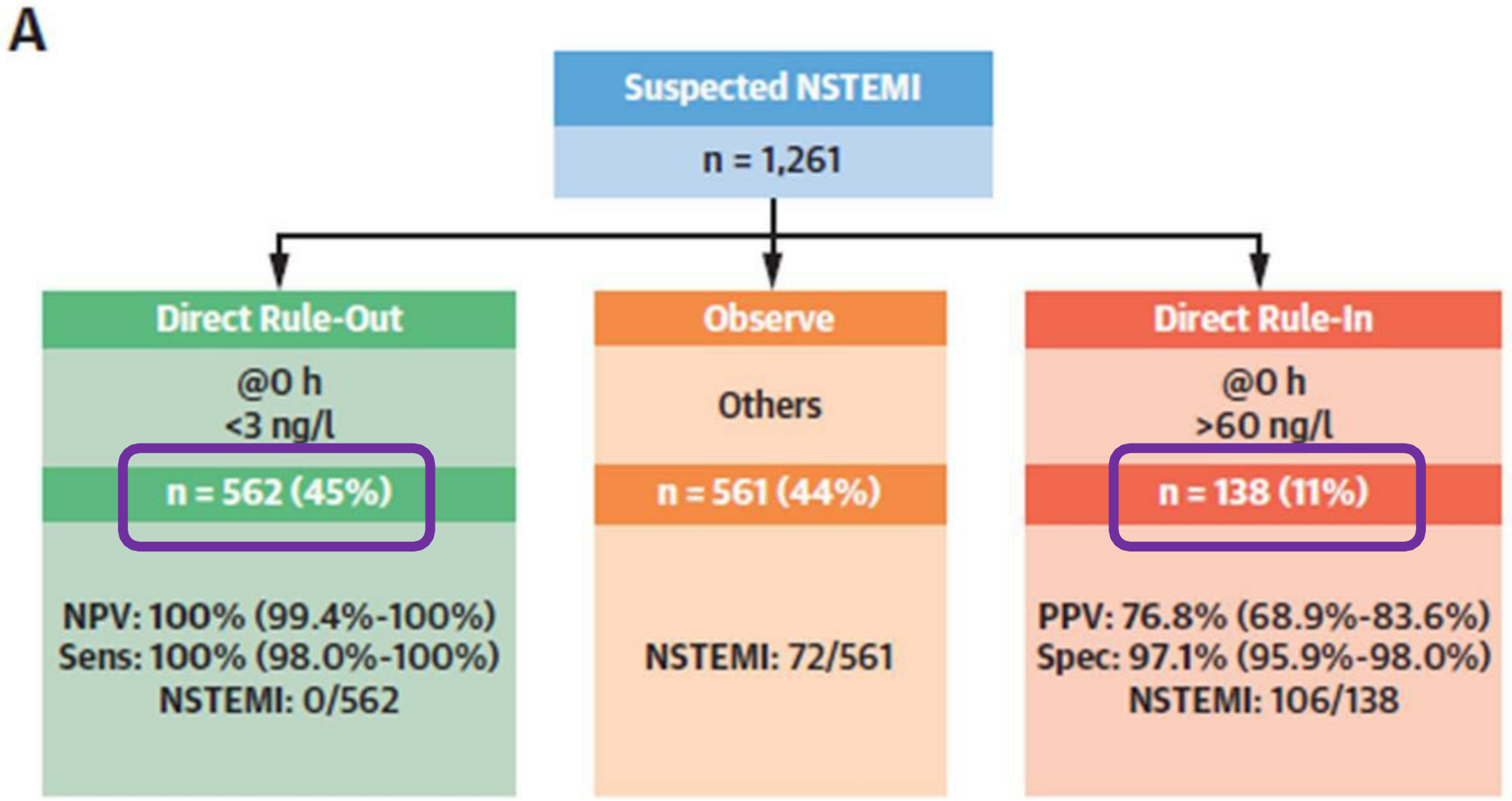
Comparable to that provided by the Roche Elecsys hs-cTnT and Abbott Architect hs-cTnI assays

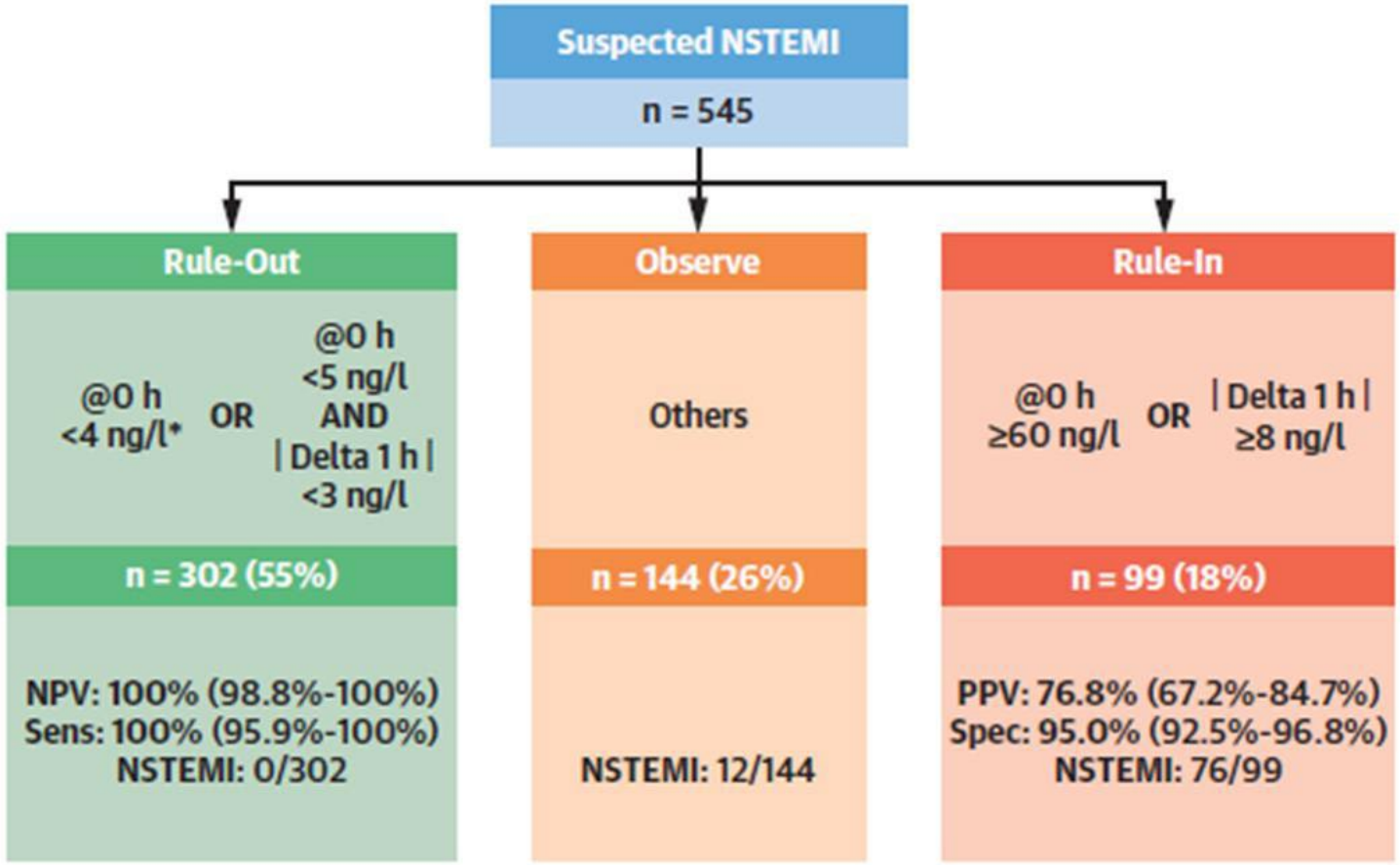
Boeddinghaus J, et al. J Am Coll Cardiol. 2020 Mar 17;75(10):1111-24

