



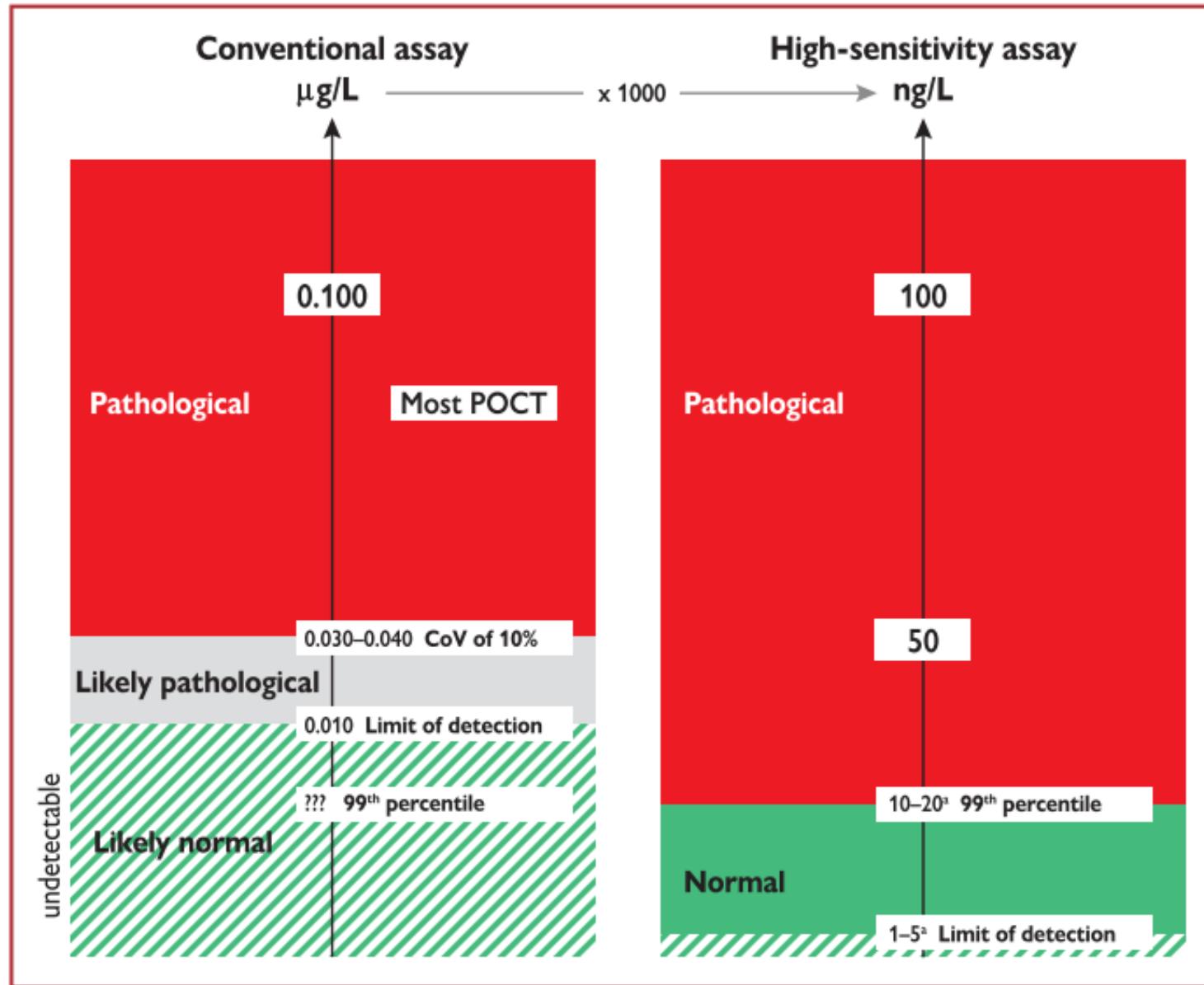
Les nouvelles guidelines de la Société européenne de Cardiologie sont-elles applicables d'un point de vue analytique ?

Corata 29/09/22

Ph. Lamtiri Mouhsine Assistant en biologie clinique

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Troponine Ultrasensible



Fourth universal definition of myocardial infarction (2018)

Kristian Thygesen* (Denmark), Joseph S. Alpert* (USA), Allan S. Jaffe (USA),
Bernard R. Chaitman (USA), Jeroen J. Bax (The Netherlands), David A. Morrow
(USA), Harvey D. White* (New Zealand): the Executive Group on behalf of the Joint
European Society of Cardiology (ESC)/American College of Cardiology (ACC)/
American Heart Association (AHA)/World Heart Federation (WHF) Task Force for
the Universal Definition of Myocardial Infarction

Acute myocardial infarction (AMI) defines cardiomyocyte necrosis in a clinical setting consistent with acute myocardial ischaemia. **A combination** of criteria is required to meet the diagnosis of AMI, namely the **detection of an increase and/or decrease of a cardiac bio-marker**, preferably high-sensitivity cardiac troponin (hs-cTn) T or I, **with at least one value above the 99th percentile of the upper reference limit** and at least **one of the following**:

- a. Symptoms of myocardial ischaemia.
- b. New ischaemic ECG changes.
- c. Development of pathological Q waves on ECG.
- d. Imaging evidence of loss of viable myocardium or new regional wall motion abnormality in a pattern consistent with an ischaemic etiology.
- e. Intracoronary thrombus detected on angiography or autopsy.

Elévation «aspécifique»

