Point of Care in Critical Biochemistry

18/11/2025

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AZORG

sciensano

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

Definition of POCT

ISO 15189:2022

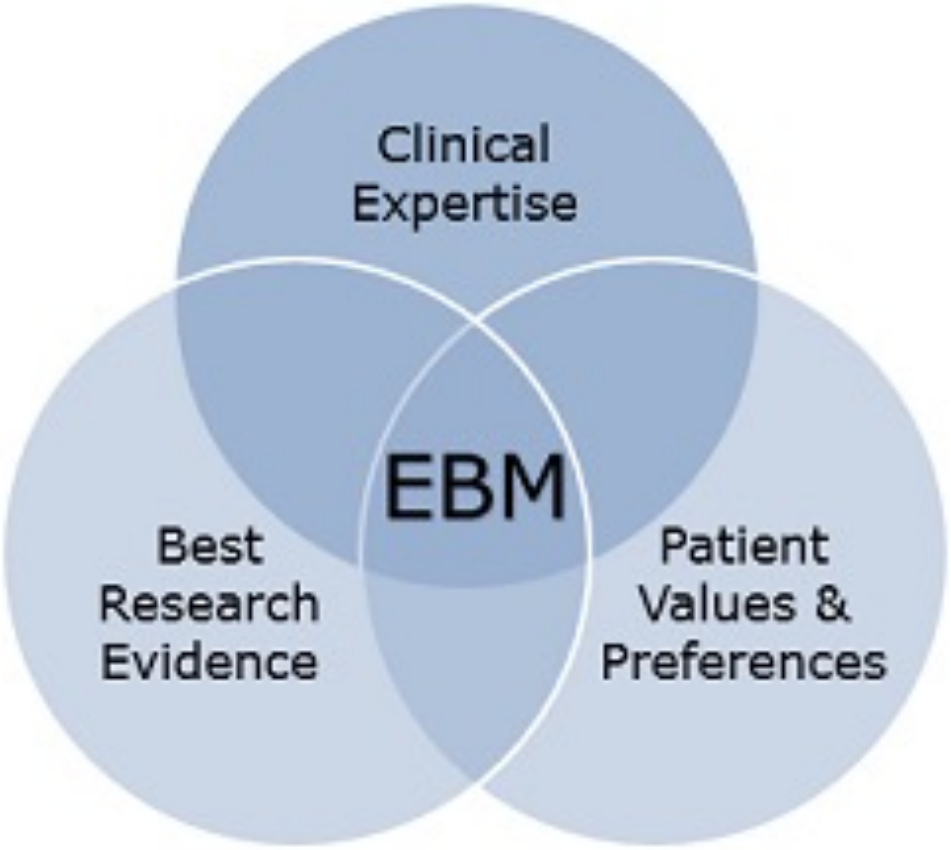
"Diagnostic testing that is performed **near to or at the site** of the patient care with the result leading to possible **change in the care** of the patient"

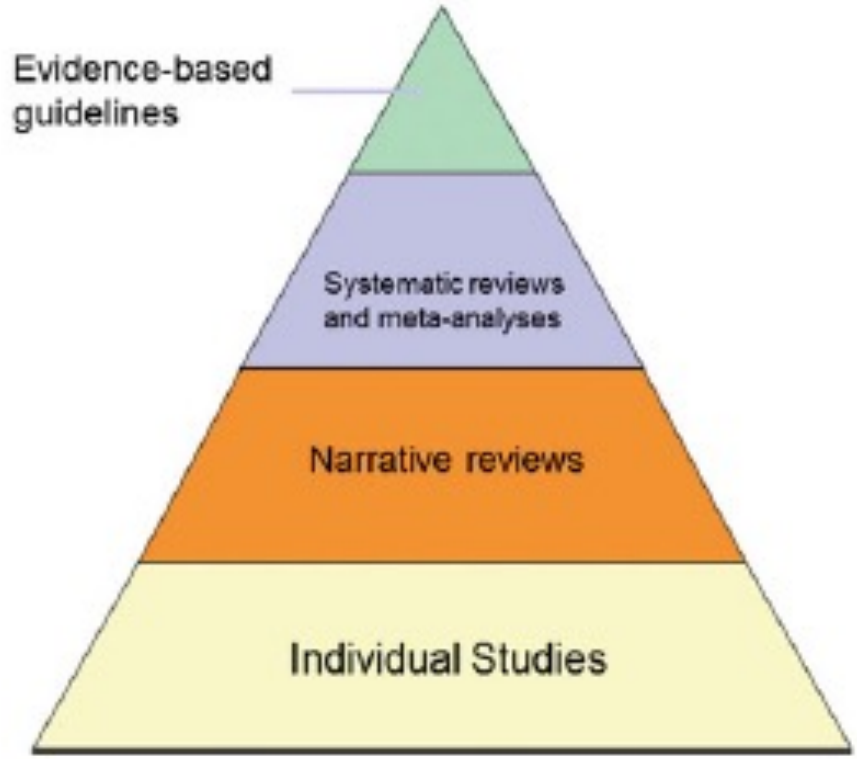
- ✓ **Proven effectivity** on direct medical acting
- ✓ **Analytical reliability** of the POCT as compared to the central lab test
- ✓ **User friendly** without increasing workload