# 0-hour (presentation) samples



# 0-hour (presentation) samples





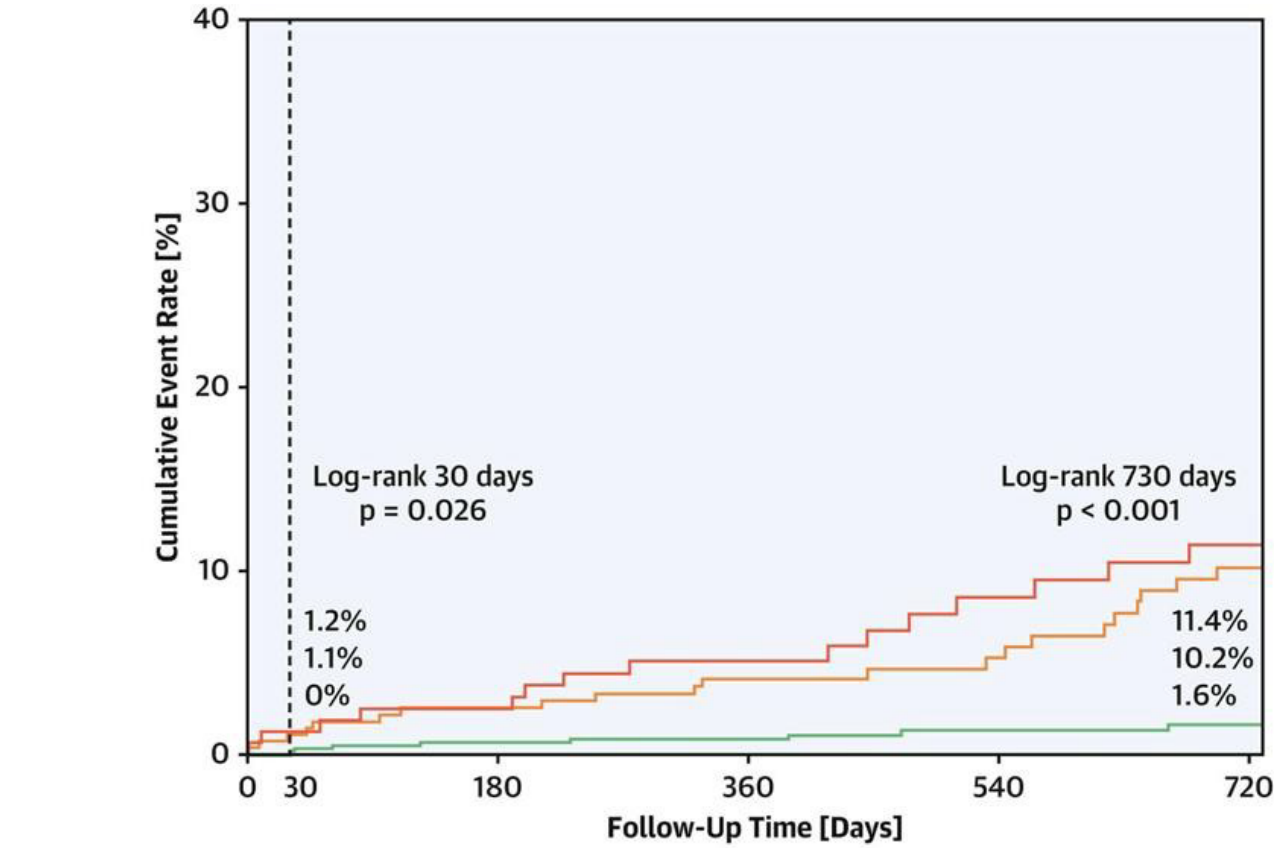

*If chest pain onset >3 h before presentation to the ED

# 0/1 hour algorithm

Results were comparable to Roche Elecsys hs-cTnT and Abbott Architect hs-cTnI

Boeddinghaus J, et al. J Am Coll Cardiol. 2020 Mar 17;75(10):1111-24. Validation cohort

# Safety of early discharge from ED




| No. at Risk: | | | | | |
|---|---|---|---|---|---|
| Rule-Out | 642 | 572 | 452 | 336 | 161 |
| Observe | 280 | 254 | 203 | 154 | 71 |
| Rule-In | 162 | 146 | 121 | 98 | 46 |

Circulation
Volume 146, Issue 25, 20 December 2022; Pages 1918-1929
https://doi.org/10.1161/CIRCULATIONAHA.122.061148

American Heart Association.

ORIGINAL RESEARCH ARTICLE

# Single High-Sensitivity Point-of-Care Whole-Blood Cardiac Troponin I Measurement to Rule Out Acute Myocardial Infarction at Low Risk

Fred S. Apple, PhD, Stephen W. Smith, MD, Jaimi H. Greenslade, PhD, Yader Sandoval, MD, William Parsonage, DM, Isuru Ranasinghe, MBChB, MMed, PhD, Niranjan Gaikwad, MD, MMed, PhD, Karen Schulz, DC, Laura Stephensen, RN, Christian W. Schmidt, MS, Brynn Okeson, MS, and Louise Cullen, MBBS

## SAFE EMERGENCY DEPARTMENT DISCHARGE RATE [SEIGE] USA

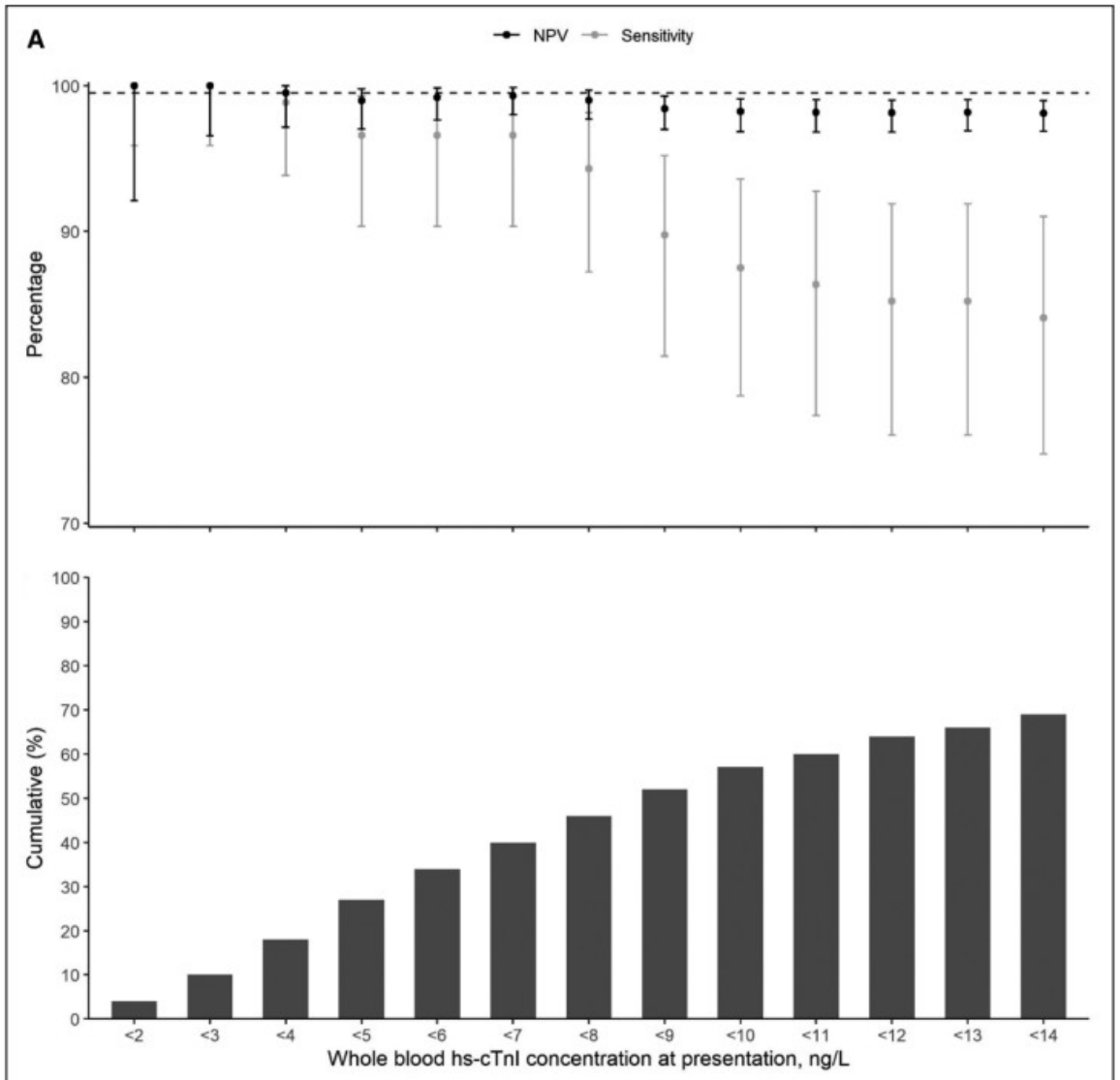
- 1086 PATIENTS
  - 8.1%MI
- WHOLE BLOOD