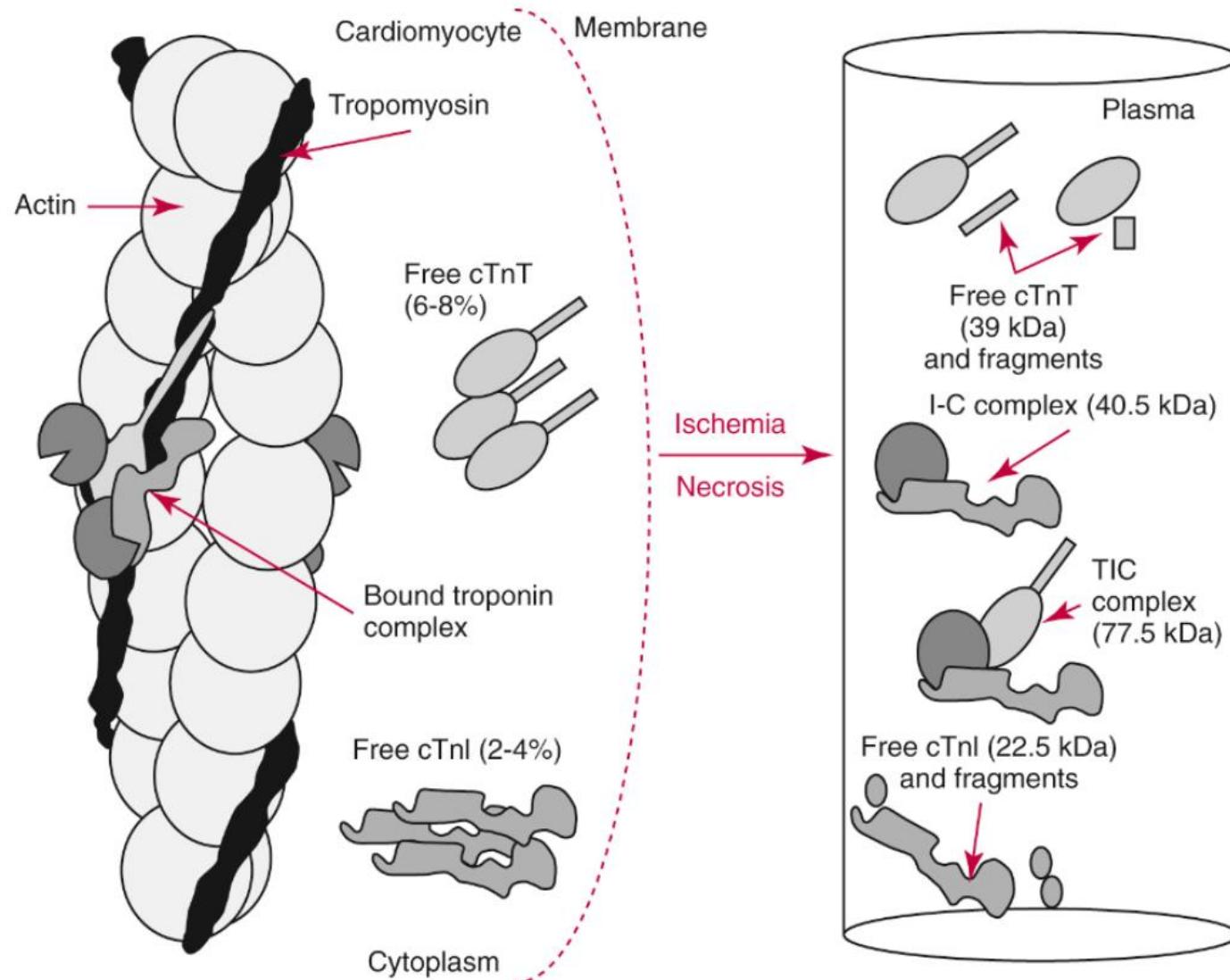
Box 58.1

Elevation of Tropionins Without Overt Ischemic Heart Disease

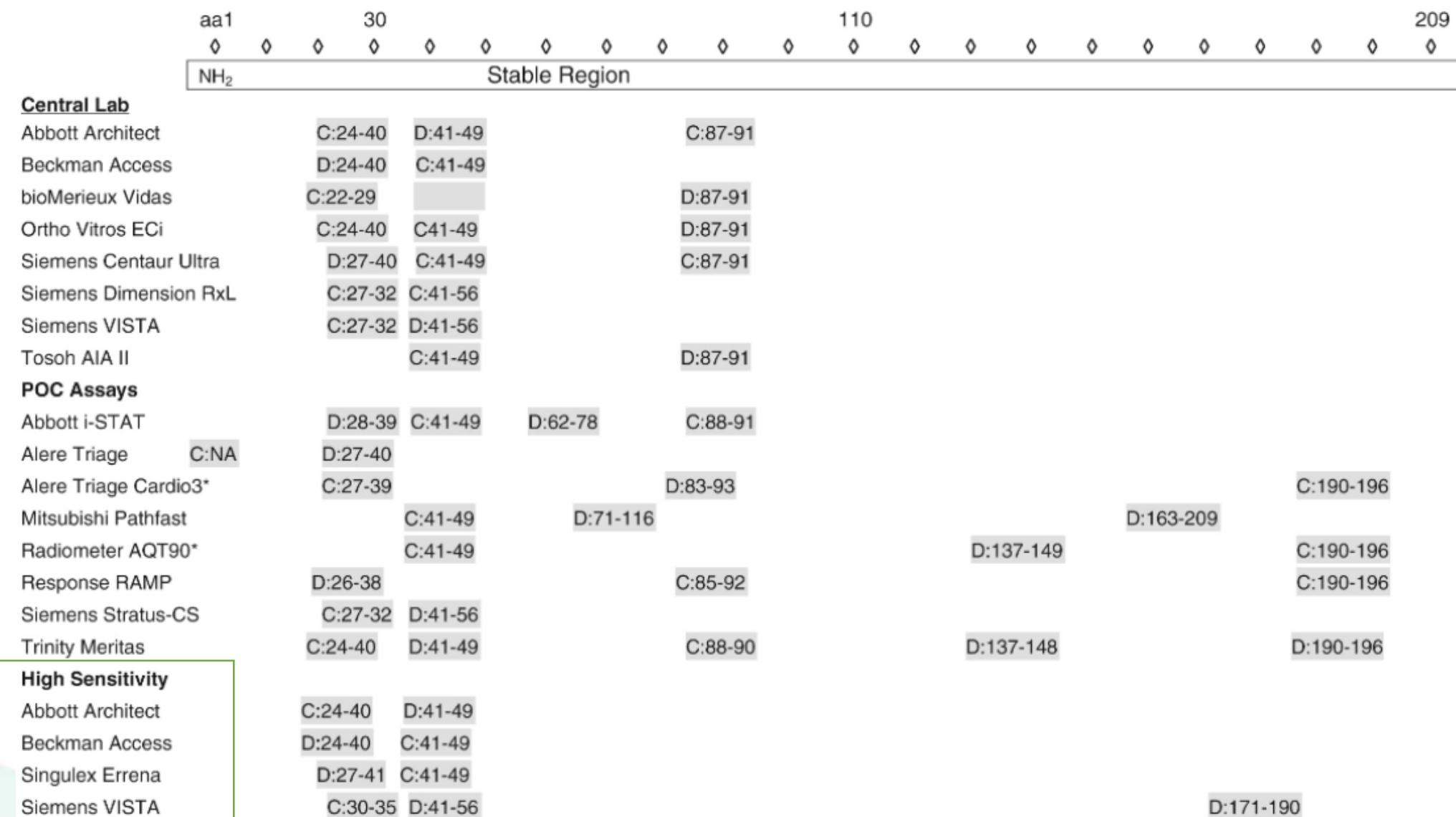
- Trauma (including contusion, ablation, pacing, and cardioversion)
- Congestive heart failure—acute and chronic
- Aortic valve disease and hypertrophic cardiomyopathy with significant left ventricular hypertrophy
- Hypertension
- Hypotension, often with arrhythmias
- Postoperative noncardiac surgery patients who seem to do well
- Renal failure
- Critically ill patients, especially those with diabetes, respiratory failure
- Drug toxicity (eg, Adriamycin, 5-fluorouracil, herceptin, snake venoms)
- Hypothyroidism
- Coronary vasospasm, including apical ballooning syndrome
- Inflammatory disease (eg, myocarditis, parvovirus B19, Kawasaki's disease, sarcoid, smallpox vaccination)
- Post-percutaneous intervention patients whose condition appears to be uncomplicated
- Pulmonary embolism, severe pulmonary hypertension
- Sepsis
- Burns, especially if total body surface area is greater than 30%
- Infiltrative disease, including amyloidosis, hemochromatosis, sarcoidosis, and scleroderma
- Acute neurologic disease, including cerebrovascular accident, subarachnoid bleeds
- Rhabdomyolysis with cardiac injury
- Transplant vasculopathy
- Vital exhaustion

L'élévation de la troponine **est spécifique d'une lésion myocardique mais n'est pas nécessairement une conséquence d'une maladie coronarienne.**

CARDIOMYOLYSE



EPITOPEs



Rapid « rule-in » and « rule-out » algorithms

- Protocoles pour **rapidement exclure l'IAM pour un maximum de patients**
- Trois types :
 1. Rapid rule out basés sur valeurs de TN et sur les delta : **ESC 0/1h et 0/2h**
 2. Basés sur les scores de risques et prédition de risque cardiaque à court terme
 3. Combinaison des deux : **ESC 0/3h**

Recommandations ESC2020

- **Choix de l'algorithme:**

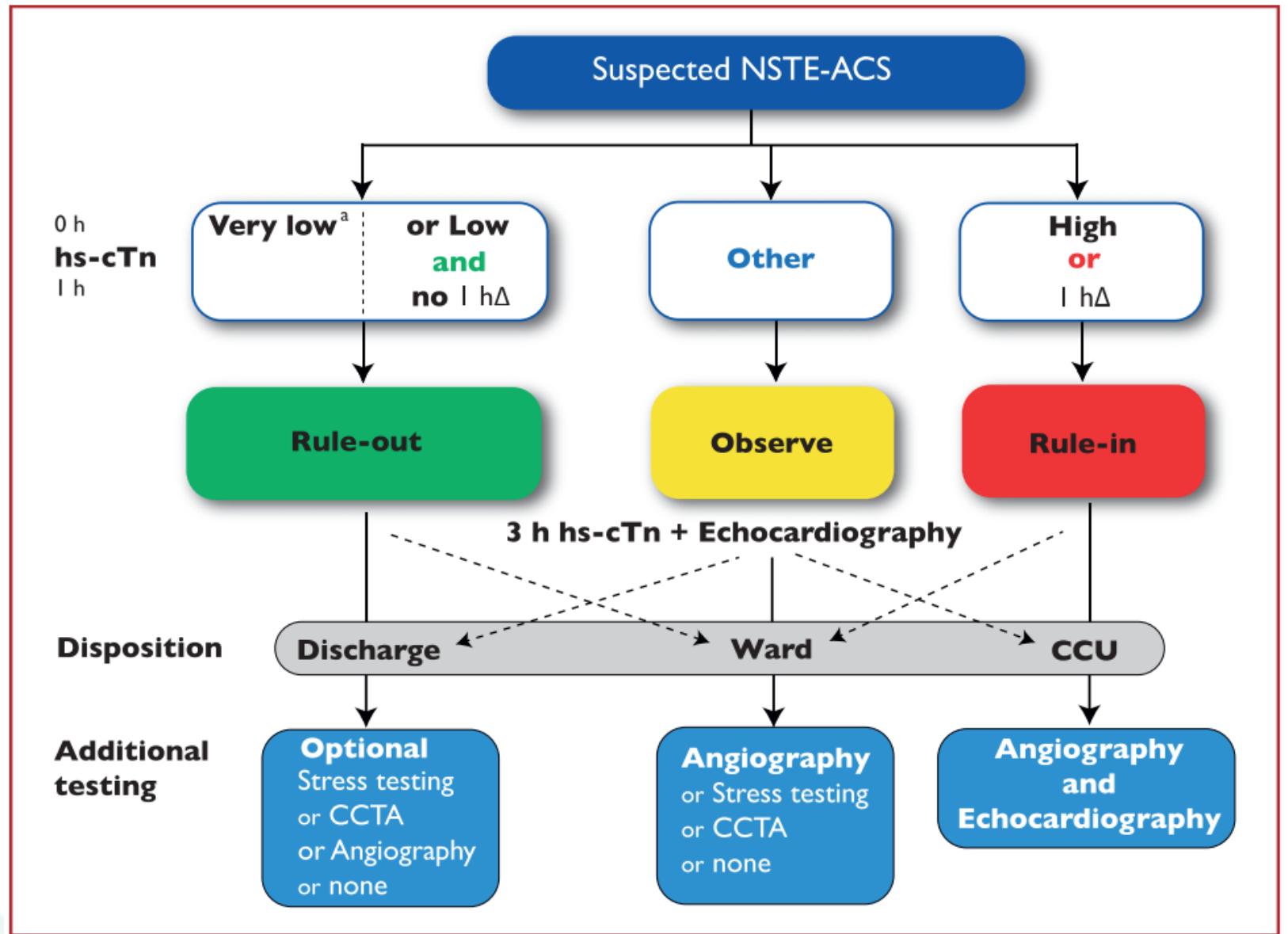
1. 0h/1h « Best choice »
2. 0h/2h « Second best choice »
3. 0h/3h Alternative

- **Troponine : T ou I**

- **Deux conditions:**

1. Rule-in \Leftrightarrow Valeur prédictive positive (**VPP**) > 70%
2. Rule-out \Leftrightarrow Valeur prédictive négative (**VPN**) > 99%

