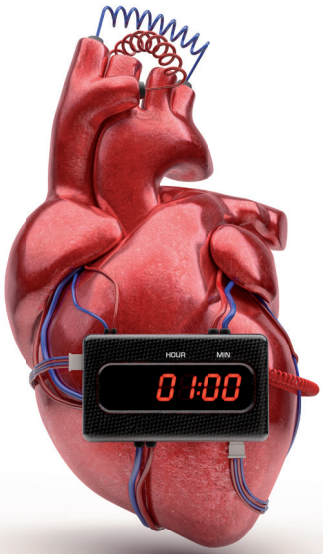
Faster diagnosis of Acute Myocardial Infarction
Pocket guide for Elecsys® Troponin T-high sensitive

Based on the 2015 NSTE-ACS
Guidelines of the European Society of Cardiology

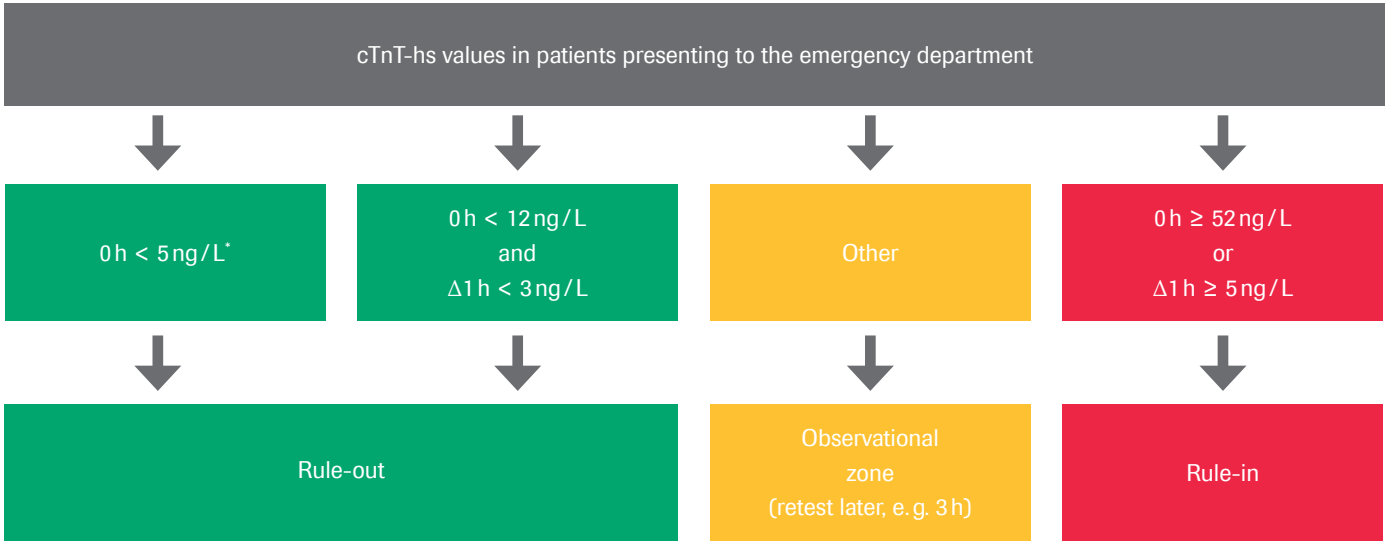


Test early.
Treat right.
Save lives.

The first algorithm to rule-in or rule-out AMI within 0 to 1 hour

New in the 2015 European Society of Cardiology (ESC) guidelines

The 0 h / 1 h algorithm complemented with ESC cut-offs for cTnT-hs[1]



* Applicable for chest pain patients with onset longer than 3 hours

Performance to rule-out AMI at admission (0 hour)

Applicable for chest pain patients with onset longer than 3 hours

- In combination with electrocardiogram (ECG) and clinical symptoms, non-ST-segment elevation myocardial infarction (NSTEMI) can be reliably ruled-out with a single value of cTnT-hs < 5 ng/L for chest pain patients with onset longer than 3 hours [1]
- The results of this approach, tested with 18,453 patients, certify a high negative predictive value (NPV) and a low 30-day mortality [2–5]

Reference	N (patients)	Patients ruled-out (%)	NPV	Events in ruled-out patients
Bandstein, N. et al., *J Am Coll Cardiol* 2014 [2]	14,636	61.0 %	99.8 %	0.02 % (30-day mortality)
Body, R. et al., *Clin Chem* 2015 [3]	463	17.3 %	100 %	0 % (30-day MACE)
Body, R. et al., *Acad Emerg Med* 2016 [4]	1,282	36.7 %*	99.6 %*	1.3 % (30-day MACE)*
Rubini Gimenez, M. et al., *Int J Cardiol* 2013 [5]	2,072	26.5 %	98.4 %	0 % (30-day mortality)