- <4NG/L PROVIDED:
  - SENSITIVITY OF 98.9% (93.8-100%)
  - NPV OF 99.5% (95% CI: 97.2-100%) FOR RULING OUT MI.
- 30-DAY ADVERSE CARDIAC EVENTS 0.1% (N=1)

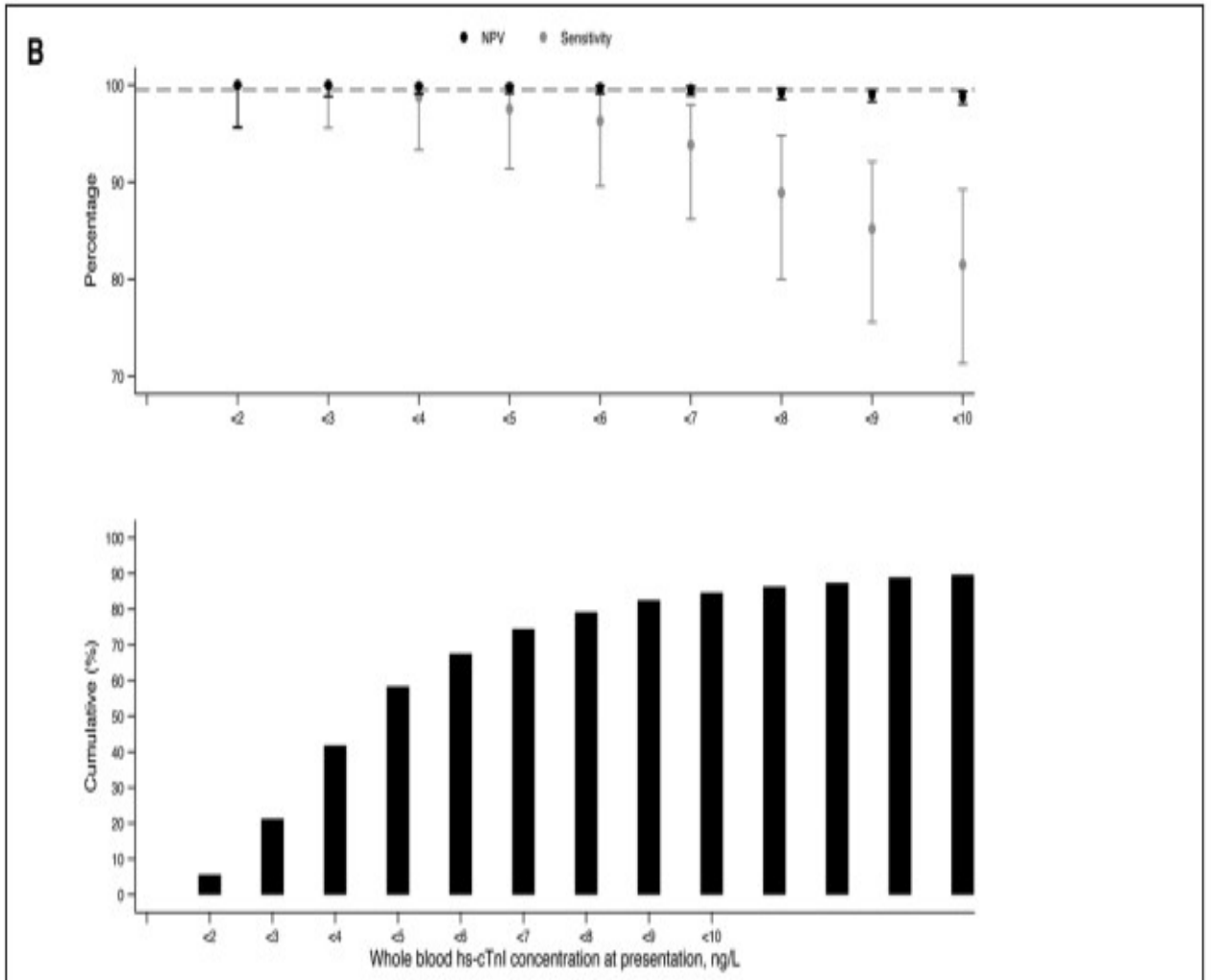
## SUSPECTED ACUTE MYOCARDIAL INFARCTION IN EMERGENCY [SAMIE] AUSTRALIA

- 1486 PATIENTS
  - 5.5% MI
- PLASMA

- VALIDATED <4NG/L:
  - SENSITIVITY OF 98.8% (93.3-100%)
  - NPV OF 99.8% (99.1-100%) FOR RULING OUT MI.
- 30-DAY ADVERSE CARDIAC EVENTS 0.8% (N=5)




| POC hs-cTnI ng/L | <2 | <3 | <4 | <5 | <6 | <7 | <8 | <9 | <10 | <11 | <12 | <13 | <14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NPV | 100 (92.1-100) | 100 (96.5-100) | 99.5 (97.2-100) | 99 (97-99.8) | 99.2 (97.7-99.8) | 99.3 (98-99.9) | 99 (97.7-99.7) | 98.4 (97-99.3) | 98.2 (96.8-99.1) | 98.2 (96.8-99) | 98.1 (96.8-99) | 98.2 (96.9-99) | 98.1 (96.9-99) |
| Sensitivity | 100 (95.9-100) | 100 (95.9-100) | 98.9 (93.8-100) | 96.6 (90.4-99.3) | 96.6 (90.4-99.3) | 96.6 (90.4-99.3) | 94.3 (87.2-98.1) | 89.8 (81.5-95.2) | 87.5 (78.7-93.6) | 86.4 (77.4-92.8) | 85.2 (76.1-91.9) | 85.2 (76.1-91.9) | 84.1 (74.8-91) |




| POC hs-cTnI ng/L | <2 | <3 | <4 | <5 | <6 | <7 | <8 | <9 | <10 |
|---|---|---|---|---|---|---|---|---|---|
| NPV | 100 (95.7-100) | 100 (98.8-100) | 99.8 (99.1-100) | 99.8 (99.2-100) | 99.7 (99.1-99.9) | 99.5 (98.9-99.9) | 99.2 (98.6-99.6) | 99 (98.3-99.5) | 98.8 (98-99.3) |
| Sensitivity | 100 (95.5-100) | 100 (95.5-100) | 98.8 (93.3-100) | 97.5 (91.4-99.7) | 96.3 (89.6-99.2) | 93.8 (86.2-98) | 88.9 (80-94.8) | 85.2 (75.6-92.1) | 81.5 (71.3-89.2) |

ESC European Society of Cardiology
European Heart Journal (2024) 45, 2508–2515
https://doi.org/10.1093/eurheartj/ehae343

CLINICAL RESEARCH
*Acute cardiovascular care*

# Point-of-care high-sensitivity cardiac troponin in suspected acute myocardial infarction assessed at baseline and 2 h

**Louise Cullen [1,2,3]*, Jaimi Greenslade [1,2,3], William Parsonage [2,4], Laura Stephensen [1], Stephen W. Smith[5], Yader Sandoval[6], Isuru Ranasinghe[3,7], Niranjan Gaikwad[7], Maryam Khorramshahi Bayat [7], Ehsan Mahmoodi[7], Karen Schulz[8], Martin Than [9], and Fred S. Apple [8,10]; on behalf of the SAMIE and SEIGE investigators†**

[1]Emergency and Trauma Centre, Royal Brisbane and Women's Hospital, Butterfield Street, Herston, 4029 Queensland, Australia; [2]Australian Centre for Health Services Innovation, Centre for Healthcare Transformation, School of Public Health and Social Work, Faculty of Health, Queensland University of Technology, Musk Avenue, Kelvin Grove, 4059 Queensland, Australia; [3]Faculty of Medicine, The University of Queensland, Herston Road, Herston, 4006 Queensland, Australia; [4]Department of Cardiology, Royal Brisbane and Women's Hospital, Brisbane, Australia; [5]Department of Emergency Medicine at Hennepin Healthcare/Hennepin County Medical Center, University of Minnesota School of Medicine, Minneapolis, MN, USA; [6]Minneapolis Heart Institute, Abbott Northwestern Hospital and Center for Coronary Artery Disease, Minneapolis Heart Institute Foundation, Minneapolis, MN, USA; [7]Department of Cardiology, The Prince Charles Hospital, Brisbane, Australia; [8]Department of Laboratory Medicine and Pathology, University of Minnesota, Minneapolis, MN, USA; [9]Emergency Department, Christchurch Hospital, Christchurch, New Zealand; and [10]Clinical and Forensic Toxicology Laboratory, Hennepin Healthcare/Hennepin County Medical Center, Minneapolis, MN, USA

*Received 16 October 2023; revised 15 April 2024; accepted 16 May 2024; online publish-ahead-of-print 6 June 2024*

**See the editorial comment for this article 'Accelerated high sensitivity troponin diagnostics: ready for an even faster pace?', by E. Giannitsis *et al.*, https://doi.org/10.1093/eurheartj/ehae344.**

## Abstract

**Background and Aims** Strategies to assess patients with suspected acute myocardial infarction (AMI) using a point-of-care (POC) high-sensitivity cardiac troponin I (hs-cTnI) assay may expedite emergency care. A 2-h POC hs-cTnI strategy for emergency patients with suspected AMI was derived and validated.