ESC Guidelines : 0/1h algorithme



Δ | Hs-cTn |

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 1h Δ	High	1h Δ
hs-cTn T (Elecsys; Roche)	<5	<12	<3	\geq 52	\geq 5
hs-cTn I (Architect; Abbott)	<4	<5	<2	\geq 64	\geq 6
hs-cTn I (Centaur; Siemens)	<3	<6	<3	\geq 120	\geq 12
hs-cTn I (Access; Beckman Coulter)	<4	<5	<4	\geq 50	\geq 15
hs-cTn I (Clarity; Singulex)	<1	<2	<1	\geq 30	\geq 6
hs-cTn I (Vitros; Clinical Diagnostics)	<1	<2	<1	\geq 40	\geq 4
hs-cTn I (Pathfast; LSI Medience)	<3	<4	<3	\geq 90	\geq 20
hs-cTn I (TriageTrue; Quidel)	<4	<5	<3	\geq 60	\geq 8
0 h/2 h algorithm	Very low	Low	No 2h Δ	High	2h Δ
hs-cTn T (Elecsys; Roche)	<5	<14	<4	\geq 52	\geq 10
hs-cTn I (Architect; Abbott)	<4	<6	<2	\geq 64	\geq 15
hs-cTn I (Centaur; Siemens)	<3	<8	<7	\geq 120	\geq 20
hs-cTn I (Access; Beckman Coulter)	<4	<5	<5	\geq 50	\geq 20
hs-cTn I (Clarity; Singulex)	<1	TBD	TBD	\geq 30	TBD
hs-cTn I (Vitros; Clinical Diagnostics)	<1	TBD	TBD	\geq 40	TBD
hs-cTn I (Pathfast; LSI Medience)	<3	TBD	TBD	\geq 90	TBD
hs-cTn I (TriageTrue; Quidel)	<4	TBD	TBD	\geq 60	TBD

These cut-offs apply irrespective of age and renal function. Optimized cut-offs for patients above 75 years of age and patients with renal dysfunction have been evaluated, but not consistently shown to provide better balance between safety and efficacy as compared to these universal cut-offs.^{35,36,69} The algorithms for additional assays are in development.

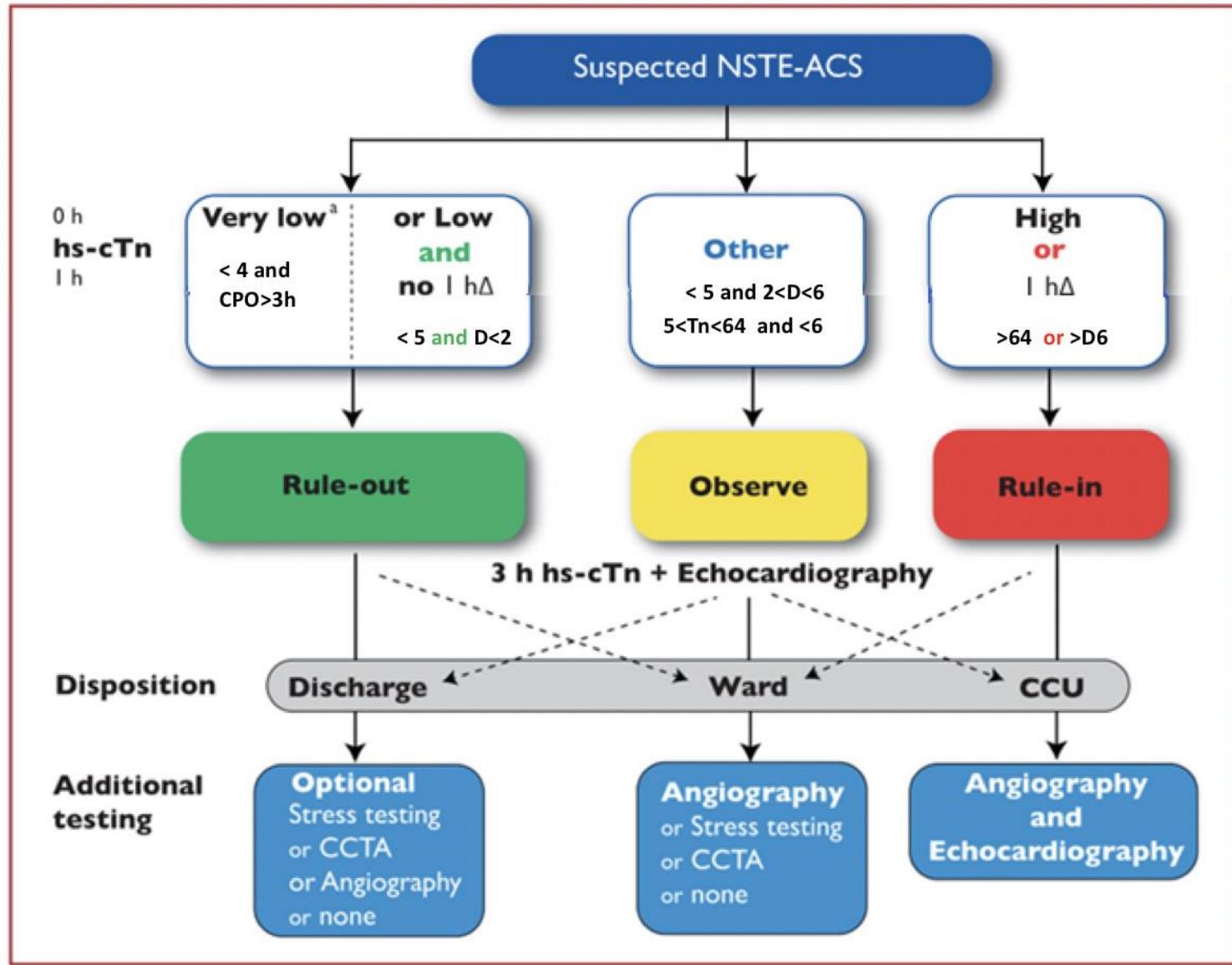
hs-cTn = high-sensitivity cardiac troponin; TBD = to be determined.^{35–37,39,40,68,69,75–84}

ESC European Heart Journal (2021) 42, 1289–1367
European Society of Cardiology doi:10.1093/euroheart/ehaa575

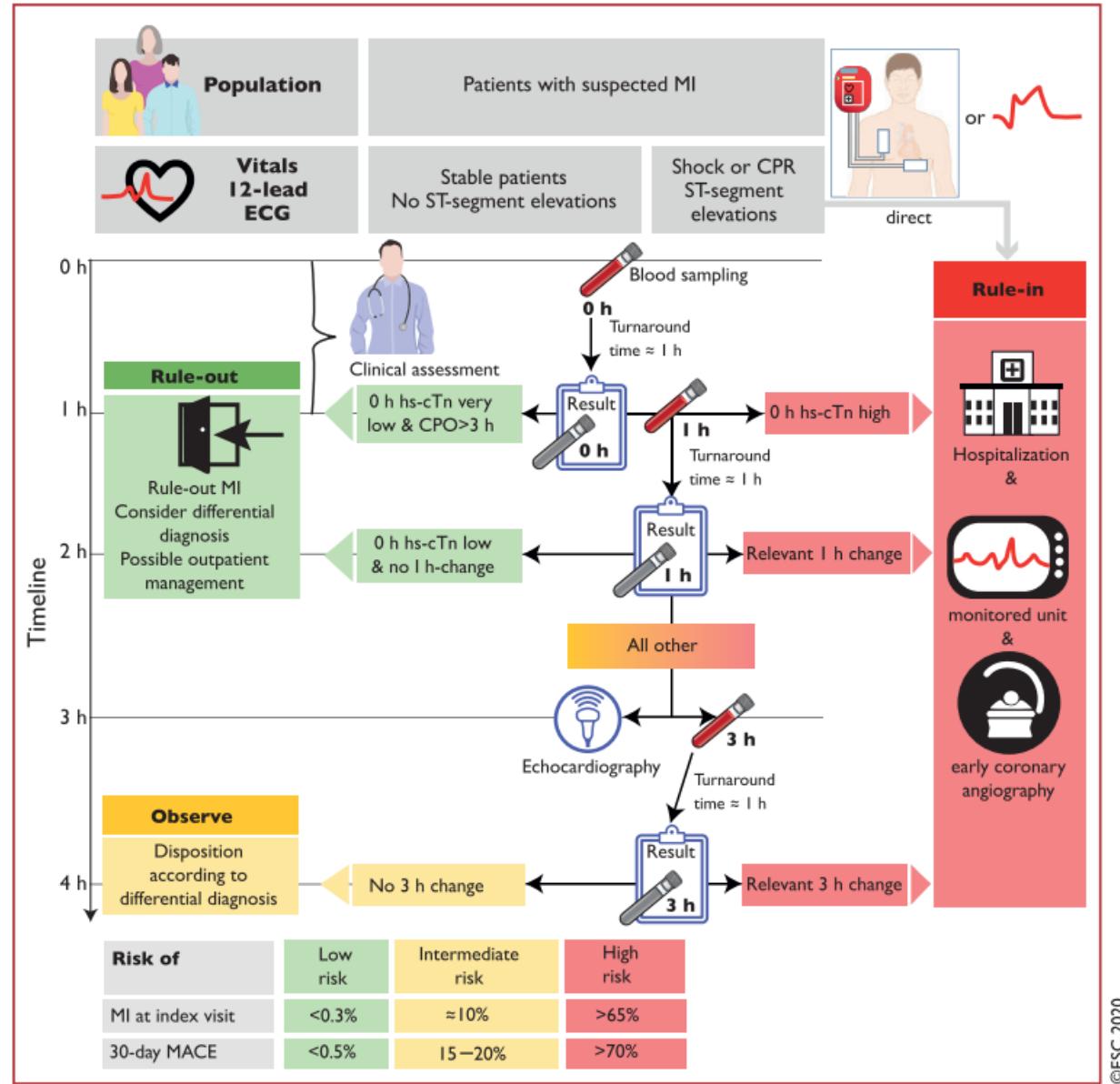
ESC GUIDELINES

2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation

ESC Guidelines : 0/1h algorithme



ESC Guidelines : 0/1h algorithme



QUID des (Extremely) early presenters ?

