Emc²

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NOVOTEL MONTE-CARLO MONACO

Impact du dosage de la troponine HS par une méthode délocalisée en médecine d'urgence

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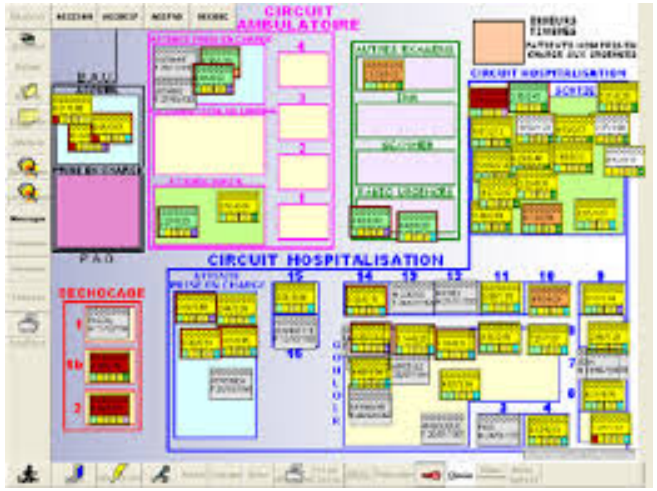
Déclaration de Conflits d'intérêts

Lectures et honoraires

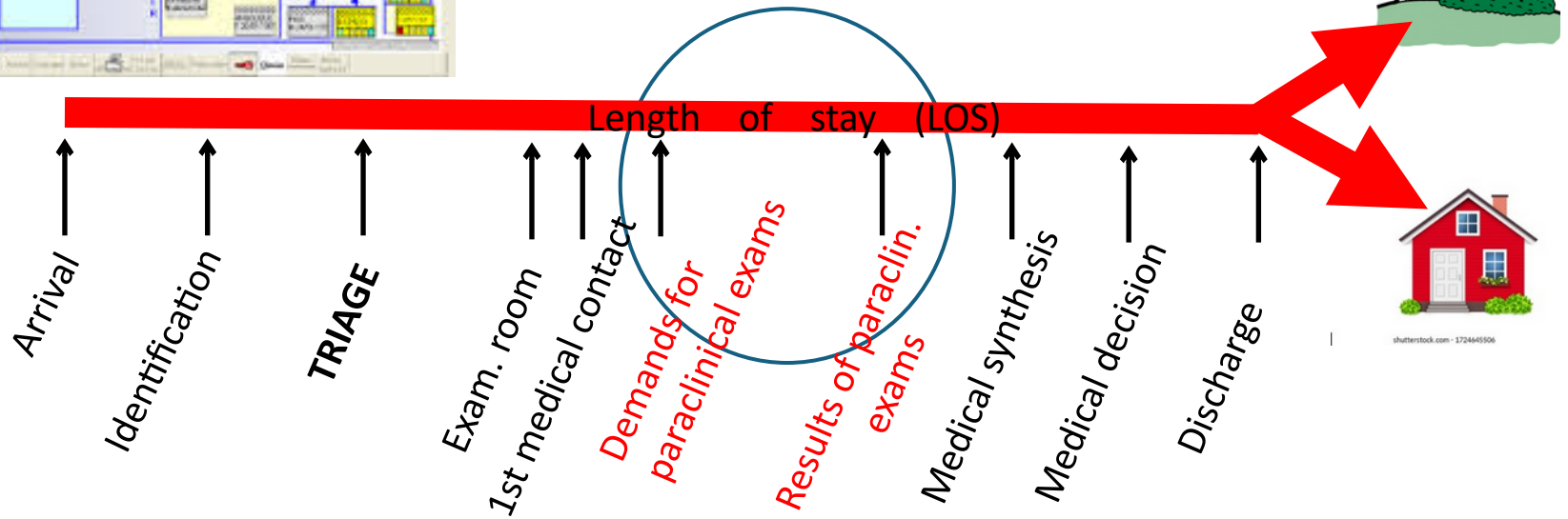
- Abbott
- Nephrotek
- QuidelOrtho
- Radiometer
- Eurobio

Objectif de la délocalisation de la biologie ?