**Methods** In two international, multi-centre, prospective, observational studies of adult emergency patients (1486 derivation cohort and 1796 validation cohort) with suspected AMI, hs-cTnI (Siemens Atellica® VTLi) was measured at admission and 2 h later. Adjudicated final diagnoses utilized the hs-cTn assay in clinical use. A risk stratification algorithm was derived and validated. The primary diagnostic outcome was index AMI (Types 1 and 2). The primary safety outcome was 30-day major adverse cardiac events incorporating AMI and cardiac death.

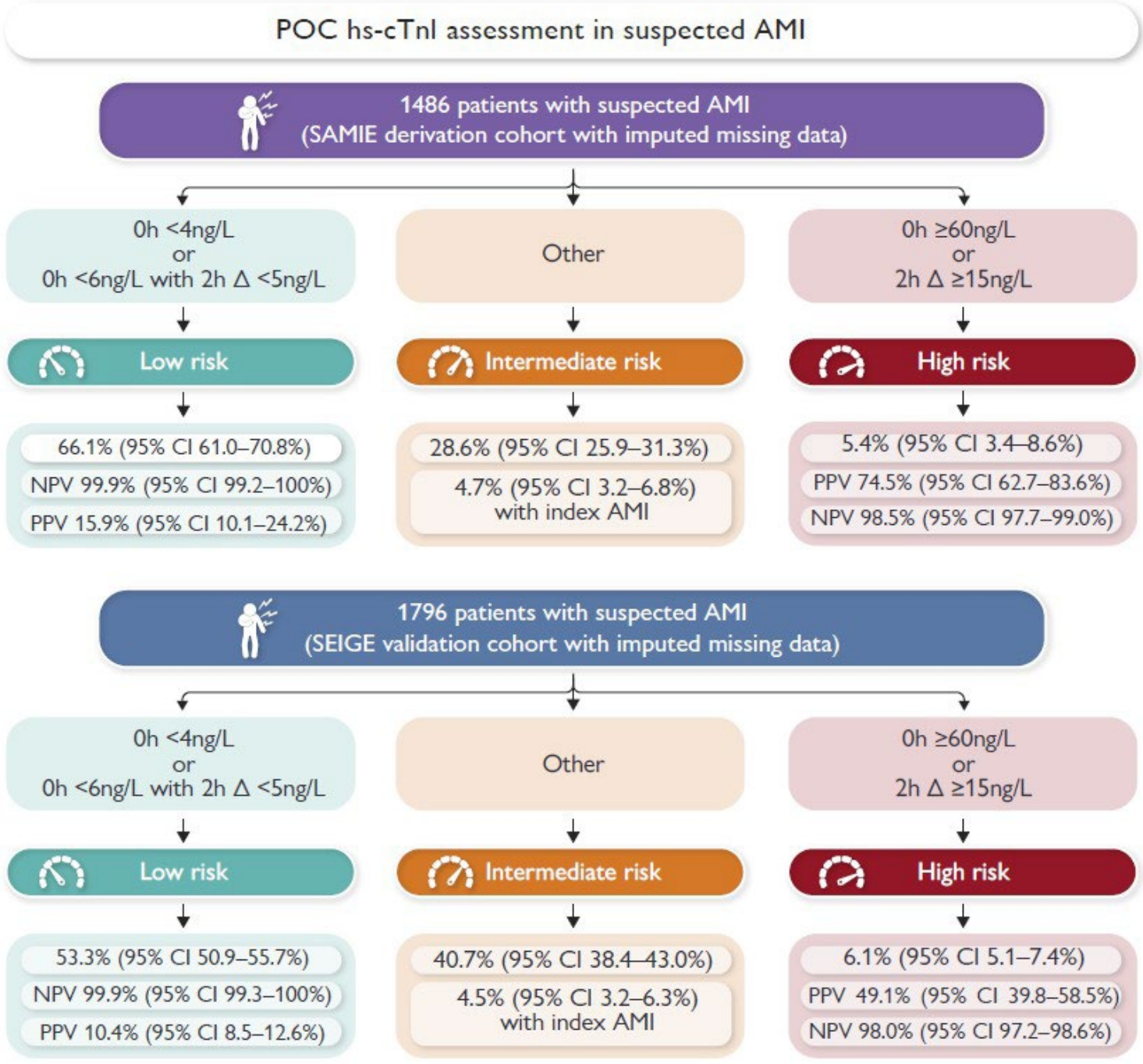
**Results** Overall, 81 (5.5%) and 88 (4.9%) patients in the derivation and validation cohorts, respectively, had AMI. The 2-h algorithm defined 66.1% as low risk with a sensitivity of 98.8% [95% confidence interval (CI) 89.3%–99.9%] and a negative predictive value of 99.9 (95% CI 99.2%–100%) for index AMI in the derivation cohort. In the validation cohort, 53.3% were low risk with a sensitivity of 98.9% (95% CI 92.4%–99.8%) and a negative predictive value of 99.9% (95% CI 99.3%–100%) for index AMI. The high-risk metrics identified 5.4% of patients with a specificity of 98.5% (95% CI 96.6%–99.4%) and a positive predictive value of 74.5% (95% CI 62.7%–83.6%) for index AMI.

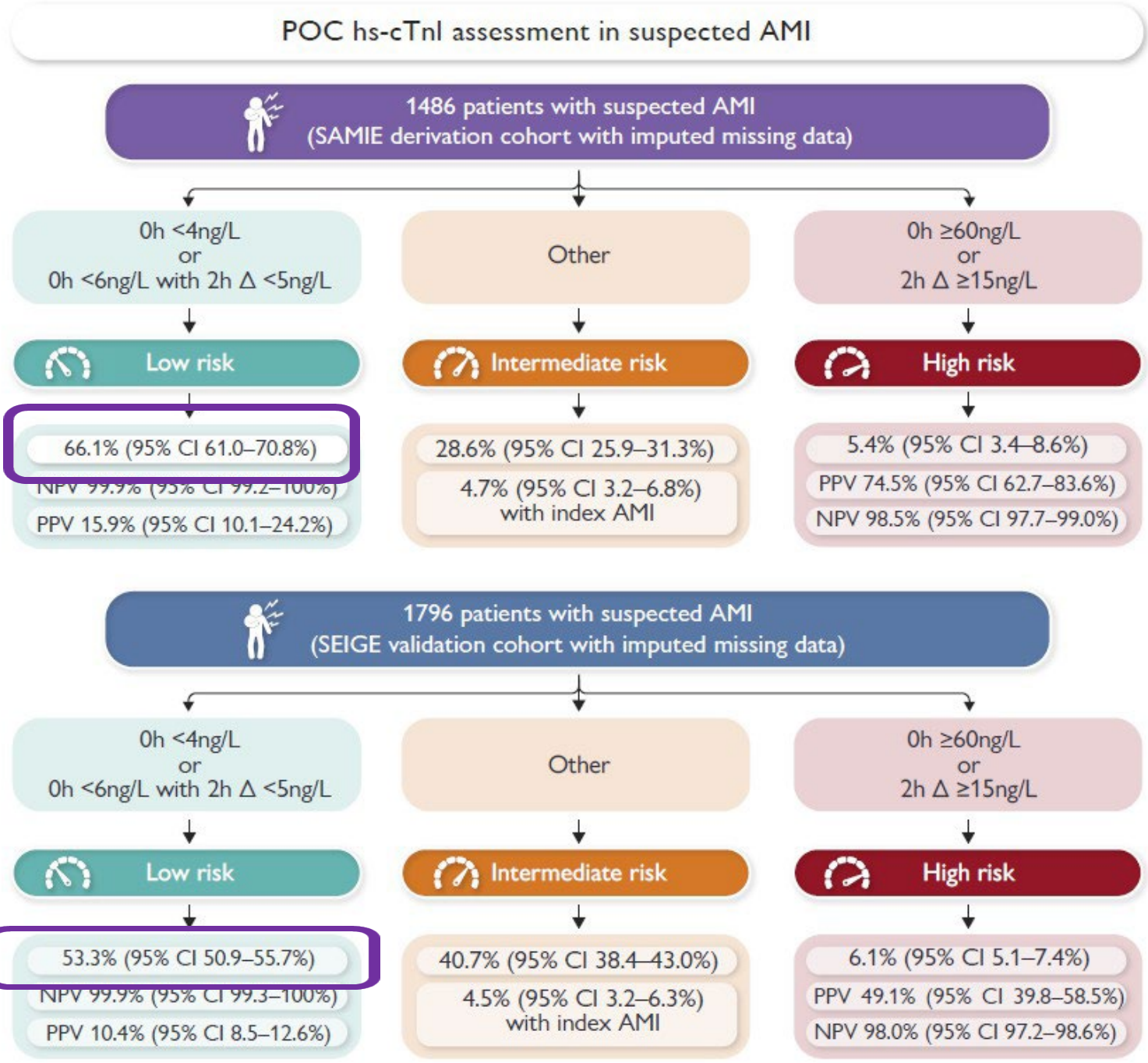
## Primary Objective:

- Derive and validate a 2-h POC hs-cTnI strategy for assessment of patients with suspected AMI.

SAMIE and SEIGE cohorts

POC-hs-cTnI Siemens Atellica VTLi


POC hs-cTnI assessment in suspected AMI
1486 patients with suspected AMI
(SAMIE derivation cohort with imputed missing data)
0h <4ng/L
or
0h <6ng/L with 2h Δ <5ng/L
Other
0h ≥60ng/L
or
2h Δ ≥15ng/L
Low risk
Intermediate risk
High risk
66.1% (95% CI 61.0–70.8%)
NPV 99.9% (95% CI 99.2–100%)
PPV 15.9% (95% CI 10.1–24.2%)
28.6% (95% CI 25.9–31.3%)
4.7% (95% CI 3.2–6.8%)
with index AMI
5.4% (95% CI 3.4–8.6%)
PPV 74.5% (95% CI 62.7–83.6%)
NPV 98.5% (95% CI 97.7–99.0%)
1796 patients with suspected AMI
(SEIGE validation cohort with imputed missing data)
0h <4ng/L
or
0h <6ng/L with 2h Δ <5ng/L
Other
0h ≥60ng/L
or
2h Δ ≥15ng/L
Low risk
Intermediate risk
High risk
53.3% (95% CI 50.9–55.7%)
NPV 99.9% (95% CI 99.3–100%)
PPV 10.4% (95% CI 8.5–12.6%)
40.7% (95% CI 38.4–43.0%)
4.5% (95% CI 3.2–6.3%)
with index AMI
6.1% (95% CI 5.1–7.4%)
PPV 49.1% (95% CI 39.8–58.5%)
NPV 98.0% (95% CI 97.2–98.6%)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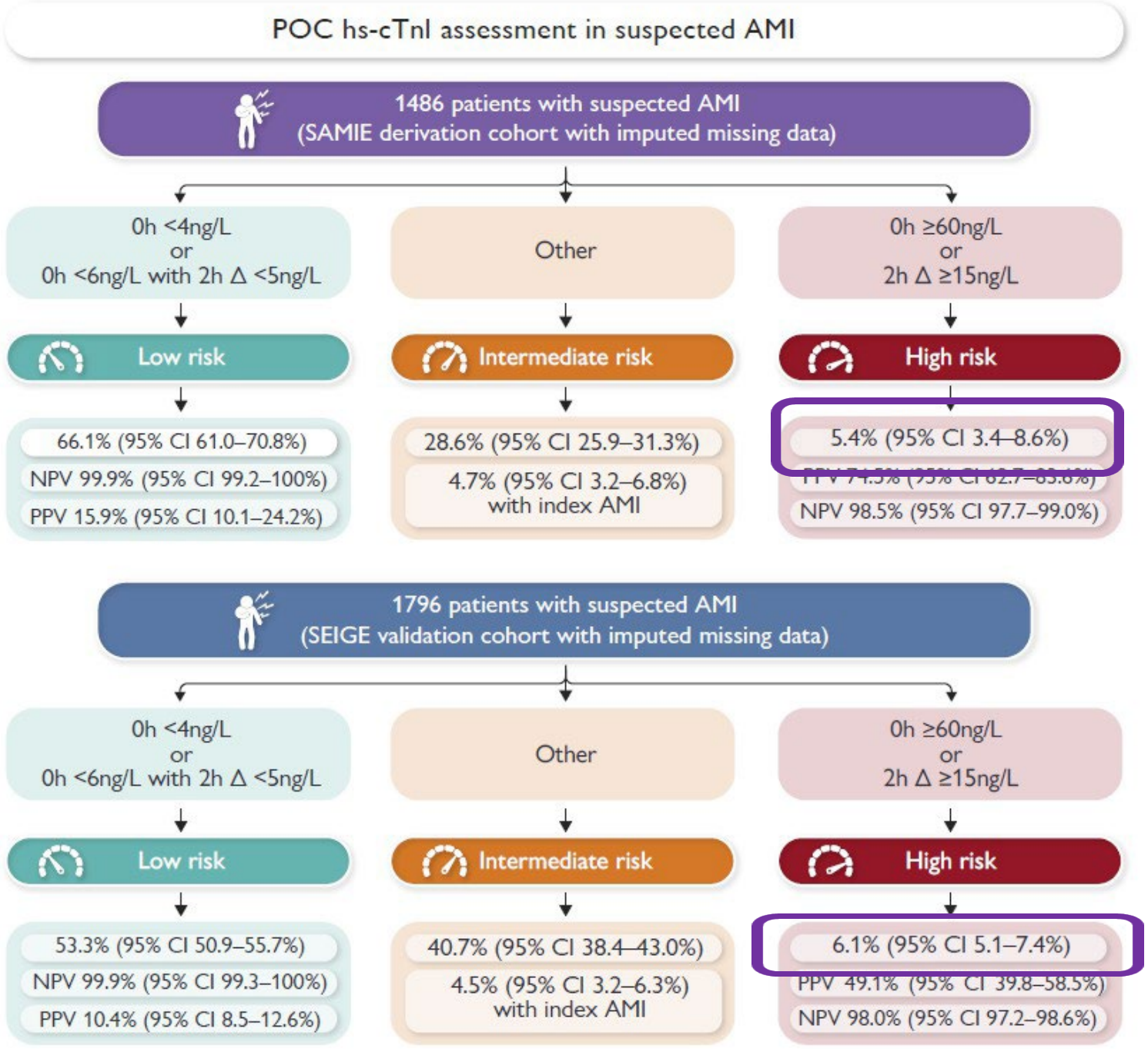
NPV 98.5% (95% CI 97.7–99.0%)
1796 patients with suspected AMI
(SEIGE validation cohort with imputed missing data)
0h <4ng/L
or
0h <6ng/L with 2h Δ <5ng/L
Other
0h ≥60ng/L
or
2h Δ ≥15ng/L
Low risk
Intermediate risk
High risk
53.3% (95% CI 50.9–55.7%)
NPV 99.9% (95% CI 99.3–100%)
PPV 10.4% (95% CI 8.5–12.6%)
40.7% (95% CI 38.4–43.0%)
4.5% (95% CI 3.2–6.3%)
with index AMI
6.1% (95% CI 5.1–7.4%)
PPV 49.1% (95% CI 39.8–58.5%)
NPV 98.0% (95% CI 97.2–98.6%)