ISO 15189:2022
https://ifcc.org/ifcc-education-division/emd-committees/c-poct/

Proven effectivity

Evidence based introduction of POCT





Florkwoski et al. Crit Rev Clin Lab Sci 2017; 54: 471-494

Analytical reliability

POCT compared to the central lab test

POCT management in cooperation with laboratory specialists

- **Evaluation** of POCT equipment

  invidiual versus collective evaluation
  CLSI protocols

SKUP
Scandinavian evaluation of laboratory equipment for point of care testing
Skandinavisk afprøvning af laboratorieudstyr til patientnære analyser
Skandinavisk utprøving av laboratorieutstyr for pasientnær analysering
Skandinavisk utprövning av laboratorieutrustning för patientnära analyser

https://skup.org

EPI-Centre
Evaluating Primary care Innovations

https://www.epi-centre.be

NIHR Diagnostic Evidence Cooperative Oxford

EDCA
EUROPEAN DIAGNOSTIC CLUSTERS ALLIANCE

https://www.oxford.dec.nihr.ac.uk/

Analytical reliability

POCT compared to the central lab test

POCT management in cooperation with laboratory specialists

Belgian legislation

- POCT in hospital: PRL 2025
- POCT outside the hospital: urgent need for legal framework

- **Evaluation** of POCT equipment
  - invidiual versus collective evaluation
  - CLSI protocols
- Internal and external **quality control** for POCT
  - continuous quality assurance
  - centralization of supply, technical support and supervision (middleware)
  - lotvalidation and lotcontrolled distribution within institution
  - training and education of users
  - result reporting
- **Regulations** and guidelines for POCT
  - Belgian legislation of POCT (PRL 2025)
  - International guidelines of POCT (IFCC, EFLM, NHG)
  - Analytical/clinical performance criteria
  - FDA, CLIA requirements
  - IVDR 2017/746/EC
  - Accrediation: JCI (ISPG 2, AOP 5.1, 5.2, 5.5)
    ISO 15189:2022

Van Hoof et al. CCA 2022; 77: 329-336

Definition of POCT

ISO 15189:2022

"Diagnostic testing that is performed **near to or at the site** of the patient care with the result leading to possible **change in the care** of the patient"

1. Glucose
2. CRP
3. Troponine
4. Creatinine

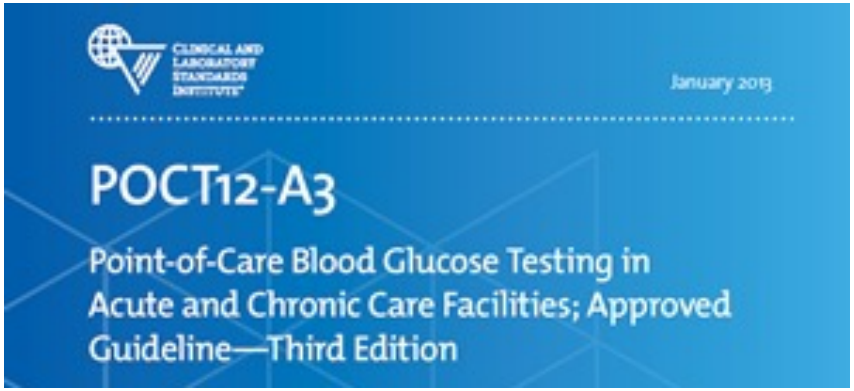
ISO 15189:2022
https://ifcc.org/ifcc-education-division/emd-committees/c-poct/