=> Need to have test result sooner for a faster triage of patients:

- For a better management of acute patients
- For a better access to imaging



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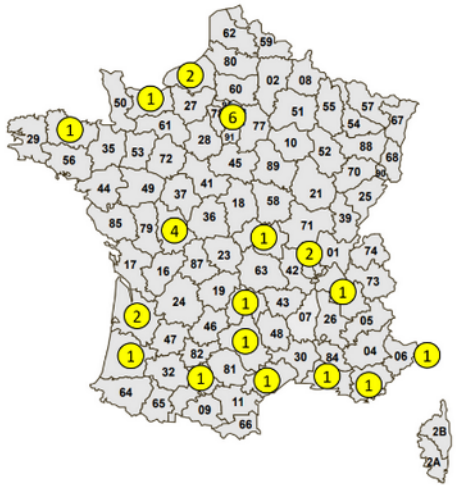
Annales de Biologie Clinique

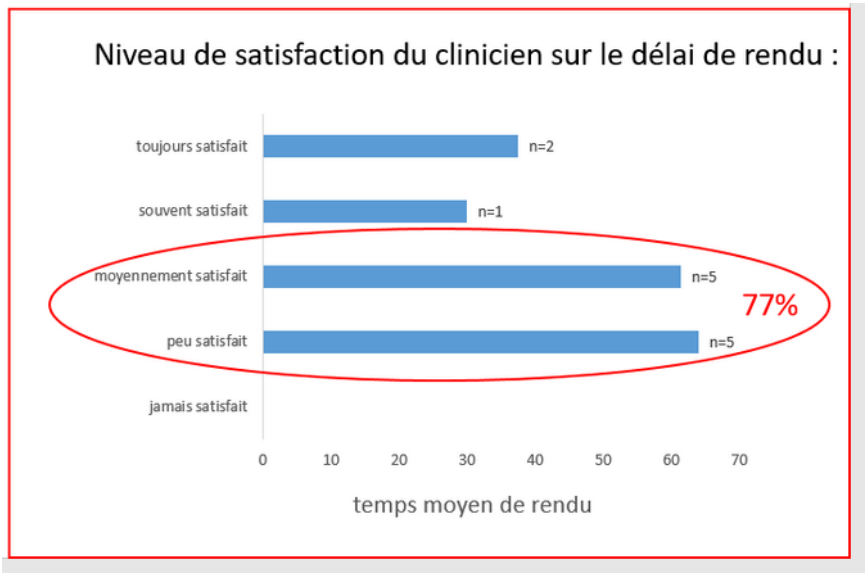
Enquête Nationale sur les délais de réalisation des analyses de TROponine prescrites aux Urgences Adultes : état des lieux de la PRISE en charge et des modalités d'interprétation - Protocole EN-TRO-PRISE

Camille Gobeaux[1], Guillaume Lefevre[2], Bruno Lehodey[3], Mathieu Kuentz[4], Valery Bourbonneux[5], Matthieu Pecquet[6], Pierre Hausfater[7], Marie-Christine Beauvieux[8], Cédric Gil-Jardine[9], Christophe Choquet[10], Valérie Machie[11], Valéry Brunel[12], Jérémy Guenezan[13], Sandrine Charpentier[14], Yann-Erick Claessens[15]

Combien de temps pour le résultat de troponine au labo central ?



Enquête « Entroprise » SFBC SFMU
28 centres participants



87 410 dossiers demandes de troponine étudiées :

Délai médian de rendu global = 81 minutes

Résultat rendu

ESC European Society of Cardiology
European Heart Journal (2023) **00**, 1–107
https://doi.org/10.1093/eurheartj/ehad191

2023 ESC Guidelines for the management of acute coronary syndromes

Developed by the task force on the management of acute coronary syndromes of the European Society of Cardiology (ESC)