* cTnT-hs < 5 ng/L and limit of detection (LOD) and negative ECG

Performance of cTnT-hs 0 h / 1 h algorithm

Validated by three multicenter trials in over 3,038 patients

	Rule-out	Observational zone	Rule-in
APACE-2012[6] (pain onset < 12 h) n = 436	60 % of patients NPV: 100 % Sensitivity: 100 %	23 % of patients (to be retested later, e. g. 3 h)	17 % of patients PPV: 84 % Specificity: 97 %
APACE-2015[7] (pain onset < 12 h) n = 1,320	60 % of patients NPV: 99.9 % Sensitivity: 99.6 %	24 % of patients (to be retested later, e. g. 3 h)	16 % of patients PPV: 78.2 % Specificity: 95.7 %
TRAPID-AMI[8] (pain onset < 6 h) n = 1,282	64 % of patients NPV: 99.1 % Sensitivity: 96.7 %	22 % of patients (to be retested later, e. g. 3 h)	14 % of patients PPV: 77.2 % Specificity: 96.1 %

NPV: Negative predictive value
PPV: Positive predictive value

Early and effective diagnosis of AMI within 0 to 1 hour

More than 75 % of suspected AMI patients triaged within 1 hour[6–8]

Adopting the novel 0 h / 1 h algorithm has the potential to:

Reduce time to diagnosis and improve patient care[9]

Lower the need for cardiac stress testing by more than 30 %[10]

Shorten the length of stay in the emergency department by nearly 80 minutes and contribute to cost savings[10,11]

When every minute counts

Early diagnosis saves lives in AMI

Test early

- Number 1 cause of death in the Western world is coronary heart disease[12]
- An early and accurate diagnosis of AMI is critical

Treat right

- In the 2015 NSTE-ACS ESC guidelines, hs-cTn is now the biomarker test preferred by the ESC. Troponin testing is mandatory in all patients with suspected NSTE-ACS. A rise and/or fall in troponin concentration, in complement with clinical symptoms and ECG, defines AMI[1]
- The time interval to the second cardiac troponin assessment can be shortened to 0 to 1 hour with the use of hs-cTn assays

Save lives

- Every 30 minute delay between symptoms and treatment increases 1-year mortality by 7.5 %[13]

The 0h / 1h algorithm using cTnT-hs is endorsed by the 2015 ESC guidelines and allows a highly accurate rapid rule-out and rule-in of AMI, when applied in combination with clinical assessment and 12-lead ECG[1, 6–8]

> 75 %

of patients triaged within

Safety aspects of the 0 h / 1 h algorithm

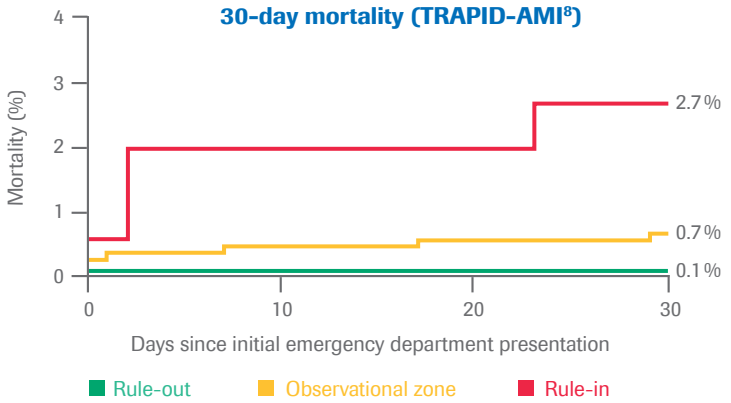
High negative predictive value and low 30-day mortality rate

High NPV to rule-out AMI within 1 hour

100 %: APACE-2012[6]

99.9 %: APACE-2015[7]

99.1 %: TRAPID-AMI[8]



Low 30-day mortality in patients ruled-out for AMI

0.2 %: APACE-2012[6]

0.0 %: APACE-2015[7]

0.1 %: TRAPID-AMI[8]

The high NPV (99.1 – 100 %) and the low 30-day mortality (0.0 – 0.2 %) in the rule-out zone confirm the safety of this approach for early discharge and support the recommendation of the 2015 ESC guidelines[1, 6-8]