Point of Care Glucose

POCT glucose: guidelines

Intensive glycemic control leads to reduced longterm complications of diabetes for Type 1 and Type 2 DM

Nathan et al. NEJM 1993; 329: 977-986
UKPDS Group. Lancet 1998; 352: 837-853



The **management of therapy** to regulate blood glucose concentrations in patients with diabetes

The rapid detection of **extreme glucose concentrations** in patients with symptoms suggesting hypo- or hyperglycemia or in patients who are unconscious without an identified cause (e.g. emergency department)

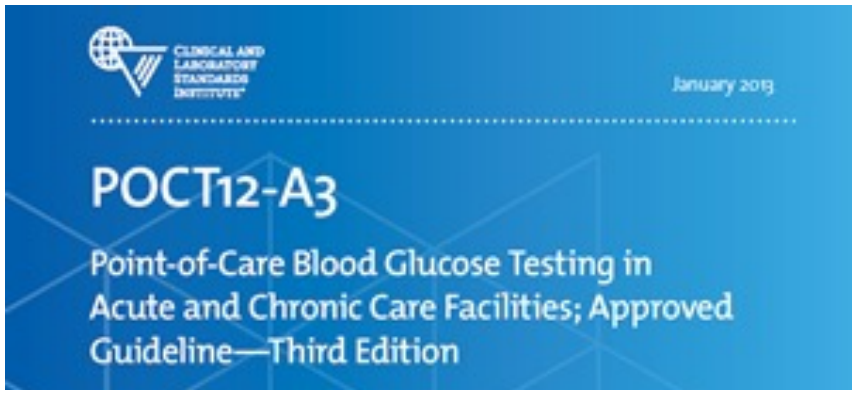
Intra- and perioperative management of blood glucose concentrations in surgical patients

The monitoring of mothers with diabetes (postpartum), as well as their infants

The monitoring of patients who receive parenteral hyperalimentation or medication likely to affect their blood glucose concentration

CLSI POCT12-A3: 2013
ADA. Diabetes Care 2025; 48: S27-S49

POCT glucose: guidelines



NO DIAGNOSIS OF DIABETES MELLITUS

The **management of therapy** to regulate blood glucose concentrations in patients with diabetes

The rapid detection of **extreme glucose concentrations** in patients with symptoms suggesting hypo- or hyperglycemia or in patients who are unconscious without an identified cause (e.g. emergency department)

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CLSI POCT12-A3: 2013
ADA. Diabetes Care 2025; 48: S27-S49

POCT glucose: guidelines

Blood Glucose Monitoring

- **Type 1 DM**: BGM is a critical part of disease management

Florkwoski et al. Crit Rev Clin Lab Sci 2017; 54: 471-494

- **Type 2 DM** (not using insulin): BGM significanly reduces HbA1c
  doubtful clinical significance

Farmer et al. BMJ 2012; 344: e486
Malanda et al. Cochrane Database Syst Rev 2012; 1: CD005060

- **ICU:** relationship between mortality and glucose

Florkwoski et al. Crit Rev Clin Lab Sci 2017; 54: 471-494

van der Berghe et al.: TGC to 80-110 mg/dL decreased mortality from 8% to 4.6%

Mesotten et al. Best Pract Res Clin Anaesthesiol 2009; 23: 421-429

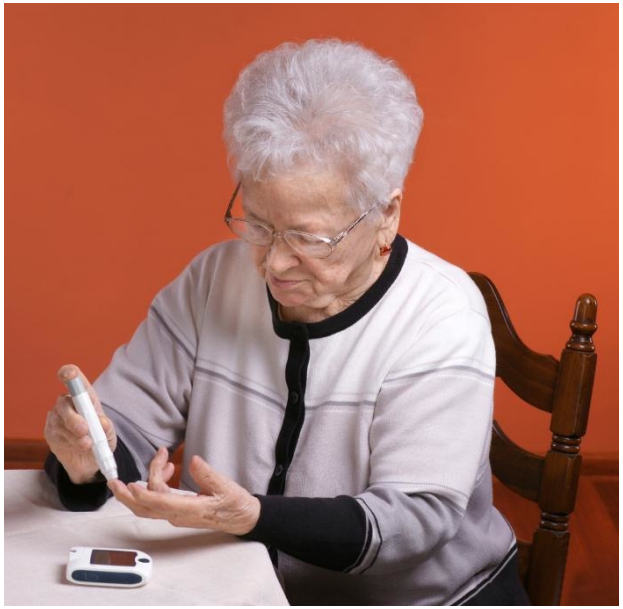
under discussion because of the risk of hypoglycemia