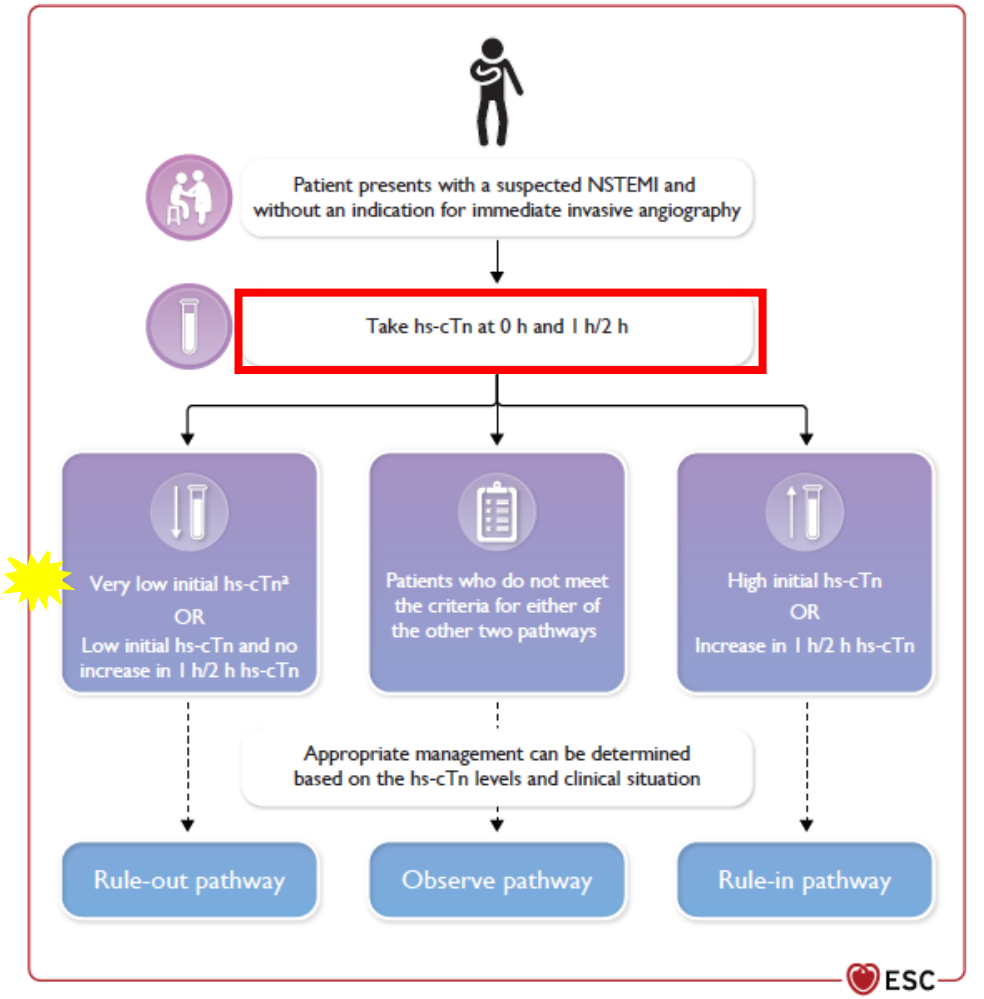


Figure 6 The 0 h/1 h or 0 h/2 h rule-out and rule-in algorithms using high-sensitivity cardiac troponin assays in patients presenting to the emergency department with suspected NSTEMI and without an indication for immediate invasive angiography. hs-cTn, high-sensitivity cardiac troponin; NSTEMI, non-ST-elevation myocardial infarction. Patients are classified into one of three pathways as per the results of their hs-cTn values at 0 h (time of initial blood test) and 1 h or 2 h later. Patients with a very low initial hs-cTn value or patients with a low initial value and no 1 h/2 h change in hs-cTn are assigned to the 'rule-out' pathway. Patients with a high initial hs-cTn value or a 1 h/2 h change in hs-cTn are assigned to the 'rule-in' pathway. Patients who do not meet the criteria for the rule-out or rule-in strategies are assigned to the 'observe' pathway, and these patients should have hs-cTn levels checked at 3 h ± echocardiography in order to decide on further management. Cut-offs are assay specific (see Supplementary material online, *Table S4*) and derived to meet pre-defined criteria for sensitivity and specificity for NSTEMI. Potential management and testing options for each of the three strategies are provided in the relevant sections of the main text.[12–15,26,27,53,55–58,100,101] [a]Only applicable if the chest pain onset was >3 h prior to the 0 h hs-cTn measurement.

[a]Only applicable if the chest pain onset was >3 h prior to the 0 h hs-cTn measurement.

Blood sampling		
It is recommended to measure cardiac troponins with high-sensitivity assays immediately after presentation and to obtain the results within 60 min of blood sampling.[15,25–27]	I	B
It is recommended to use an ESC algorithmic approach with serial hs-cTn measurements (0 h/1 h or 0 h/2 h) to rule in and rule out NSTEMI.[28–44]	I	B
Additional testing after 3 h is recommended if the first two hs-cTn measurements of the 0 h/1 h algorithm are inconclusive and no alternative diagnoses explaining the condition have been made.[45,46]	I	B

Byrne RA, et al. 2023 ESC Guidelines for the management of acute coronary syndromes. Eur Heart J Acute Cardiovasc Care. 2024 Feb 9;13(1):55-161. doi: 10.1093/ehjacc/zuad107.