The 0 to 3 hours alternative algorithm to rule-in or rule-out AMI

Confirmed by the 2015 ESC guidelines and based on studies investigating cTnT-hs

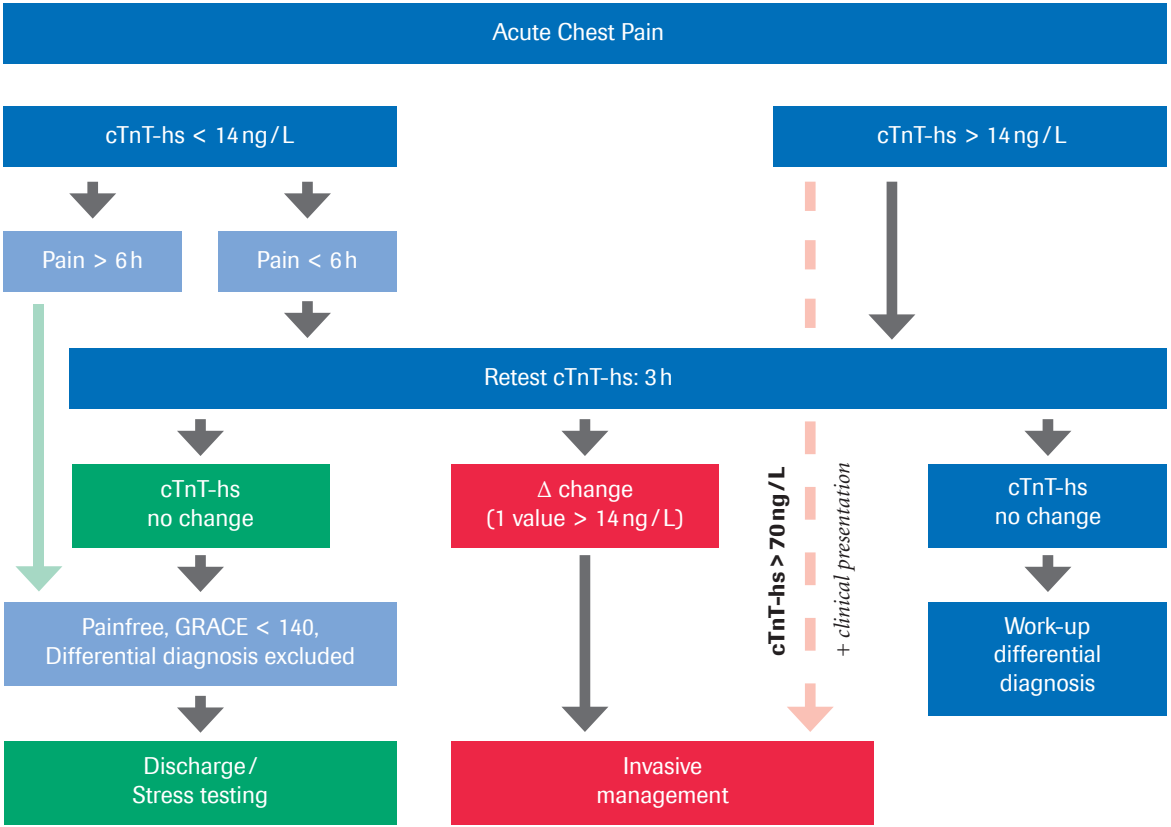
This algorithm has been established based on studies which mainly investigated cTnT-hs

- This approach requires the use of high sensitivity troponin tests and reduces the observation time from 6 to 3 hours as compared to conventional cTn tests [1]
- It can also be used for patients remaining in the observational zone of the 0 h/1 h algorithm

The recommended cut-off values and minimum Δ change between 0 and 3 hours: [14,15]

- 7 ng/L (= 50 % of the ULN) for values ≤ 14 ng/L (the upper limit of normal [ULN], 99th percentile of healthy controls corresponding to 14 ng/L for cTnT-hs) [14]
- 20 % for values > 14 ng/L
- Higly abnormal cTnT-hs value defined as > 70 ng/L (>5-fold of the ULN)[1]

The 0 h / 3 h algorithm, complemented with ESC cut-offs for cTnT-hs [1]