POC hs-cTnI assessment in suspected AMI
1486 patients with suspected AMI
(SAMIE derivation cohort with imputed missing data)
0h <4ng/L
or
0h <6ng/L with 2h Δ <5ng/L
Other
0h ≥60ng/L
or
2h Δ ≥15ng/L
Low risk
Intermediate risk
High risk
66.1% (95% CI 61.0–70.8%)
NPV 99.9% (95% CI 99.2–100%)
PPV 15.9% (95% CI 10.1–24.2%)
28.6% (95% CI 25.9–31.3%)
4.7% (95% CI 3.2–6.8%)
with index AMI
5.4% (95% CI 3.4–8.6%)
NPV 98.5% (95% CI 97.7–99.0%)
1796 patients with suspected AMI
(SEIGE validation cohort with imputed missing data)
0h <4ng/L
or
0h <6ng/L with 2h Δ <5ng/L
Other
0h ≥60ng/L
or
2h Δ ≥15ng/L
Low risk
Intermediate risk
High risk
53.3% (95% CI 50.9–55.7%)
NPV 99.9% (95% CI 99.3–100%)
PPV 10.4% (95% CI 8.5–12.6%)
40.7% (95% CI 38.4–43.0%)
4.5% (95% CI 3.2–6.3%)
with index AMI
6.1% (95% CI 5.1–7.4%)
PPV 49.1% (95% CI 39.8–58.5%)
NPV 98.0% (95% CI 97.2–98.6%)

# For consideration

Sample type

Intended users

Real world experience


IMPLEMENTATION

ANZCTR
Australian New Zealand Clinical Trials Registry

Improving care by faster risk-stratification by use of next generation point-of-care troponin in patients presenting with possible acute coronary syndrome in the emergency department.

# Icare-FASTER trial

doi: 10.1136/bmj.h391 | *BMJ* 2015;351:h391 | the**bmj**

ESC European Society of Cardiology

European Heart Journal: Acute Cardiovascular Care (2024) **13**, 838–842
https://doi.org/10.1093/ehjacc/zuae114

**BRIEF REPORT**
*Acute Coronary Syndromes*

# Emergency department use of a high-sensitivity point-of-care troponin assay reduces length of stay: an implementation study preliminary report

**John W. Pickering [1,2], Laura R. Joyce [3], Christopher M. Florkowski[4], Vanessa Buchan[4], Laura Hamill [5], and Martin P. Than [1,2,6]***

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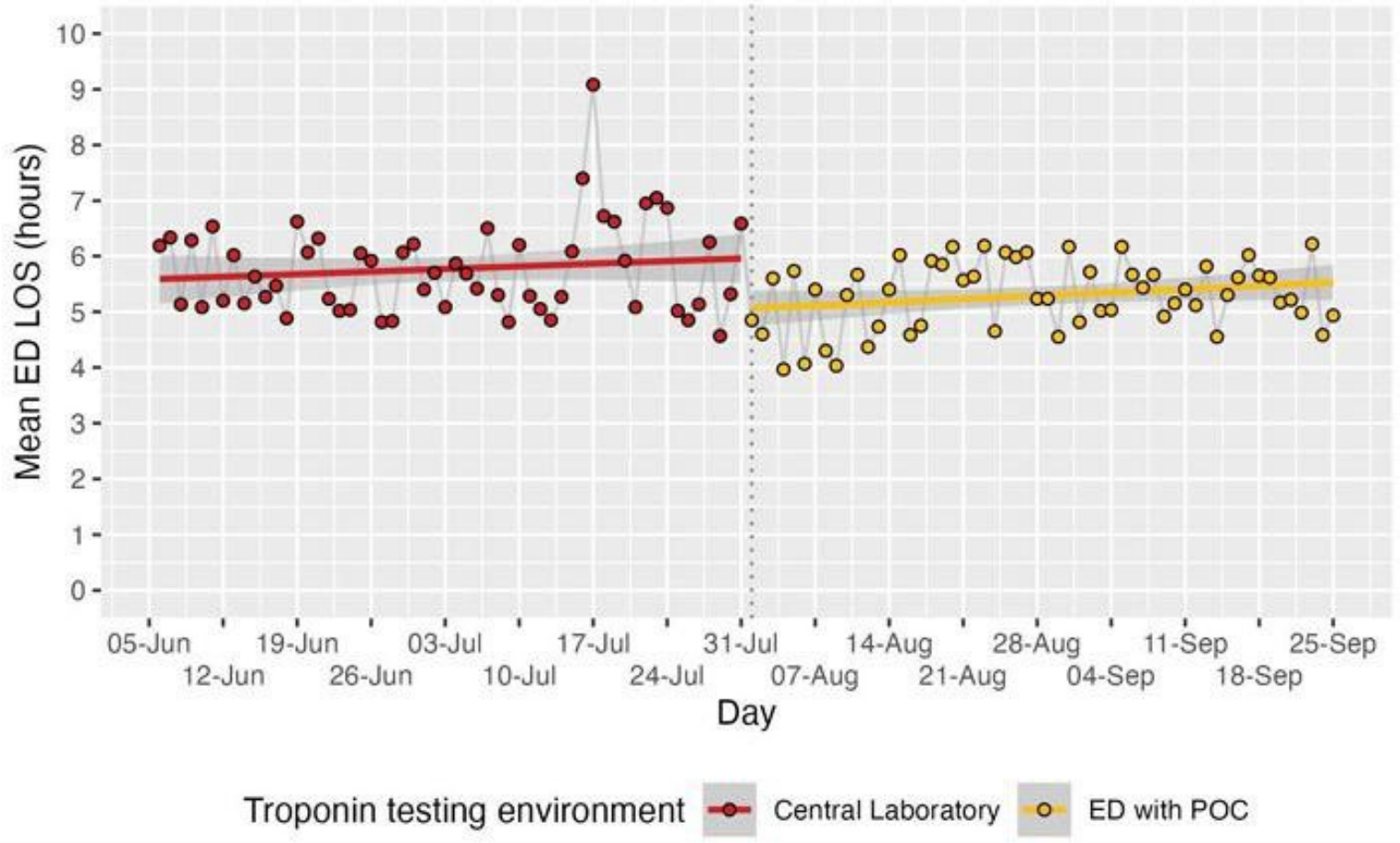



**Figure 1** Daily mean lengths of ED stay of patients receiving a troponin test for the eight weeks before and after the deployment of the POC test in the ED.

Mean reduction in LoS of

**32 mins.**

21.4 fewer patient-hours each day

(1196 hours over 8 weeks)