Comment délocaliser ?

POCT ***= point of care testing***

= biologie en dehors du laboratoire central

= biologie au lit du malade / au poste de soin

= biologie délocalisée

C'est le personnel soignant qui réalise

l'examen de biologie

<u>Justification +++ :</u>

- Urgence vitales
- Eloignement géographique du lab
- Epargne sanguine
- Organisationnelle

Quelles méthodes délocalisables ?

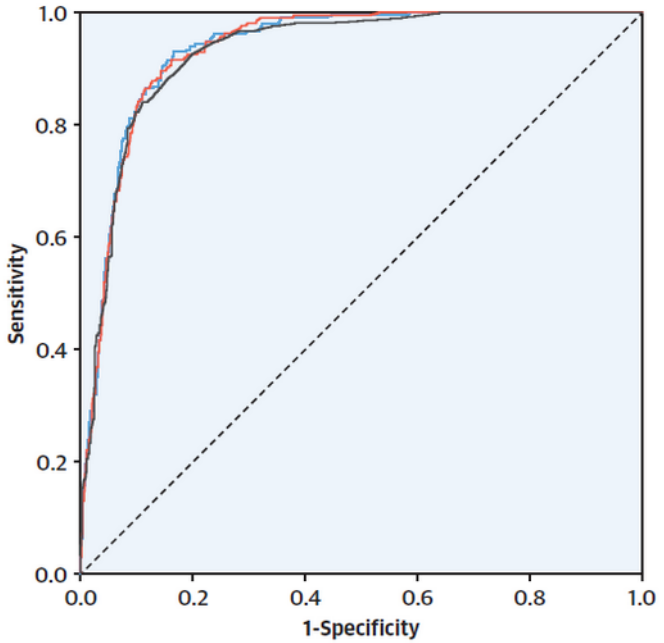
Table 1 Characteristics, analytical, and clinical performance of high-sensitivity cardiac troponin assays available at the point of care

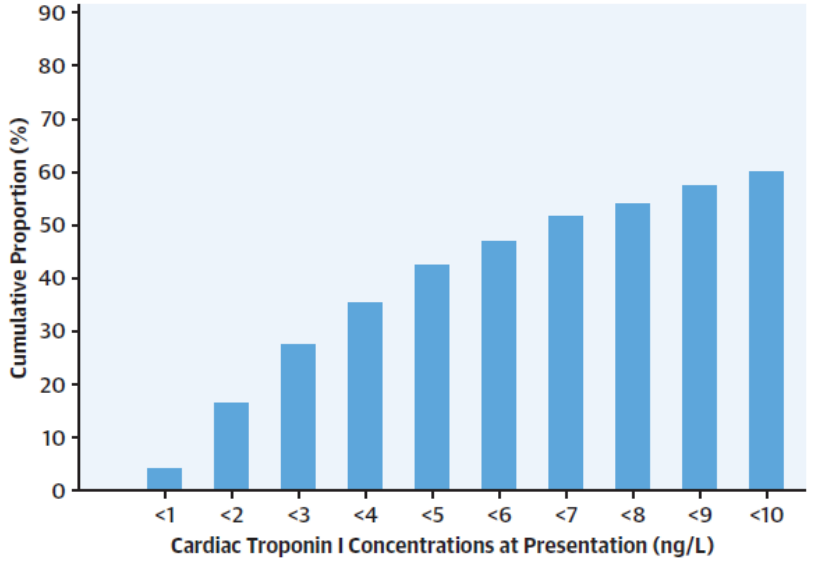
Platform	LoD (ng/L)	10% CV (ng/L)	URL (overall; ng/L)	URL male (ng/L)	URL female (ng/L)	Detectable proportion of the reference population	Time to results	Specimen	Approved for capillary testing	Analytical evaluation studies	Clinical performance studies
Bench top platforms											
Pathfast (LSI Medience, formerly Mitsubishi)	2.3	15	28	30	21	>52%	<17 min	Heparinized or EDTA plasma or venous whole blood	NA	YES[11,16]	YES[16] Rule-out <4 ng/L Rule-in ≥90 ng/L
SpinChip (SpinChip Diagnostics)	1.1 (plasma) 1.2 (whole blood)	3.7	31.7	36.9	27.3	>62%	~10 min	Heparinized plasma or whole blood	NA	YES[13]	YES[13] Rule-out <7 ng/L Rule-in ≥36 ng/L
Pylon (ET Healthcare)	1.2–1.4	10 (whole blood) 5 (plasma)	27	27	21	>89%	<20 min	EDTA plasma, EDTA whole blood	NA	YES[12]	NO
Portable handheld testing platforms											
i-STAT-1 Alinity (Abbott)	1.6 (whole blood) 1.1 (plasma)	6.9 (whole blood) 3.7 (plasma)	21	28	13	>50%	~15 min	lithium heparin plasma or whole blood	No	No	Yes[19] Rule-out <3 ng/L
Atellica VTLi (Siemens Healthineers)	1.2 (plasma) 1.6 (whole blood)	6.7 (plasma) 8.9 (whole blood)	23	27	18	≥80%	~8 Mins	lithium heparin plasma or whole blood	Yes[20]	Yes[21,22]	Yes[15,23,24] Rule-out <4 ng/L Rule-in >54 ng/L
TriageTrue (QuidelOrtho)	1.6 (plasma) 1.9 (whole blood)	8.4 (plasma), 6.2 (whole blood)	20.5	25.7	14.4	≥50%	<20 min	EDTA plasma or whole blood	No	Yes[25]	Yes[14,25] Rule-out <3 ng/L Rule-in >60 ng/L