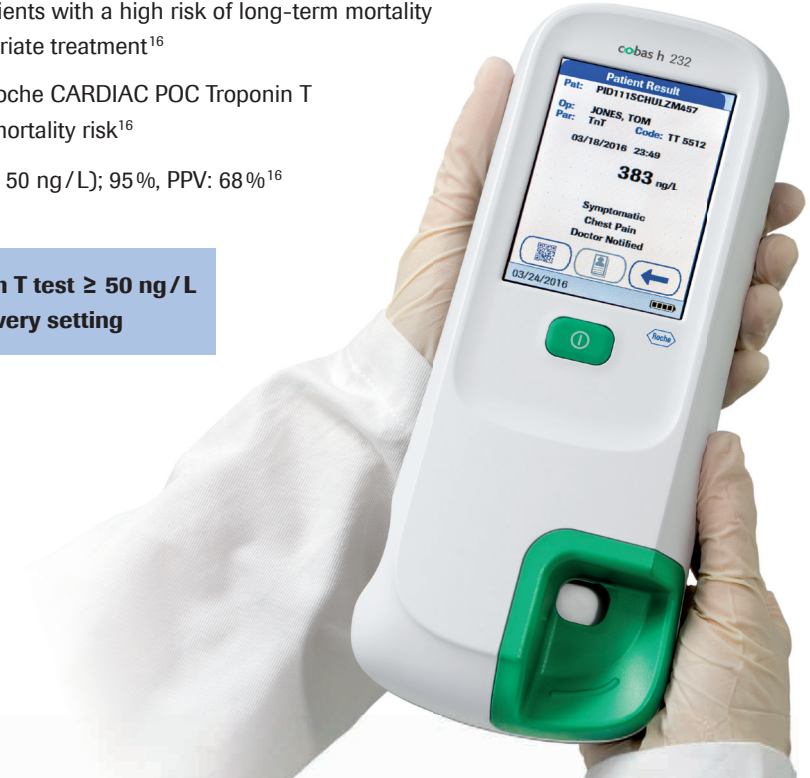
GRACE = Global Registry of Acute Coronary Events score; cTnT-hs = Elecsys® cardiac Troponin T high-sensitive; ULN = upper limit of normal, 99th percentile of healthy controls. Delta change dependent on assay.

Point Of Care option with Roche cobas® h 232 system

Immediate rule-in for high-risk AMI patients with initial sample

- Easy to use even in mobile situations and ensures fast turn-around time with results available in just 12 minutes[16,17]
- POC cTnT ≥ 50 ng/L can be used to identify patients with a high risk of long-term mortality for accelerated medical investigation and appropriate treatment[16]
- Pre-hospital patients with suspected AMI with Roche CARDIAC POC Troponin T ≥ 50 ng/L have a 3-10 times higher long-term mortality risk[16]
- Specificity for the diagnosis of AMI (POC cTnT ≥ 50 ng/L); 95%, PPV: 68%[16]

Roche CARDIAC POC Troponin T test ≥ 50 ng/L allows fast triaging in every setting

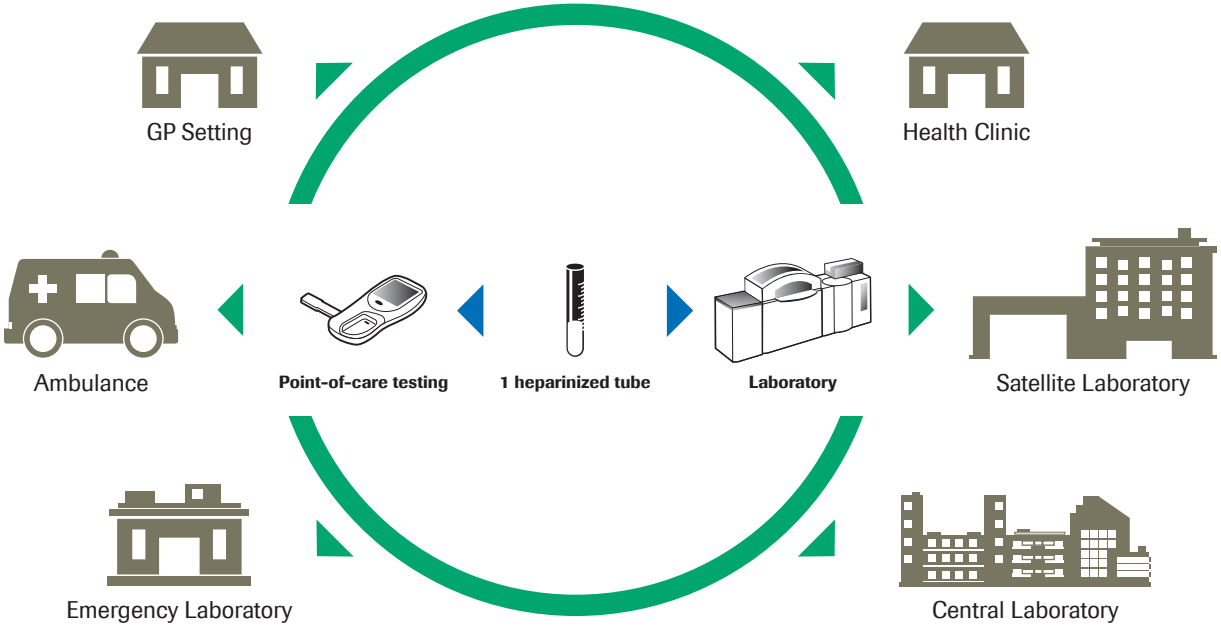


POC cTnT: Roche CARDIAC POC Troponin T

Standardized Troponin T results among all locations

From pre-hospital and emergency rooms to laboratories

Comparable cardiac Troponin T results with immediate rule-in cut-offs (≈ 50 ng / L) among any cobas® integrated platforms[17]



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Not for distribution in the USA.