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Prospective Validation of the 0/1-h Algorithm for Early Diagnosis of Myocardial Infarction

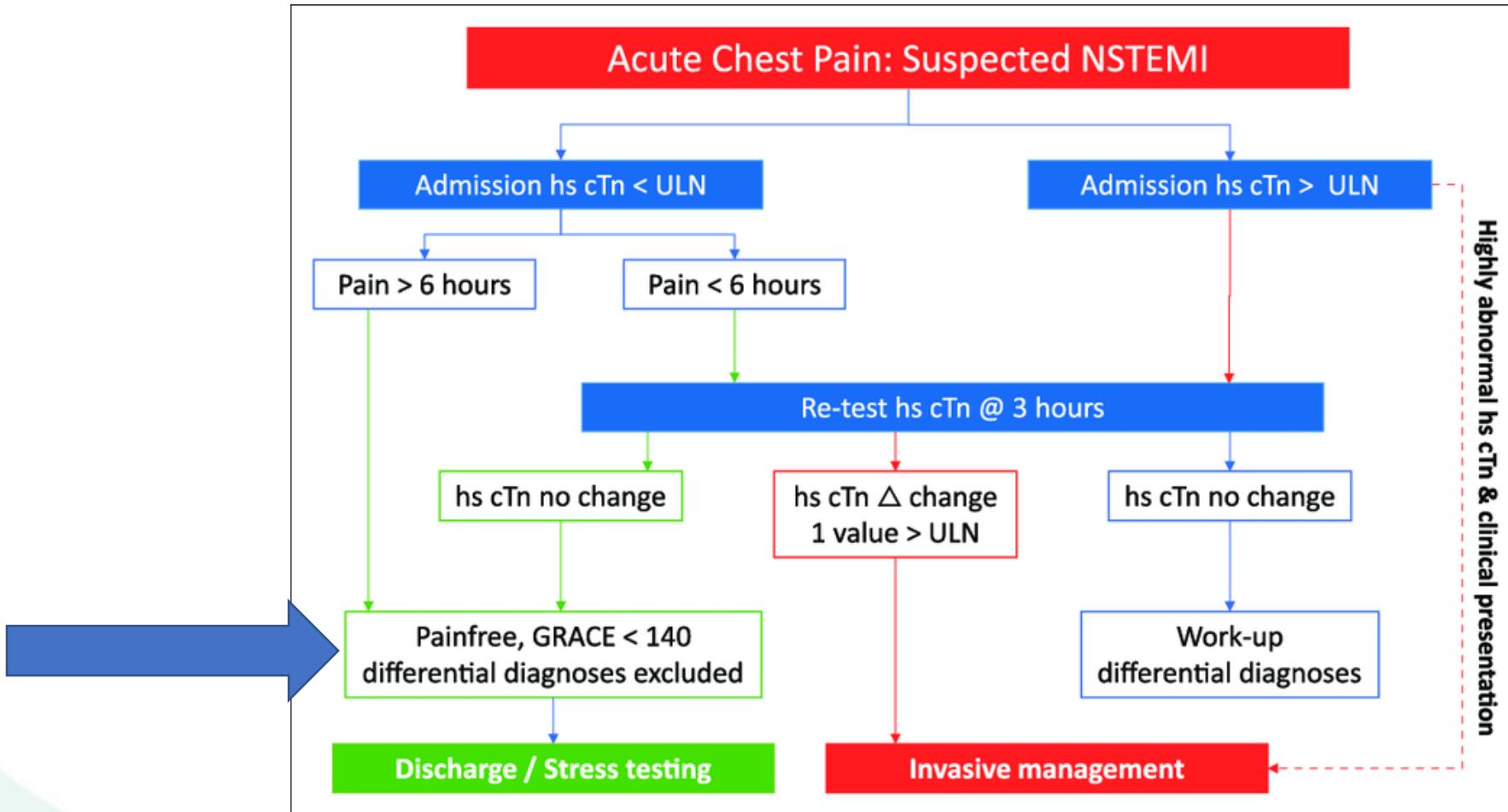


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- 0/1h et 0/2h s'appliquent à tous les patients même à ceux qui présentent une douleur thoracique <2h **MAIS** attention aux patients < 1 heure, **un dosage de troponine à 3h doit être considéré.**



ESC Guidelines 0-3h



RESUME



TABLE 2 Summary of hs-cTn Rapid Rule-Out and Rule-In Accelerated Diagnostic Panels

	0/3h	High STEACS	0/2h	0/1h
Rule-out criteria				
hs-cTnT	<14 ng/l at 0 and 3 h* and GRACE score <140	NA	<14 ng/l at 0 and 2 h and Δ <4 ng/l	<12 ng/l at 0 and 1 h Δ <3 ng/l
hs-cTnI†	<26 ng/l at 0 and 3 h* and GRACE score <140	<5 ng/l at 0 h or a 3-h value: <16 ng/l in women <34 ng/l in men and Δ <3 ng/l	<6 ng/l at 0 and 2 h and Δ <2 ng/l	<5 ng/l at 0 and 1 h Δ <2 ng/l
NPV for MI	98.3%-100%	99.5%	99.4%- 99.9%	98.9%-100%
Sensitivity for MI	98.9%-100%	97.7%	96.0%-99.6%	96.7%-100%
Proportion ruled out	39.8%-49.1%	74.2%	56.0%-77.8%	47.9%-64.2%
Rule-in criteria				
hs-cTnT	>14 ng/l at 0 or 3 h	N.A.	≥53 ng/l at 0 h or ≥10 ng/l Δ at 2 h	≥52 ng/l at 0 h or 1 h Δ ≥ 5 ng/l
hs-cTnI	>26 ng/l at 0 or 3 h	>16 ng/l in women >34 ng/l in men at 0 or 3 h	≥64 ng/l at 0 h or ≥15 ng/l Δ at 2 h	≥52 ng/l at 0 h or 1 h Δ ≥ 6 ng/l
PPV for MI	72.0%-83.5%	59.5%	75.8%-85.0%	63.4%-84.0%
Specificity for MI	96.7%-98.2%	87.6%	95.2%-99.0%	93.8%-97%
Proportion ruled-in	9.7%-38.2%	22.0%	7.7%-16.7%	13.1%-23.0%

*In patients with ≥6 h of pain, only a single value below this threshold is required. †Abbott ARCHITECT hs-cTnI.

0/1h = accelerated diagnostic protocol to rule out MI in patients presenting >3 h from symptoms using a single hs-cTn measurement at presentation, whereas for other patients, an absolute hs-cTn at presentation and 1-h delta are used to rule out or rule in MI or to place patients in an observational zone; 0/2h = accelerated diagnostic protocol that uses maximal levels and absolute delta hs-cTnI or T concentrations at 0 and 2 h to rule out or rule in MI or place patients in an observational zone; 0/3h = accelerated diagnostic protocol that incorporates hs-cTn at 0 and 3 h, hs-cTn change, and time since pain onset to determine which patients are appropriate for discharge or stress testing versus invasive management; GRACE = Global Registry of Acute Coronary Events; High STEACS = High-Sensitivity Troponin in the Evaluation of Patients With Acute Coronary Syndrome; hs-cTnI = high-sensitivity cardiac troponin I; hs-cTnT = high-sensitivity cardiac troponin T; MI = myocardial infarction; NA = not applicable; NPV = negative predictive value; PPV = positive predictive value.

CHU de Liège

- 5 Alinity CI-séries, Abbott
- Dosage Alinity i STAT High sensitive Troponin i (CMIA)
- **Differentes causes de variabilité :**
- Performance propre à l'automate (Répéta, Repro...)
- Réactif (Lot, expiration, durée à bord)
- Calibrations différentes
- Matrice
- ...



Variabilité totale observée

Variabilité totale observée

Variabilité biologique

Variabilité analytique

Composante intra-individuelle

Composante interindividuelle

Composante intra-série

Composante inter-série

RESULTAT BIOLOGIQUEMENT SIGNIFICATIF

$$RCV = \sqrt{2} \times z \times \sqrt{(CV_A^2 + CV_I^2)}$$



Analytical point of view

Interanalyzer Analytical Variation of a High-Sensitivity Cardiac Troponin T Assay Can Exceed the Cutoff of the European Society of Cardiology 1-Hour Algorithm for Ruling Out Non-ST-Segment Elevated Myocardial Infarction

To the Editor:

St.George Hospital, London :

- « A large clinical biochemistry diagnostic laboratory usually has multiple analyzers performing a hscTnT assay to meet service demand. Zero- and 1-h samples for hs-cTnT from the same patient are likely to be processed on different analyzers ».
- **The aim** of this study was to determine whether the interanalyzer analytical variation of the Roche hs-cTnT assay over an 8-h period is satisfactory for the adoption of the ESC 0- to 1-h algorithm.
- Intra- and interanalyzer precision was assessed on the Roche Cobas (**3 Cobas e602 and 2 Cobas e801**) modules and and the emergency department stat laboratory (**1 Cobas e411**) via a serum pool with a hs-cTnT concentration of approximately 6 ng/L at St George's Hospital.
- **Intra- and interanalyzer repeatability** (short-term precision) was assessed by analysis of the serum pool **25 times on each analytical cell** on each Cobas module within 1 h
- The **Cobas e411** module demonstrated the poorest intra-analyzer repeatability, with a CV of **9.6%** and a range of **3 ng/L** (n = 25)
- The **Cobas e602 and e801** modules demonstrated improved intraanalyzer repeatability, with CVs **< 5,7%** and ranges **< 2ng/L** (n=125)

- The interanalyzer analytical variation between separate **Cobas e601 and e802** modules is **satisfactory** for the implementation of the ESC 0- to 1-h NSTEMI ruleout algorithm.
- The independent **Cobas e411** module **should not be used** to provide the baseline or repeat hs-cTnT measurement for use in this algorithm.