Cullen L, et al. High-sensitivity point-of-care measurement of cardiac troponin. Eur Heart J. 2025 Aug 7:ehaf407. doi: 10.1093/eurheartj/ehaf407. Epub ahead of print. PMID: 40795130.

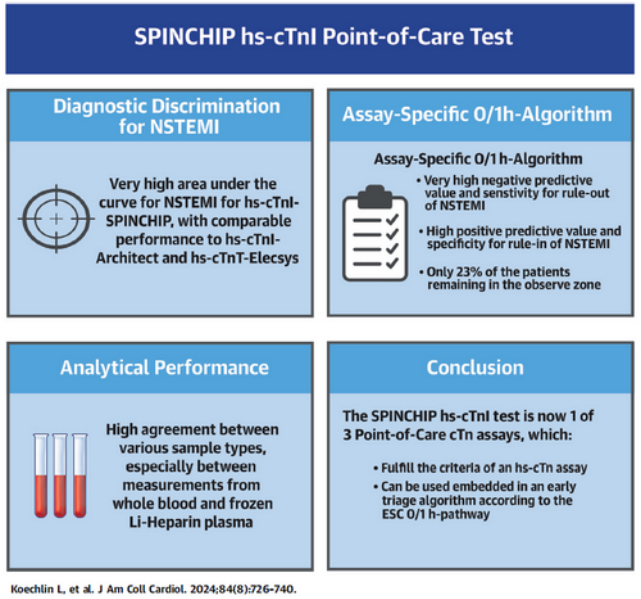
A propos de SpinChip

FIGURE 2 Diagnostic Discrimination of hs-cTnI/T at Presentation for NSTEMI





Concentration (ng/L)	<1	<2	<3	<4	<5	<6	<7	<8	<9	<10
Cumulative events (n)	0	0	0	1	1	2	2	4	7	8
Cumulative events (%)	0.0	0.0	0.0	0.3	0.2	0.4	0.4	0.7	1.1	1.2
Cumulative number (n)	46	182	300	393	466	518	564	596	633	662
Cumulative number (%)	4	17	27	36	42	47	51	54	57	60
Sensitivity (%)	100.0	100.0	100.0	99.5	99.5	99.1	99.1	98.1	96.7	96.3
NPV (%)	100.0	100.0	100.0	99.7	99.8	99.6	99.6	99.3	98.9	98.8



✓ 51% rule-out
✓ 22% observe
✓ 27% rule-in

Koechlin L, Boeddinghaus J, Lopez-Ayala P, Reber C, Nestelberger T, Wildi K, Spagnuolo CC, Strebel I, Glaeser J, Bima P, Crisanti L, Herraiz-Recuenco L, Dubach E, Miró Ò, Martin-Sanchez FJ, Kawecki D, Keller DI, Christ M, Buser A, Giménez MR, Størvold GL, Broughton MN, Omland T, Lyngbakken MN, Røsjø H, Mueller C; APACE Investigators. Clinical and Analytical Performance of a Novel Point-of-Care High-Sensitivity Cardiac Troponin I Assay. J Am Coll Cardiol. 2024 Aug 20;84(8):726-740. doi: 10.1016/j.jacc.2024.05.056. PMID: 39142727.