Preiser et al. Intensive Care Med 2009; 35: 1738-1748
Finfer et al. NEJM 2009; 360: 1283-1297
Finfer et al. NEJM 2012; 367: 1108-1118

TGC with conventional target: 180 mg/dL or lower

POCT glucose: analytical reliability

Applications: settings



Home testing

Care facility

Critical care

Quality requirements

IFCC. CCLM 2013: 51: 943-952

POCT glucose: analytical reliability

Quality requirements

Glucose	ISO 15197 2003	ISO 15197 2013	CLSI POCT12-A3 2013	FDA 2014 (draft)	CRITICAL CARE 2013	RICOS 1999
Cutoff (mg/dL)	75	100	100	70	100	90
Criterion **< cutoff** **> cutoff**	 ± 15 mg/dL ± 20%	 ± 15 mg/dL ± 15%	 ± 12,5 mg/dL ± 12,5%	 ±7 mg/dL ±10%	 ± 10 mg/dL ±12,5%	10,4%
Coverage (%)	95	95 max. 1% > 20%	95 max. 2% > 20%	99 1% max. ± 15%	98 2% max. ± 20%	95

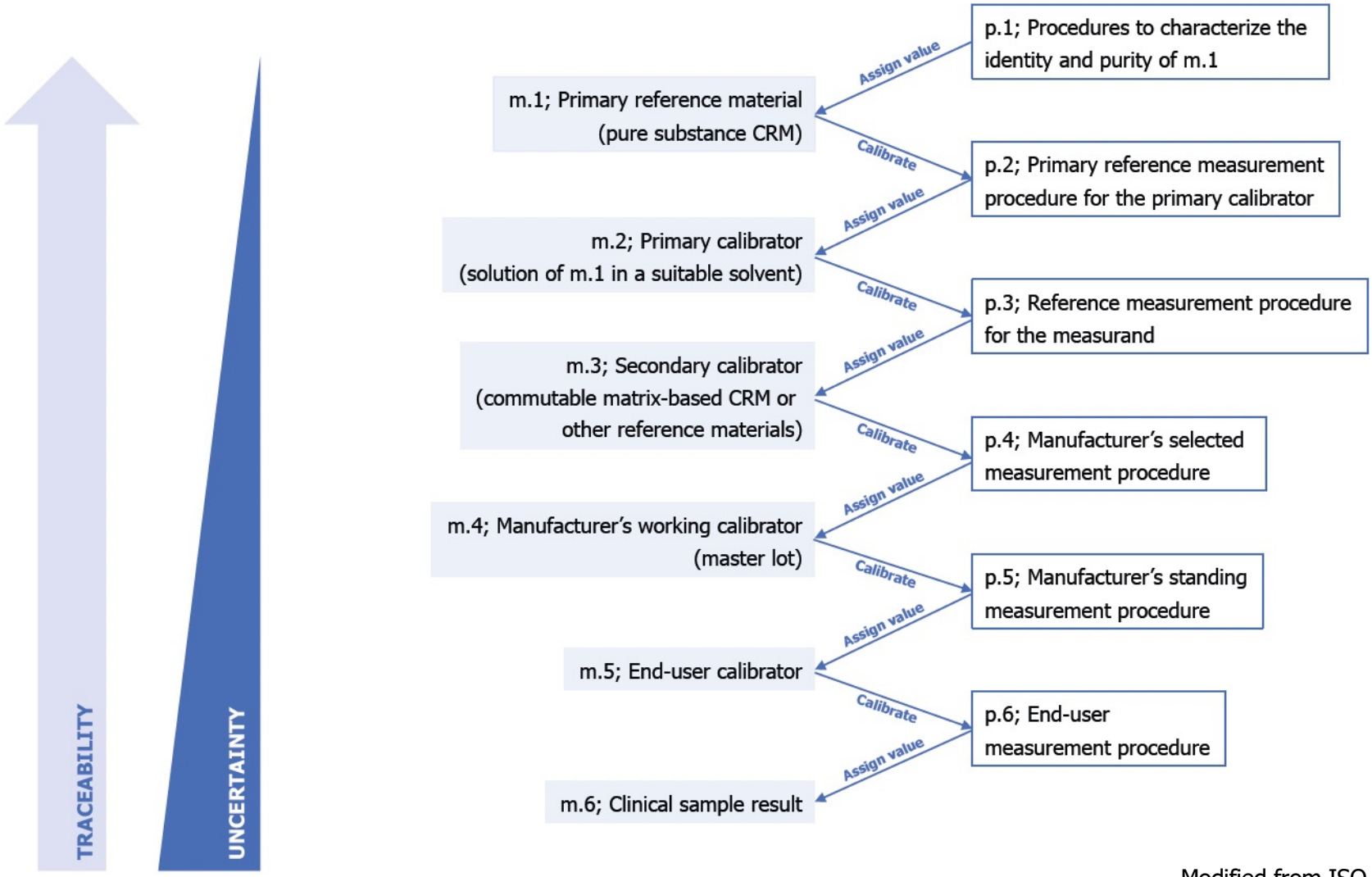
The laboratory method used for the comparison:
- imprecision ≤2.9%
- bias ≤2.2%
- total error ≤6.9%
- be traceable to a ID-GC/MS reference method