Table 1. Interanalyzer analytical variation of the Roche high-sensitivity cardiac troponin assay over an 8-h period.

Hours (Cobas module)	Mean, ng/L	Range, ng/L	CV, %	SD	95% CI of SD
0 (e411)(n = 10)	5.46	4-6	11.5	0.63	0.43-1.14
2 (e601/e802)(n = 5)	6.34	6-7	5.4	0.34	0.21-0.99
4 (e601/e802)(n = 5)	6.42	6-7	6.6	0.42	0.25-1.22
6 (e601/e802)(n = 5)	6.03	6-6	4.6	0.28	0.17-0.80
8 (e601/e802)(n = 5)	6.43	6-7	3.4	0.22	0.13-0.62
Mean (n = 30)	6.02	4-7	10.0	0.60	0.48-0.81
Mean excluding 0-h baseline (n = 20)	6.30	6-7	5.4	0.34	0.26-0.50



How Does the Analytical Quality of the High-Sensitivity Cardiac Troponin T Assay Affect the ESC Rule Out Algorithm for NSTEMI?

To the Editor:

Haukeland University Hospital :

$$CV_A = \sqrt{\frac{RCV^2}{2z^2} - CV_I^2}$$

- 10 pool (5 et 12ng/L) dosés 10 x / h et sur 3 jours.
- Cobas E801 (routine/backup)

[Hs-TnT]	RCV théorique (%)	Cv _a théorique (%)	Cv _a intra-analyseur (%)	Cv _a inter-analyseur (%)
5	40	17,1	5,2	9,6 (6,3-12,8)
12	17	7,1	1,5	4,6 (3,4-5,5)



How Does the Analytical Quality of the High-Sensitivity Cardiac Troponin T Assay Affect the ESC Rule Out Algorithm for NSTEMI?

To the Editor:

- Dosage 1 x chaque aliquot de chaque pool à chaque changement de lot et comparer à la moyenne totale.
- Novembre 2013 à Mars 2018.

The difference between results from the same pool ranged from approximately 3.5 ng/L at 6 ng/L falling to 3 ng/L at higher concentrations

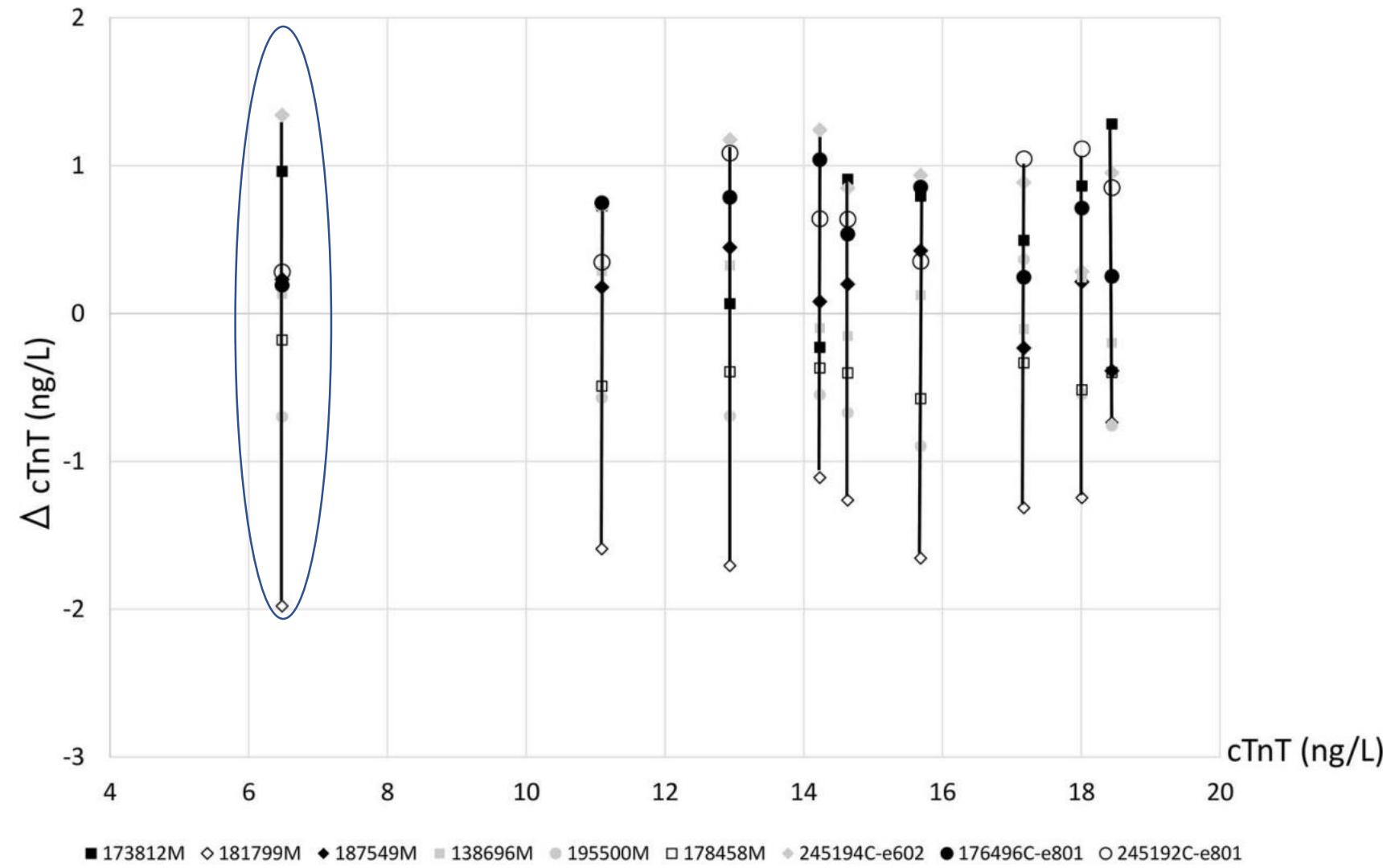
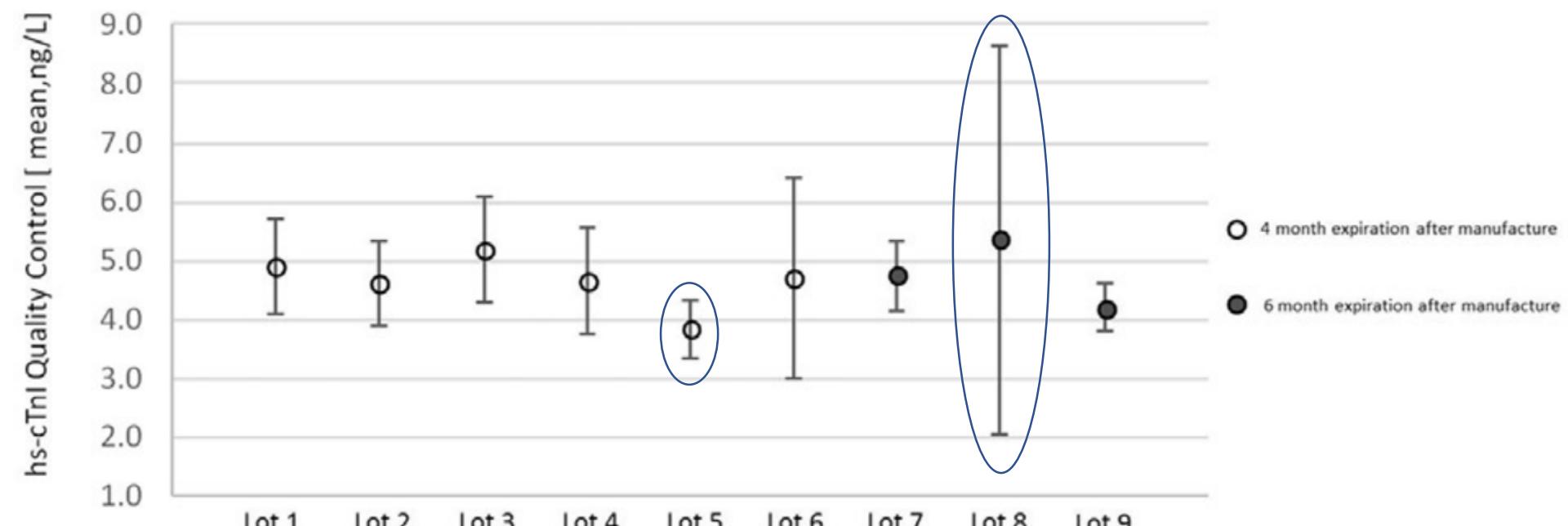


Fig. 1. Difference between lots when measured in fresh frozen serum.

All lots are measured in 9 serum pools with increasing concentrations from 5–19 ng/L: x-axis, mean of all results; y-axis, difference between a lot and the mean value. The Modular E170 are denoted M and the Cobas instruments are denoted C-e602 and C-e801, respectively.