Cahier des charges de la biologie délocalisée

Fiabilité équivalente au laboratoire, Qualité

Praticabilité, connectabilité

Dosage sur sang total - Sg veineux ou sg capillaire?

Nécessité ++ Validation des seuils d’interprétation

Justification médico-économique

…

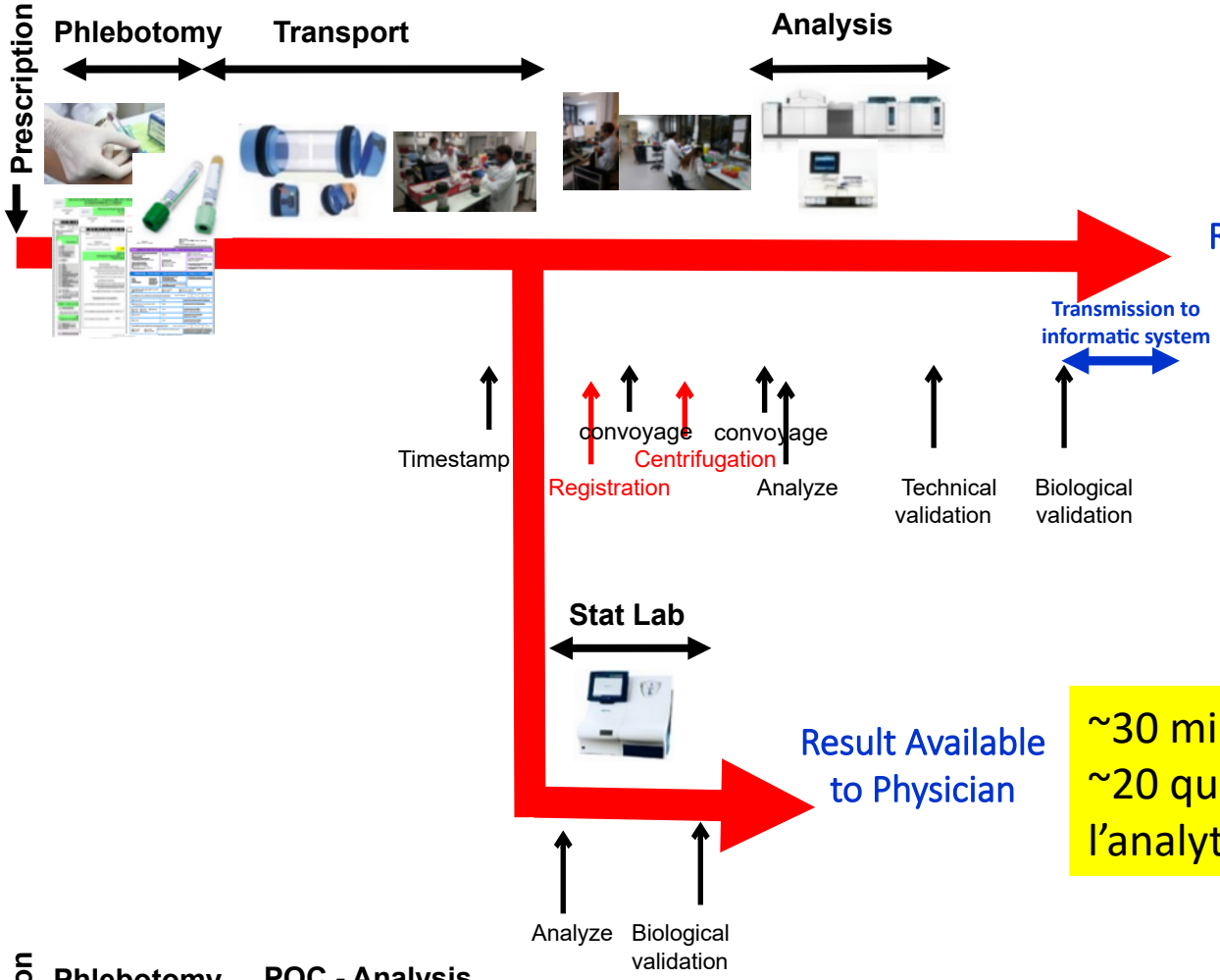
ANR

POCER

Délocaliser le dosage de la troponine HS …

- Pour avoir le résultat plus rapidement
  et pouvoir appliquer l'algorithme H0/H1
  Pour exclure plus rapidement
- Pour réduire la Durée médicale de séjour
- Pour faire des économies ?