Quality requirements

IFCC Working Group GMECC: How Should Glucose Meters Be Evaluated For Critical Care; 10/12/2017
CLSI POCT12-A3: 2013

POCT glucose: analytical reliability

Metrological traceability

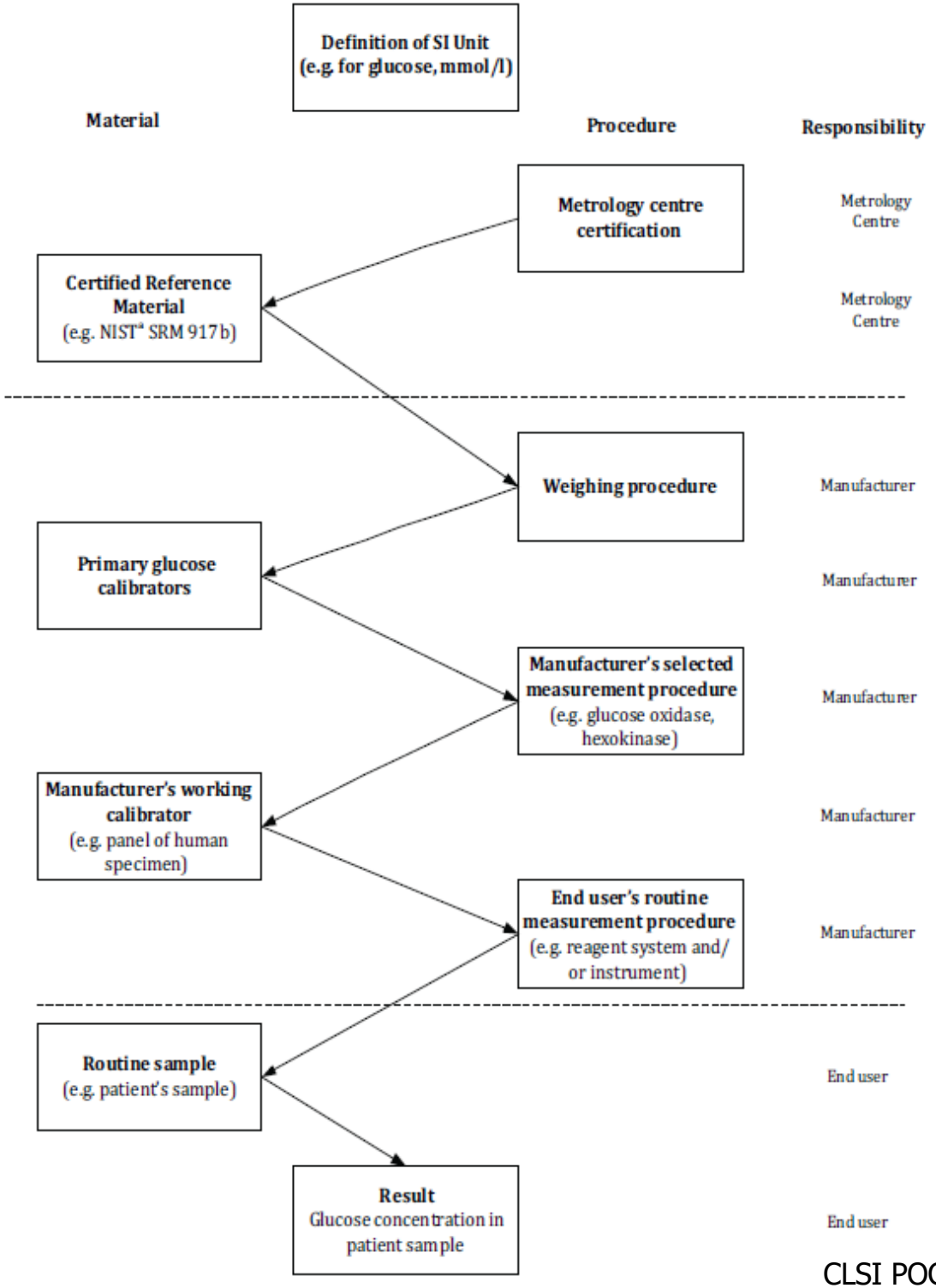


Modified from ISO 17511:2020

ID-GC/MS

Routine central lab glucose analysis (Hexokinase)