Variability Between Reagent Lots for High-Sensitivity Cardiac Troponin I May Affect Performance of Early Rule Out Strategies
To the Editor:
A
100-test pack reagent lots and normal concentration QC material


LOT 5	LOT 8
QC mean : 3.8 ng/L	QC mean : 5.4 ng/L
SD: 0.5 ng/L	SD : 3.3 ng/L

Feb/16/2016 To May/5/2016 To Jul/4/2016 To Aug/27/2016 To Oct/12/2016 To Jan/8/2017 To Feb/23/2017 To Jun/25/2017 To Sep/6/2017 To Sep/12/2017

Different Reagent Lots over 574 days

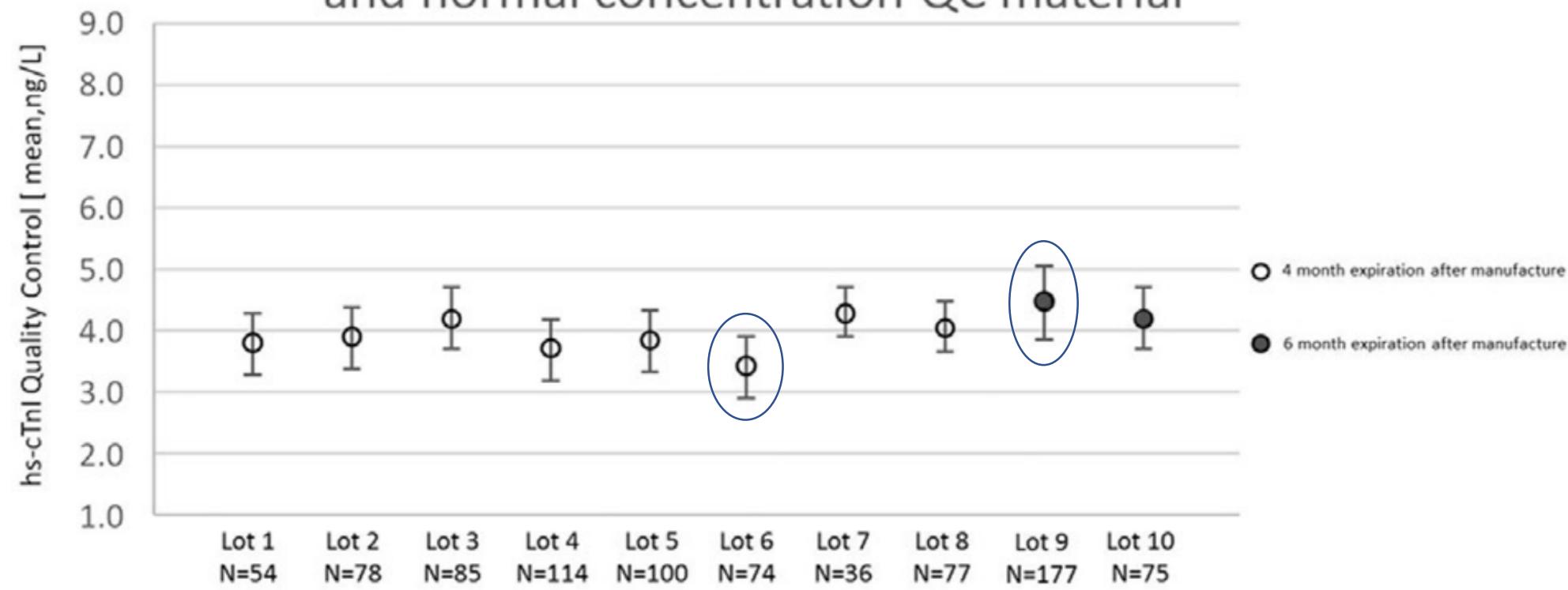
Letters to the Editor

Variability Between Reagent Lots for High-Sensitivity Cardiac Troponin I May Affect Performance of Early Rule Out Strategies

To the Editor:

B

500-test pack reagent lots
and normal concentration QC material



LOT 6	LOT 9
QC mean : 3.4 ng/L	QC mean : 4.5 ng/L
SD: 0.5 ng/L	SD : 0,6 ng/L

Different Reagent Lots over 573 days

$$RCV = \sqrt{2} \times z \times \sqrt{({CV_A}^2 + {CV_I}^2)}$$

$$RCV = \Delta 2, Z = 1,96 \text{ et } CVI = 1.2$$

Using the European Society of Cardiology 1-h algorithm for ruling out non-ST- segment elevated myocardial infarction to define acceptable analytical performance limits for a cardiac troponin T assay

Table I. QC limits as defined using the ESC 1-hour algorithm for ruling out non-ST-segment elevated myocardial infarction.

Baseline cTnT (ng/L)	RCV to detect $\Delta = 2 \text{ ng/L } (\%)$	CV _A (%)	SD _A (ng/L)	IQC low (ng/L)	IQC high (ng/L)
12	17	5.9	0.71	10.59	13.41
11	18	6.4	0.71	9.58	12.42
10	20	7.1	0.71	8.58	11.42
9	22	7.9	0.71	7.57	10.43
8	25	8.9	0.72	6.57	9.43
7	29	10.2	0.72	5.57	8.43
6	33	12.0	0.72	4.56	7.44
5	40	14.4	0.72	3.56	6.44

Revisiting the Biological Variability of Cardiac Troponin: Implications for Clinical Practice

 *Nick SR Lan,^{1,2} Damon A Bell^{2,3,4,5}
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Author	Assay	Time frame	n	CV _A	CV _I	RCV	Log-normal RCV	CV _G	II
hs-cTnI									
Wu et al. ¹¹	Singulex	4 hours	12	8.3	9.7	-	+46/-32	57	0.21
		8 weeks	17	15	14	-	+81/-45	63	0.39
Apple et al. ⁶⁷	Abbott Architect	Short*	*	13.8	15.2	50.1	+69.3/-40.9	70.5	0.22
	Beckman Coulter	Short*	*	14.5	6.1	44.5	+63.8/-38.9	34.8	0.46
	Siemens Dimension	Short*	*	13.0	12.9	47	+57.5/-36.5	12.3	0.11
Goldberg et al. ⁶⁸	Abbott Architect	Short*	*	16.9	37.1	113	-	179.2	0.23
		Long*	*	16.9	117	328	-	179.2	0.66
Vasile et al. ⁶⁹	Beckman Coulter	4 hours	20	3.5	3.4	-	+45.2/-15.8	45.3	0.1
		8 weeks	20	2.7	2.6	-	+14/-10.6	41.6	0.1
Wu et al. ⁷⁰	Singulex	9 months	17	15	28	-	+98/-49	71	0.45
Aakre et al. ⁷¹	Abbott Architect	6 hours	17	17.3	5.0	-	+64/-39	37.7	0.48
		10 weeks	15	13.8	15.6	-	+77/-44	25.9	0.80
Schindler et al. ⁷²	Abbott Architect	3 weeks	20	4.8	14.5	37	+53/-34	44.0	0.3
		3 months	20	4.8	14.7	36	+53/-35	56.7	0.3
van der Linden et al. ⁷³	Abbott Architect	24 hours	18	10.0	8.6	36.7	+44.0/-30.6	49.4	0.27
Koerbin et al. ^{32†}	Abbott Architect	4 years	453	*	33	-	+147/-59	106	0.36

Cv_a maximal

RCV = z value x

$$\sqrt{2} \times (\sqrt{CV_A^2 + CV_I^2})$$



$$CV_A = \sqrt{\frac{RCV^2}{2z^2} - CV_I^2}$$

Ex RULE OUT : Shift 5 => 7 => 40% of difference $\Leftrightarrow RCV = 40\%$

Cv_a maximal

$$CV_A = \sqrt{\frac{RCV^2}{2z^2} - CV_I^2}$$

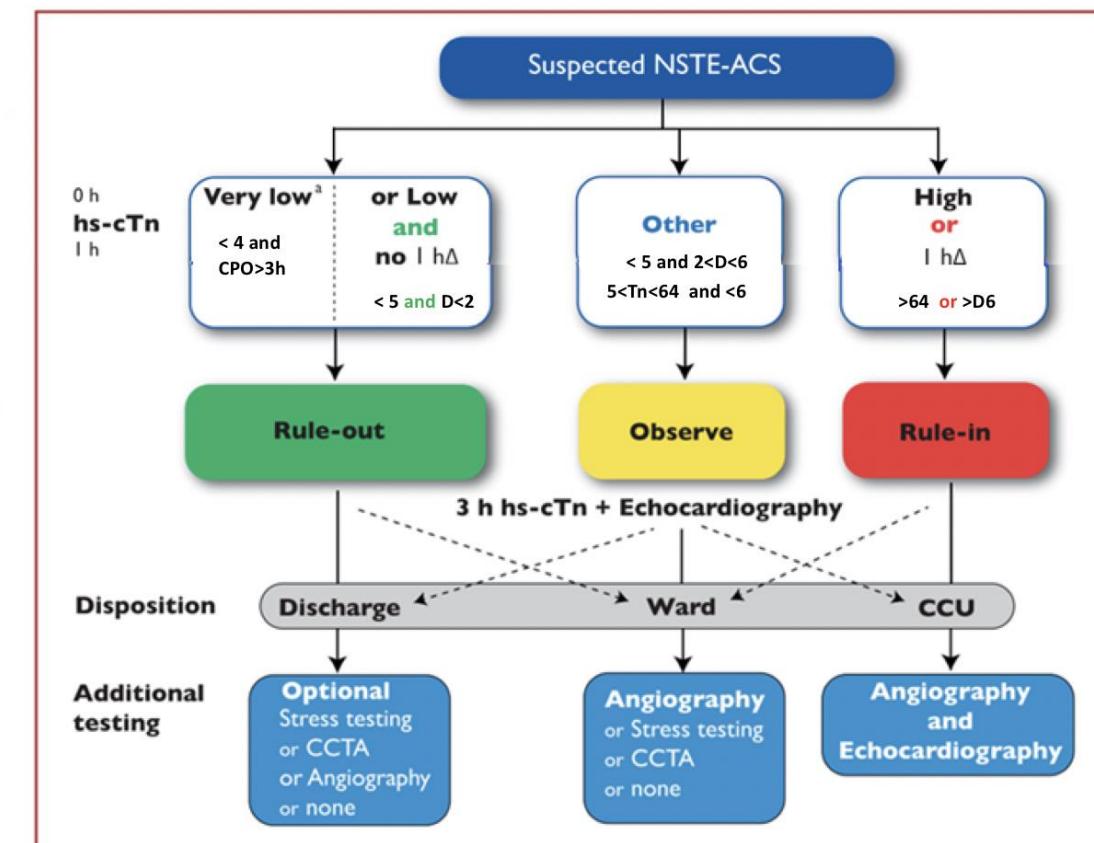
- Cv_i : 3,4%
- Z value = 1,96 (99% CI)