=> Améliorer l'organisation des soins aux urgences et la prise en charge du patient avec suspicion SCA



~80 minutes… dont ~65 qui ne sont pas de l'analytique

~30 minutes… dont ~20 qui ne sont pas de l'analytique

- ✓ Analyseurs restent au laboratoire, pas de glissement de tâche
- ✓ pas de centrifugation
- ✓ Pas d'enregistrement, auto-création du dossier sur l'analyseur
- ✓ Panel d'analyses + large que solution EBMD
- ✓ Démarche qualité moins lourde pour le laboratoire

- ✓ Pas de tps d'acheminement
- ✓ Équipes soignantes PNM et PM motivées

Pour réduire la DMS

Référence	Type d'étude	Plan d'expérience, population	Intervention	Contrôle	RR(95% IC)	Différence moyennes	Notes
Shinde et al. 2024 39246852	Observationnel prospective	Dosage POC vs central pour chaque patient	14.9 +/- 0.5	119.1 +/- 5.03'		(- 172.36')	70 patients
Zalama-Sánchez et al. 2024 390640	Observationnel prospective	Dosage POC vs central pour chaque patient	15'	83'		(-68')	POC : The Siemens Atellica® VTLi hs-cTn POC (Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen, Germany) vs laboratory analysis was performed using the Roche Elecsys® (Roche diagnostics Basel, Switzerland)
Hight et al. 2020 33308833	Observationnel prospective	Dosage POC vs central pour chaque patient	11 [10;15.5]	40 [31.5;52.5]		(-29')	60 patients needed a troponin in the evaluation of low-risk chest pain (HEART score <4). POCT was performed with the same blood sample obtained for a conventional troponin assay.
Hertz et al 2020 32772764	Pré-post	Dosage POCT à l'IOA systématique pour SOB ou chest pain vs usual care. Outcome principal = diagnostic SCA	681 patients	339 patients	7.51 (3.52-19.7)		
He et al. 2020 32742399	Observationnel prospective	Dosage POC vs central pour chaque patient	15'	60'			391 patients. 57 patients = MI. AUC of the central model was 0.787 (0.709-0.865) with a Sp = 76.7%, Se = 71.9%, VPN 94.1 and VPP 34.5%. AUC of the disposable strip model was 0.792 (0.729-0.855), VPN 94.9%, VPP 28.9%, Sp 66.8% and Se 79.0%.
Boeddinghaus et al. 2020	Observationnel prospective	The primary objective was to directly compare diagnostic accuracy of POC-hs-cTnI-TriageTrue versus best-validated central laboratory assays					POChs-cTnI-TriageTrue AUC at presentation was 0.95 (0.93 to 0.96) and vs hs-cTnT-Elecsys (AUC: 0.94; 0.93 to 0.96) and hs-cTnI-Architect (AUC: 0.92; 0.90 to 0.93). A single cutoff concentration <3 ng/l at presentation identified 45% of patients at low risk with a NPV of 100% (99.4% to 100%). Ruled-out patients had cumulative event rates of 0% at 30 days and 1.6% at 2 years
Singer et al. 2018 29887410	Prospective, case-controlled trial	POCT vs central	52 patients	52 patients		POCT had shorter median ED care time than matched controls (7.6, 5.1-9.5 vs. 8.5, 6.2-11.3 h)	
Pines et al. 2018 29754458	pré-post	POCT vs central	24,705 patients = 90 minutes	22,694 patients = 66 minutes		21.1' (–28.3 to –13.9)	
Singer et al. 2015 25836947	Pré-post	POCT vs central. Primary end point = ED LOS.	1405 patients = 263' [163-398]	981 patients = 230' [135-413]		(-33')	
Koehler et al. 2013 23899951	Pré-post	POCT vs central. Primary end point = ED LOS.	290'	255'			Average door-to-troponin result time significantly decreased from 105 to 51 min (p < 0.000)
Goodacre et al. 2011 21616014	RCT	POCT vs central. Primary end point = ED LOS.	1132 patients	1131 patients (14.2h)		(-324')	

Etude randomisée

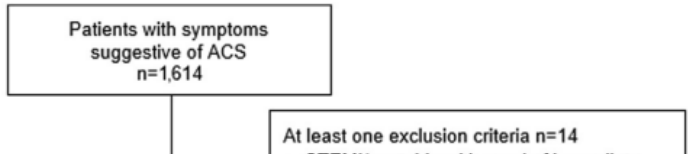


Table 2. Effectiveness outcomes.