POCT glucose analysis

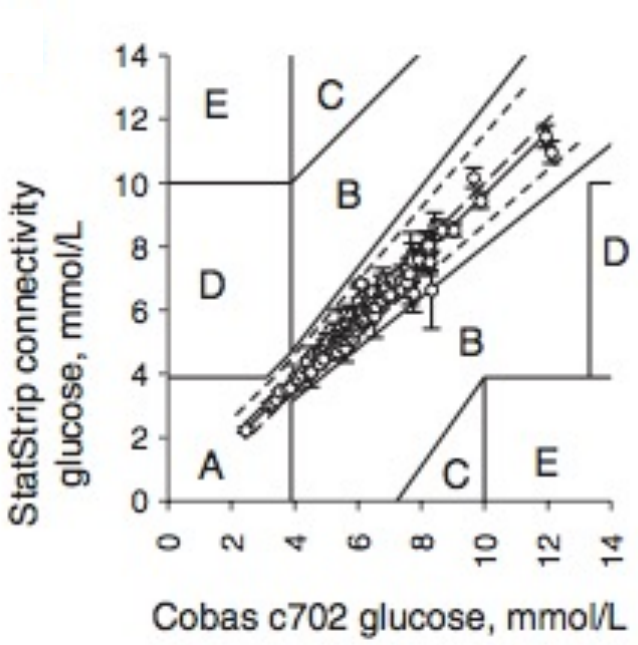


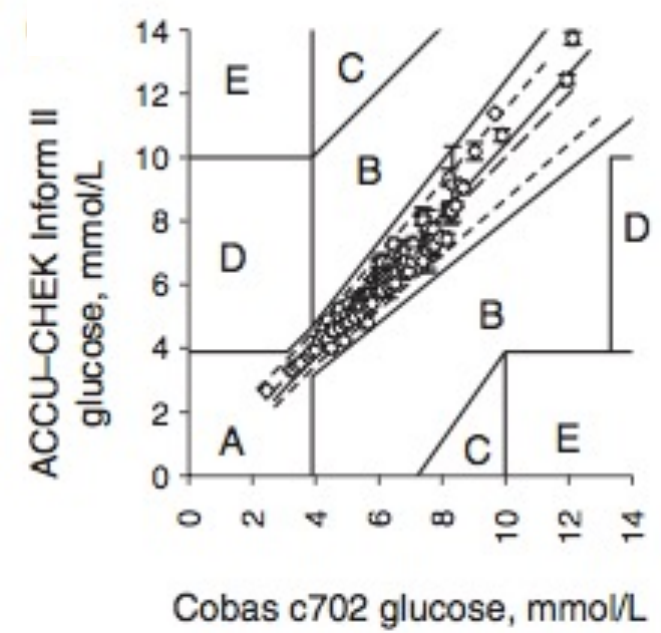
IFCC. CCLM 2013: 51: 943-952

CLSI POCT12-A3: 2013

POCT glucose: analytical reliability

Consensus error grid



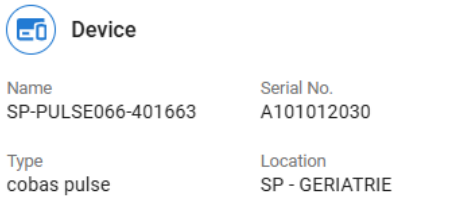


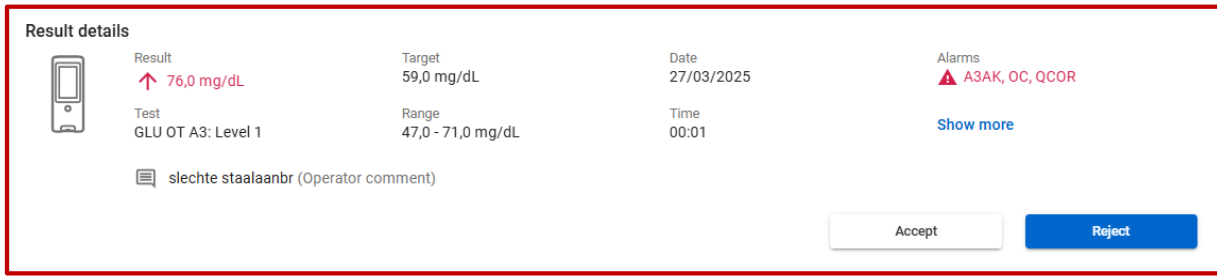
Risk level (CEG zone)	Risk to diabetic patient
A	No effect on clinical action.