# 100,000 patients annually

# 100,000 patients annually

## 8,000 with suspected ACS

# 100,000 patients annually

## 8,000 with suspected ACS

**Saving of 32 mins per patient**

# 100,000 patients annually

## 8,000 with suspected ACS

**Saving of 32 mins per patient**

**Saving of 4,266 hour per year**

# 100,000 patients annually

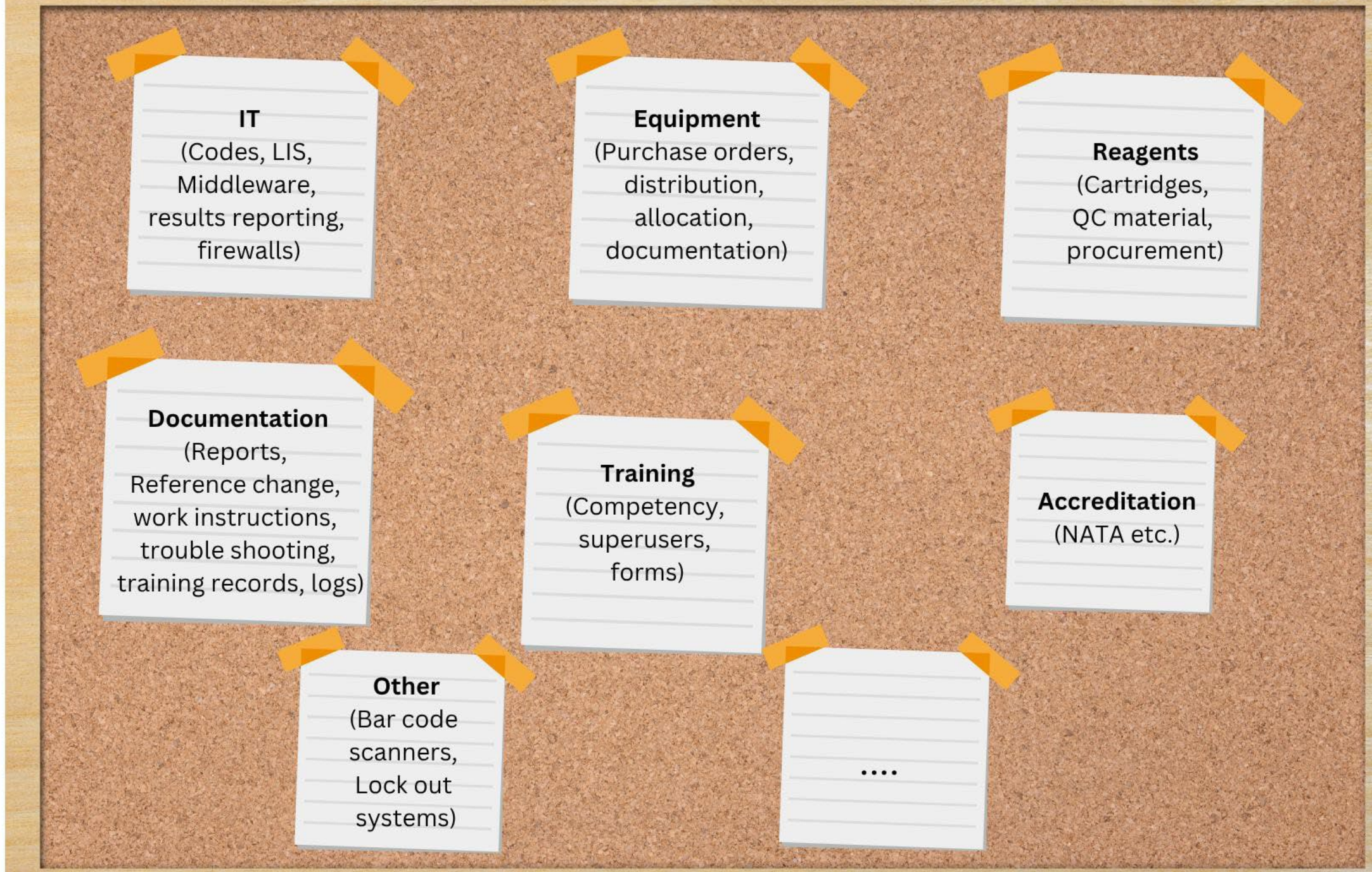
## 8,000 with suspected ACS

**Saving of 32 mins per patient**

**Saving of 4,266 hour per year**

**Saving of 178 days per year**

# Implementation: Practical tips


**IT**
(Codes, LIS, Middleware, results reporting, firewalls)
**Equipment**
(Purchase orders, distribution, allocation, documentation)
**Reagents**
(Cartridges, QC material, procurement)
**Documentation**
(Reports, Reference change, work instructions, trouble shooting, training records, logs)
**Training**
(Competency, superusers, forms)
**Accreditation**
(NATA etc.)
**Other**
(Bar code scanners, Lock out systems)
....