Outcome	POC (n = 728)	Control (n = 766)	Difference (95% CI)
LOS in the ED, min, median (95% CI)	174 (167-181)	180 (175-189)	6 (−4 to 17)
LOS in the hospital, h, median (95% CI)	21 (19-22)	20 (18-21)	1 (−3 to 2)
Total LOS <3 h, n, % (95% CI)	115 16 (13-19)	113 15 (12-17)	1 (−5 to 2)
Total LOS <6 h, n, % (95% CI)	273 38 (34-41)	290 38 (35-41)	0 (−5 to 5)

POC, point of care; *LOS*, length of stay; *ED*, emergency department.

Thulin VIL, Jordalen SMF, Myrmel GMS, Lekven OC, Krishnapillai J, Steiro OT, Body R, Collinson P, Apple FS, Cullen L, Norekvål TM, Wisløff T, Vikenes K, Bjørneklett RO, Omland T, Aakre KM. Effectiveness of Point-of-Care High-Sensitivity Troponin Testing in the Emergency Department: A Randomized Controlled Trial. Ann Emerg Med. 2025 Aug;86(2):124-135. doi: 10.1016/j.annemergmed.2025.03.005. Epub 2025 Apr 9. PMID: 40202469.

Proportion de rule-out

Table 2 Overview on the performance of fast rule-out strategies based on single and serial blood draw at 0 hour/1 hour

	Test principle	Company	Meta-analysis cohorts	Troponin (ng/L)	Sensitivity (pooled)	NPV (pooled)	Proportion eligible for rule-out	Event rate after rule-out		
								MACE	Death	MI
0-hour rule-out: single hs-cTNT <LoD (SMS)										
Pickering, *et al*[29]	hs-cTnT		11 cohorts 9241 patients	<LoD (<5 ng/L)	98.7% (96.6 to 99.5)	99.3% (97.3 to 99.8)	30.60%	21/8059	1.30%	14/8059
ESC 0/1 hour: either very low 0 hour <LoD or low hs-cTn *and* small δ between 0 and 1 hour										
Chiang, *et al*[28] 15 cohorts: 11 014 patients	hs-cTnI	Abbott	4 cohorts	Either very low 0 hour (<2 ng/L), or low hs-cTnI (<5 ng/L) and small δ (<2 ng/L) between 0 and 1 hour	98.1% (94.6 to 99.3)	99% (96.0 to 100)	50.00%	NA	0.10%	NA
	hs-cTnI	Siemens	4 cohorts	Either very low 0 hour (<0.5 ng/L), or low hs-cTnI (<5 ng/L) and small δ (<2 ng/L) between 0 and 1 hour	98.7% (97.3 to 99.3)	100% (99 to 100)	51.00%	NA	0.10%	NA
	hs-cTnT	Roche	7 cohorts 7744 patients	Either very low 0 hour (<5 ng/L), or low hs-cTnT (<12 ng/L) and small δ (<3 ng/L) between 0 and 1 hour	98.4% (95.1 to 99.5)	99.6% (99.0 to 99.9)	55.00%	NA	0.10%	NA

ESC, European Society of Cardiology; hs-cTnI, high-sensitivity cardiac troponin I; LoD, limit of detection; MACE, major adverse cardiac events; MI, myocardial infarction; NA, not available; NPV, negative predictive value; SMS, single marker strategy.

Impact de la délocalisation sur les équipes

Laboratoire	Service de soin
Gestion d'un parc d'analyseur plus important	Implication des cadres nécessaire pour orchestrer les formations
Gestion des réactifs	Temps infirmier à la réalisation des analyse
Temps biologiste	Formations
Temps technicien	Prévoir procédure dégradée
Gestion de méthodes de dosages différents	Organiser l'aval (ex: cardiologie)

→ Meilleure PEC du

Take away messages

Impact du dosage de la troponine HS par une méthode délocalisée en médecine d'urgence

- ✓ Application des dernières recommandations
- ✓ Diminution des délais de rendus du résultat
- ✓ Diminution DMS
- ✓ Économies ?
  - ✓ Activité en plus
    - ✓ pour le laboratoire
    - ✓ Pour le service des Urgences