Ex :

$$1) \ 5 \Rightarrow 7 : \sqrt{\left(\frac{40^2}{2 \times 1,962}\right) - 3,4^2} = 14\%$$

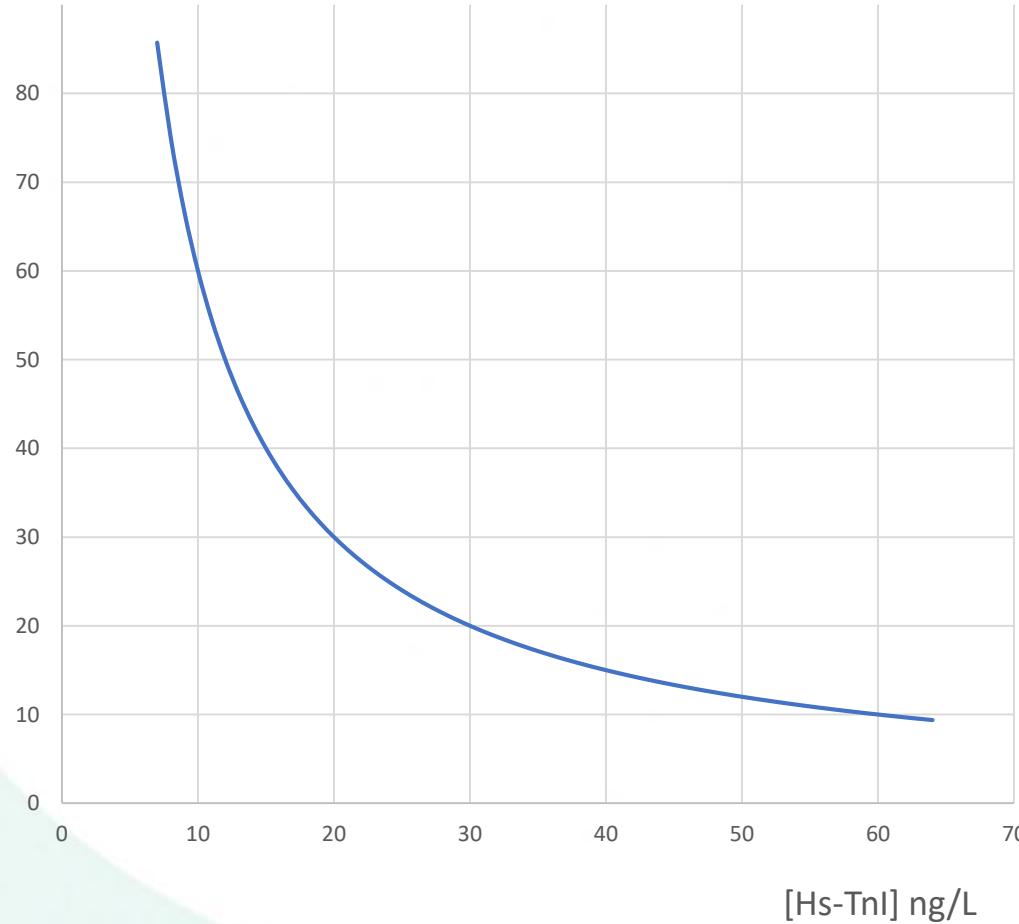
$$2) \ 6 \Rightarrow 12. : \sqrt{\left(\frac{100^2}{2 \times 1,962}\right) - 3,4^2} = 35\%$$

$$3) \ 63 \Rightarrow 69 : \sqrt{\left(\frac{9,5^2}{2 \times 1,962}\right) - 3,4^2} = 0,4\%$$

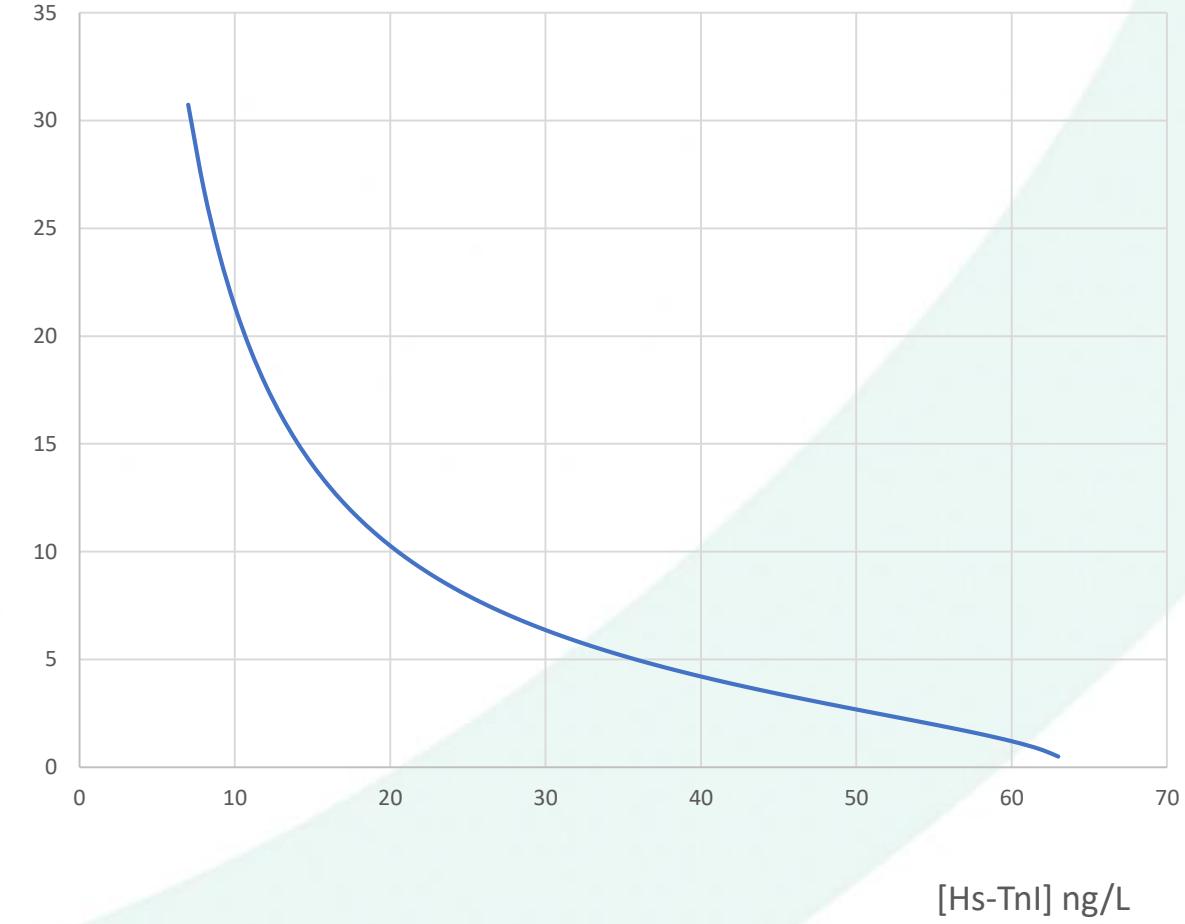


C_v_a maximal

RCV (%)



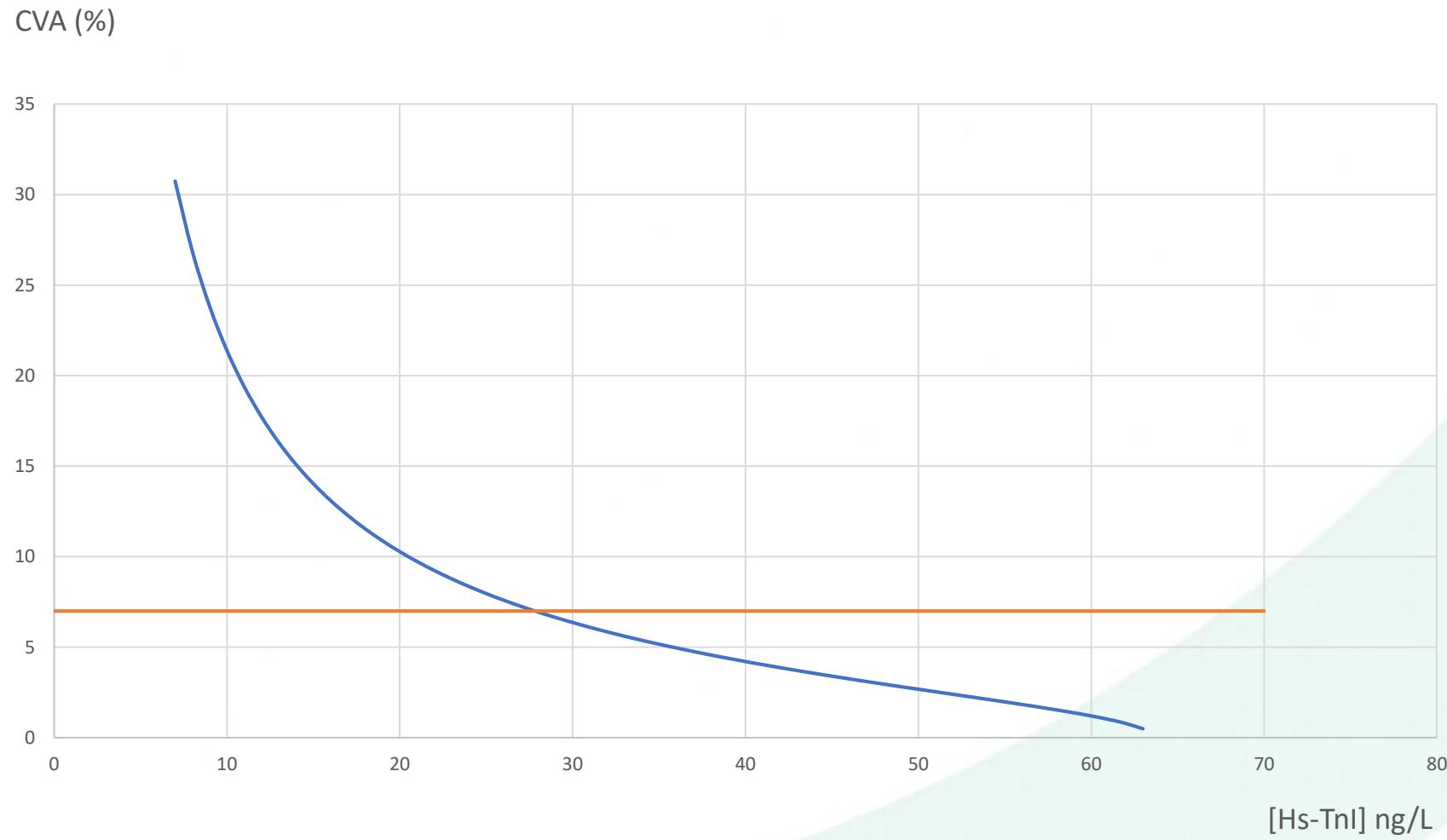
C_v_a (%)