B	Altered clinical action — little or no effect on clinical outcome.
C	Altered clinical action — likely to affect clinical outcome.
D	Altered clinical action — could have significant medical risk.
E	Altered clinical action — could have dangerous consequences.

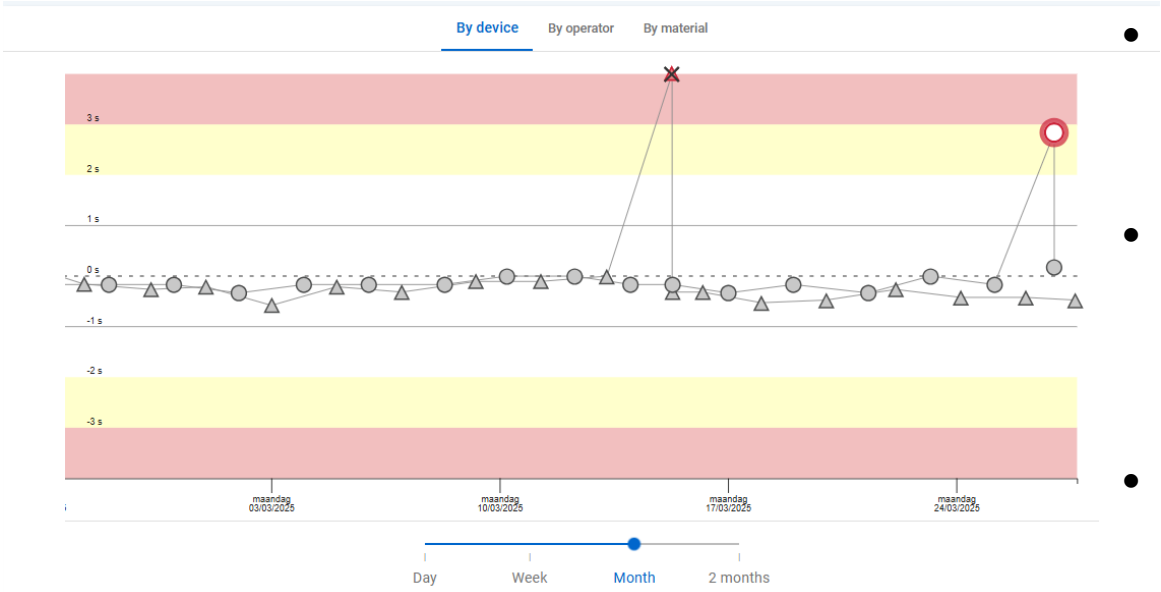
Claerhout H *et al.* CCLM 2016; 54: 169-80
https://skup.org