# Instructions for use

Instructions for use

Patient results reporting

## Instructions for use

## Patient results reporting

## Reporting units - ng/L

Instructions for use

Patient results reporting

Reporting units - ng/L

Lowest reportable level - LoD, LoQ

Instructions for use

Patient results reporting

Reporting units - ng/L

Lowest reportable level - LoD, LoQ

Reference intervals: 99$^{th}$ percentile sex-specific URLs

Instructions for use

Patient results reporting

Reporting units - ng/L

Lowest reportable level - LoD, LoQ

Reference intervals: 99$^{th}$ percentile sex-specific URLs

Reporting results for lab and POC assays clearly identifiable

# Implementation

Laboratory expertise

Clinical expertise

Project team

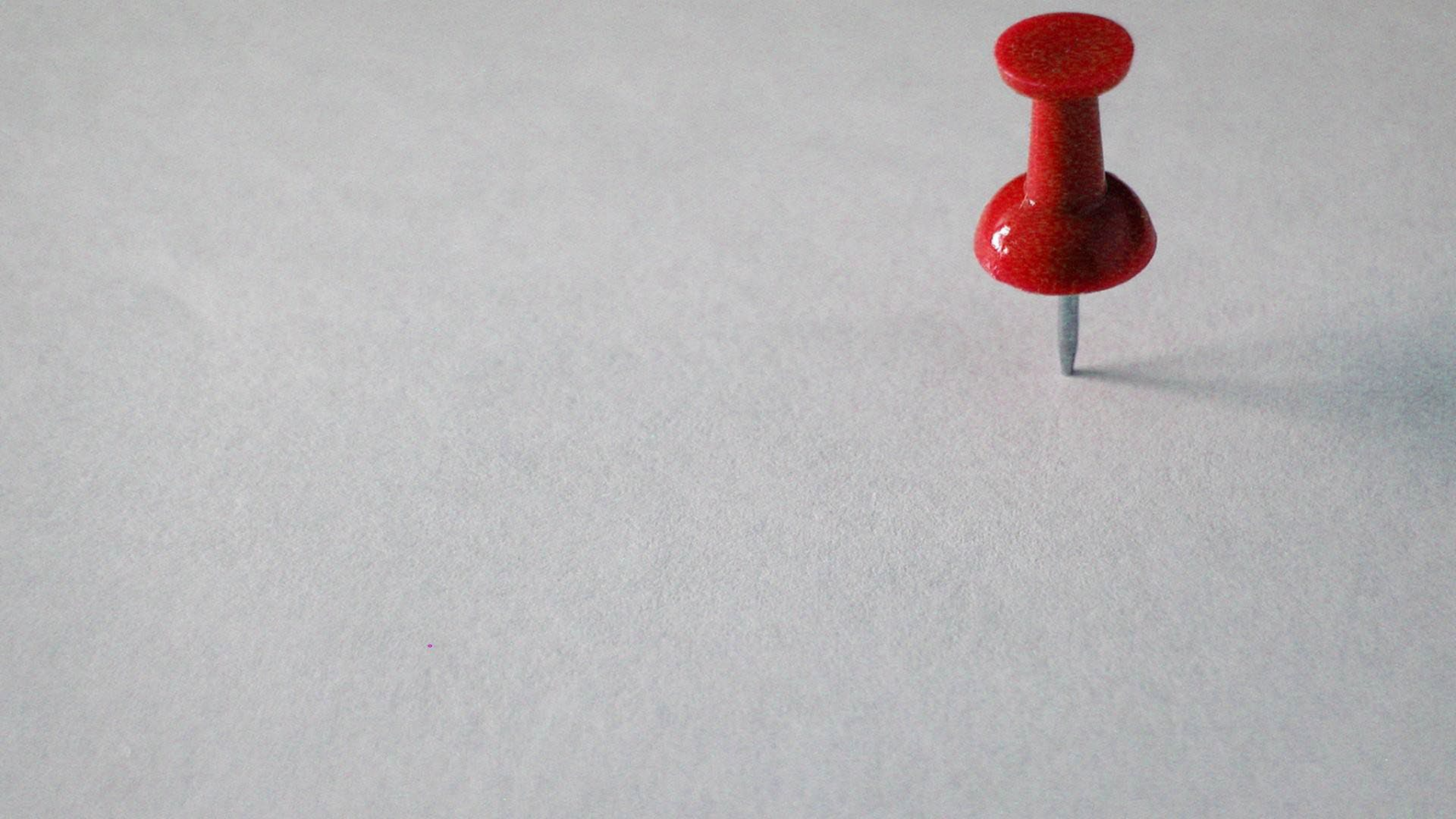
Laboratory expertise

Clinical expertise

Project team

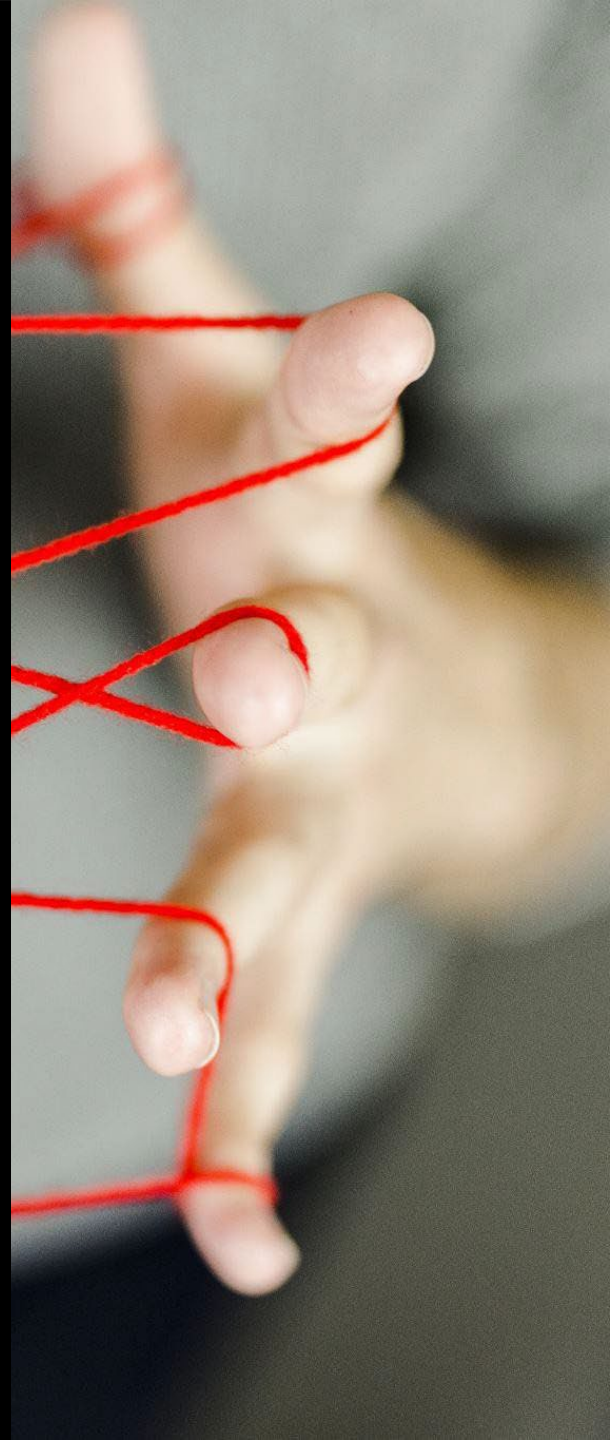
**Executive leadership**

# ED aspects adopting POC technology



The magic is not in the box.

# Practical aspects



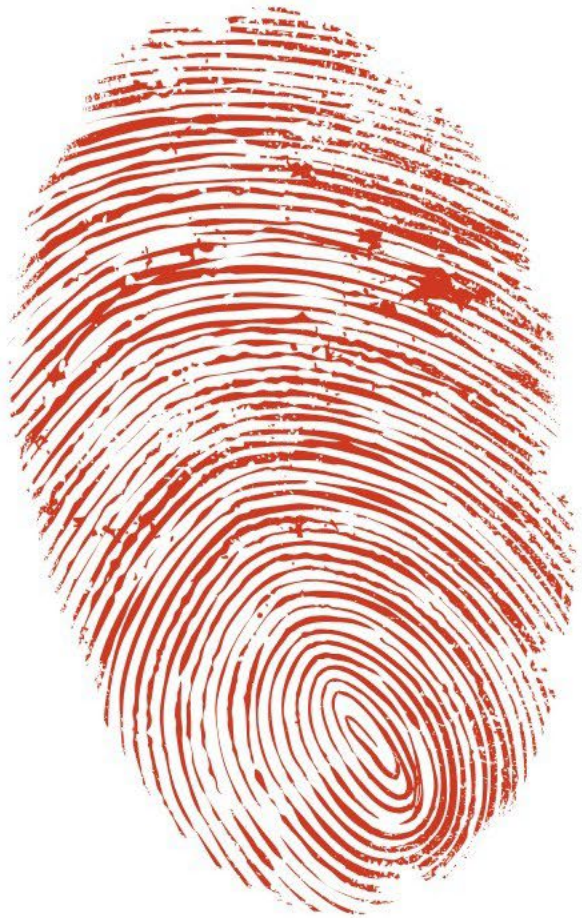

Don’t be too busy to improve?
No thanks!
We are too busy
Created by Håkan Forss @hakanforss http://hakanforss.wordpress.com
BY NC SA


TRUST


**“Wait for the formal results.”**

“That’s just POC, we can’t act on that!”

**“Don’t have all the information needed.”**



- Analytical performance
- Device performance
- Patient needs
- ED needs

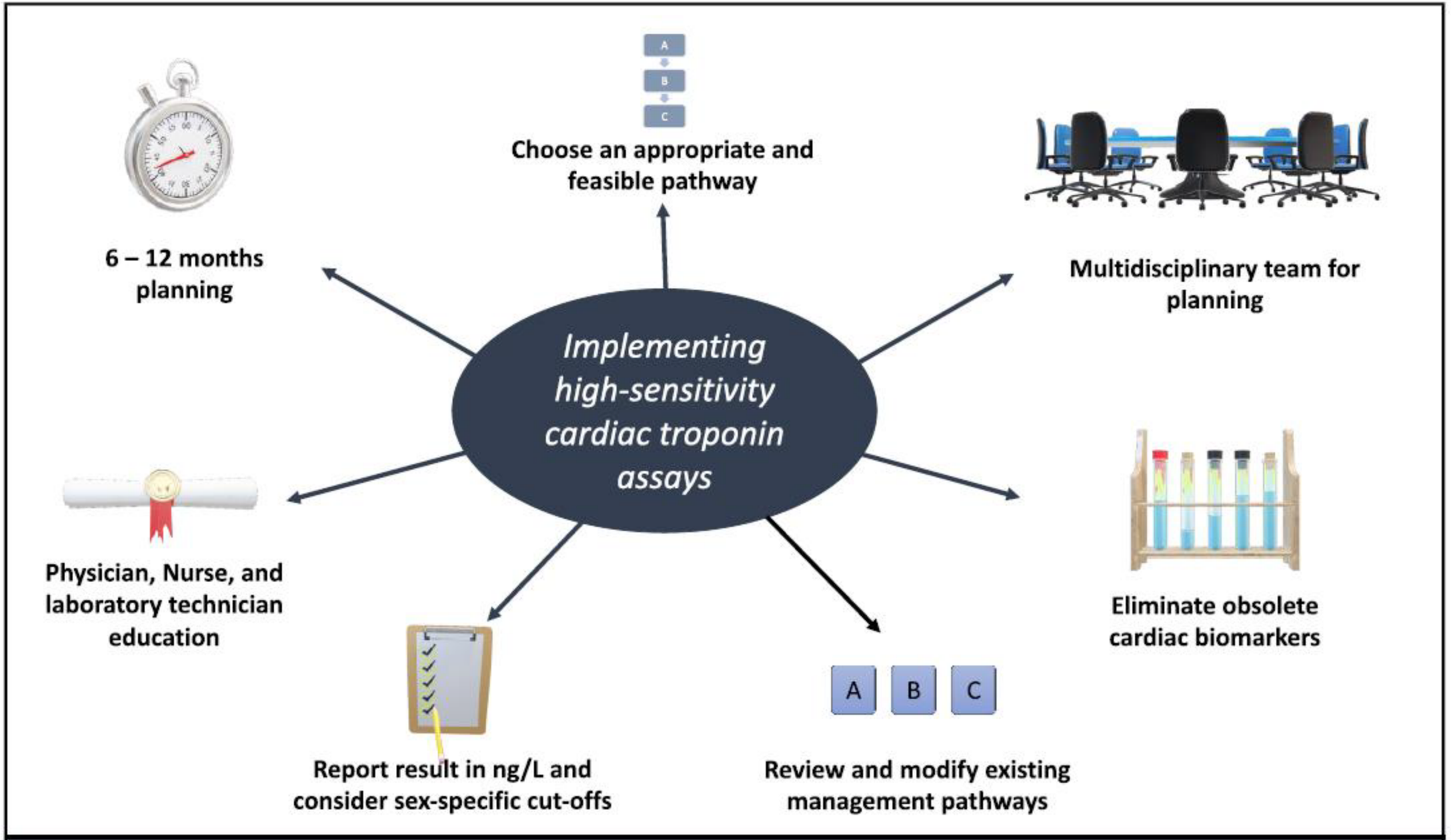



**Fig. 1. Practical tips for implementing a hs-cTn assay.**

High-Sensitivity Cardiac Troponin Assays: From Implementation to Resource Utilization and Cost Effectiveness

Lee et al. JALM 2024

# FAST FORWARD

Opportunities for POC hscTn Assays

# FAST FORWARD

Opportunities for POC hscTn Assays

## Prehospital ambulance services

Correct disposition of patients with suspected ACS and + troponin

## Primary care

Single RO AMI testing of patients with suspected ACS

## Specialist rooms and Outpatients

Assessment and monitoring of patients with acute and chronic conditions

Need evidence for impact of POC hs Troponin assays in many areas of health care delivery

# Questions?

Thank you for listening.