CV CHU de Liège

		Alinity 1 (Ai02606)	Alinity 2 (Ai01149)	Alinity 3 (Ai02640)	Alinity 4 (Ai03288)	Alinity 5 (Ai01128)
Reproductibilité (CHU)	QC1 (20,97)	7,06	7	7,16	8,17	7,2
	QC3 (1608,42)	7,83	7,39	6,05	7,21	6,05

Evolution du Cv_a en fonction de la concentration en Tnl



ΔTNI en fonction de la performance du laboratoire

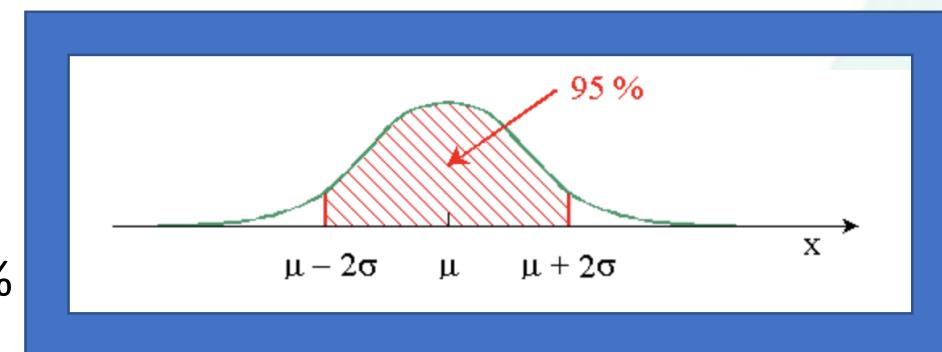
Considérons $[Hs-TnI]$ avec un CV_a ou $Cv_{interanalyseur}$ calculé au laboratoire.

Soit on surestime soit on sous-estime par le $CV_a/CV_{internalyseur}$

Donc à partir d'une $[Hs-TnI]$:

$$Cv_{inter} = \frac{\sigma}{\mu} \times 100$$

l'intervalle à 95%



$$[Hs-TnI]_{max} : [Hs-TnI] + 2 \times \frac{[Hs-TnI] \times Cv_{inter}}{100}$$

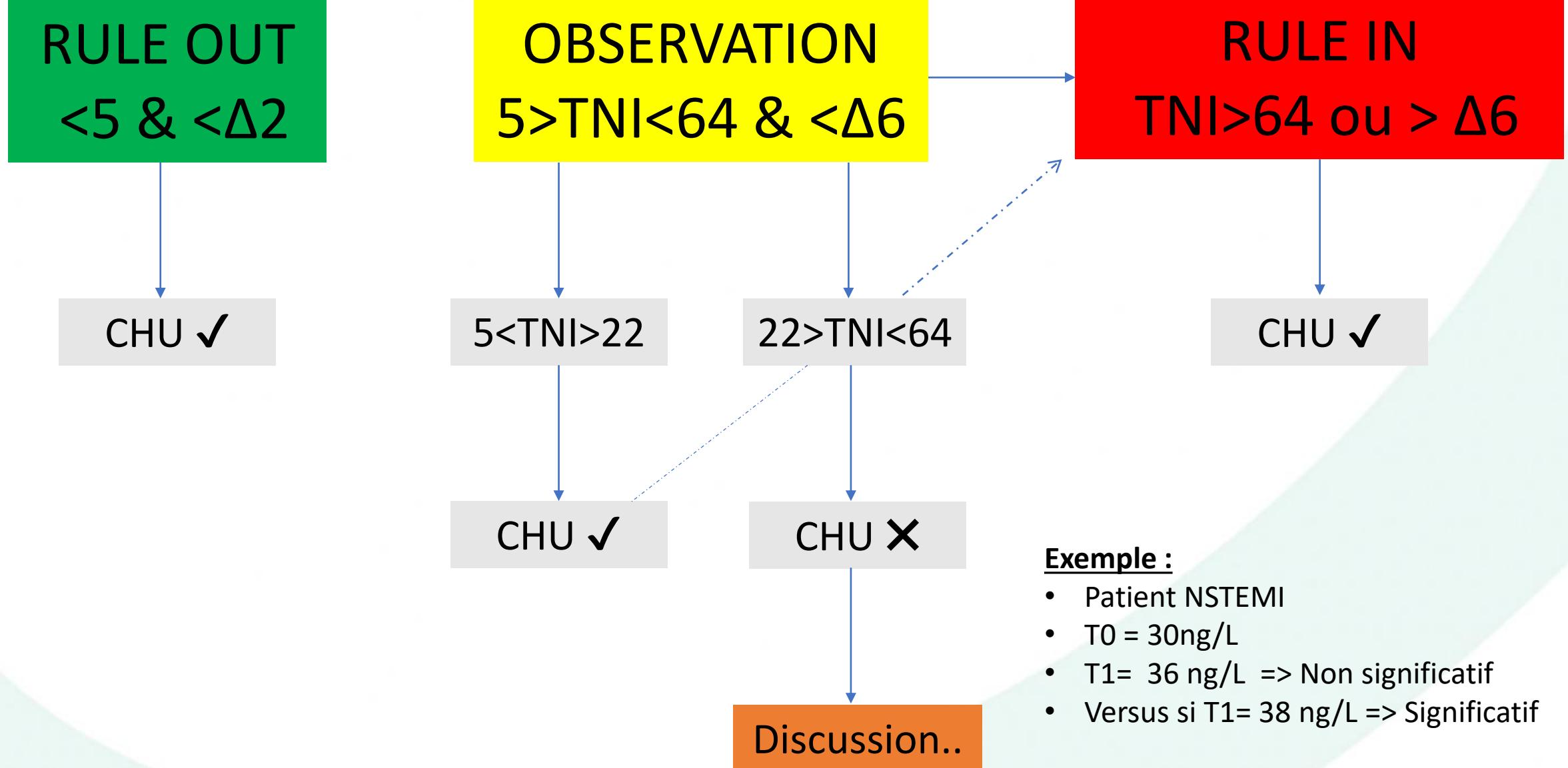
$$\& [Hs-TnI]_{min} : [Hs-TnI] - 2 \times \frac{[Hs-TnI] \times Cv_{inter}}{100}$$

Après soustraction de $[Hs-TnI]_{max}$ et de $[Hs-TnI]_{min}$ nous obtenons le $\Delta_{analytique}$ via la formule :

$$\Delta_{analytique} = 4 \times \frac{[Hs-TnI] \times Cv_{inter}}{100}$$

$$\Delta_{\text{analytique}} = 4 \times \frac{[\text{Hs-TnI}] \times Cvinter}{100}$$

[TnI] ng/L	[TnI] _{min}	[TnI] _{max}	Δ [TnI]
3,0	3,4	2,6	0,8
4,0	4,6	3,4	1,1
5,0	5,7	4,3	1,4
6,0	6,8	5,2	1,7
7,0	8,0	6,0	2,0
8,0	9,1	6,9	2,2
9,0	10,3	7,7	2,5
10,0	11,4	8,6	2,8
11,0	12,5	9,5	3,1
12,0	13,7	10,3	3,4
13,0	14,8	11,2	3,6
14,0	16,0	12,0	3,9
15,0	17,1	12,9	4,2
16,0	18,2	13,8	4,5
17,0	19,4	14,6	4,8
18,0	20,5	15,5	5,0
19,0	21,7	16,3	5,3
20,0	22,8	17,2	5,6
21,0	23,9	18,1	5,9
22,0	25,1	18,9	6,2
...
30,0	26,0	34,0	8,0
...
62,0	70,7	53,3	17,4
63,0	71,8	54,2	17,6
64,0	73,0	55,0	17,9



Exemple :

- Patient NSTEMI
- $T_0 = 30 \text{ ng/L}$
- $T_1 = 36 \text{ ng/L} \Rightarrow \text{Non significatif}$
- Versus si $T_1 = 38 \text{ ng/L} \Rightarrow \text{Significatif}$

LIMITES ET PERPECTIVES

- **Limites :**
 - Moyen de détermination du CVa (répétabilité, reproductibilité, valeurs QCI)
 - Choix/Détermination CVi pour le calcul (pathologies chroniques..)
 - Calcul théorique sur base d'une formule
- **Perspectives:**
 - QC a des valeurs basses
 - Lots de QC
 - Quid du CVa inter-tubes (Hépariné versus Sec)
 - Adaptation de l'algorithme en fonction du CVa du laboratoire ?

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