POCT glucose: analytical reliability

Continuous QA: iQC







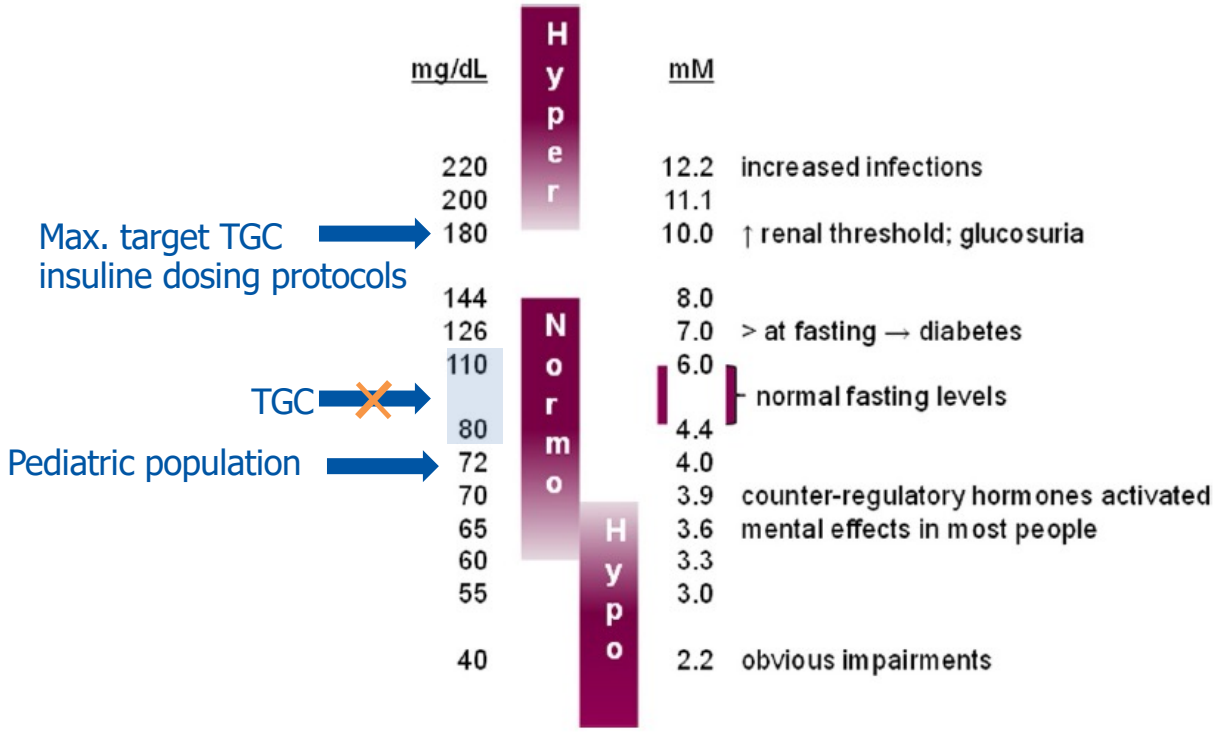
- **Before use**
  - Meter blocked if not performed
  - Meter blocked if '1-3s'
- **Alternating low/high iQC range**
  - Manufacturer iQC (target 59 and 318 mg/dL)
  - CV% < 5%
  - **Daily** supervision by central lab (middleware)
- **Other reasons to perform iQC :**
  - Opening new bottle of strips
  - When unexpected results are obtained
  - After meter problems

Gidske *et al*. Clin Chem Lab Med 2022; 60: 740-747
Stavelin *et al*. Crit Rev Clin Lab Sci 2024; 61: 164-177

POCT glucose: analytical reliability

Imprecision

Goal: imprecision < 10%
ideally < 5%



IFCC Working Group GMECC: How Should Glucose Meters Be Evaluated For Critical Care; 10/12/2017

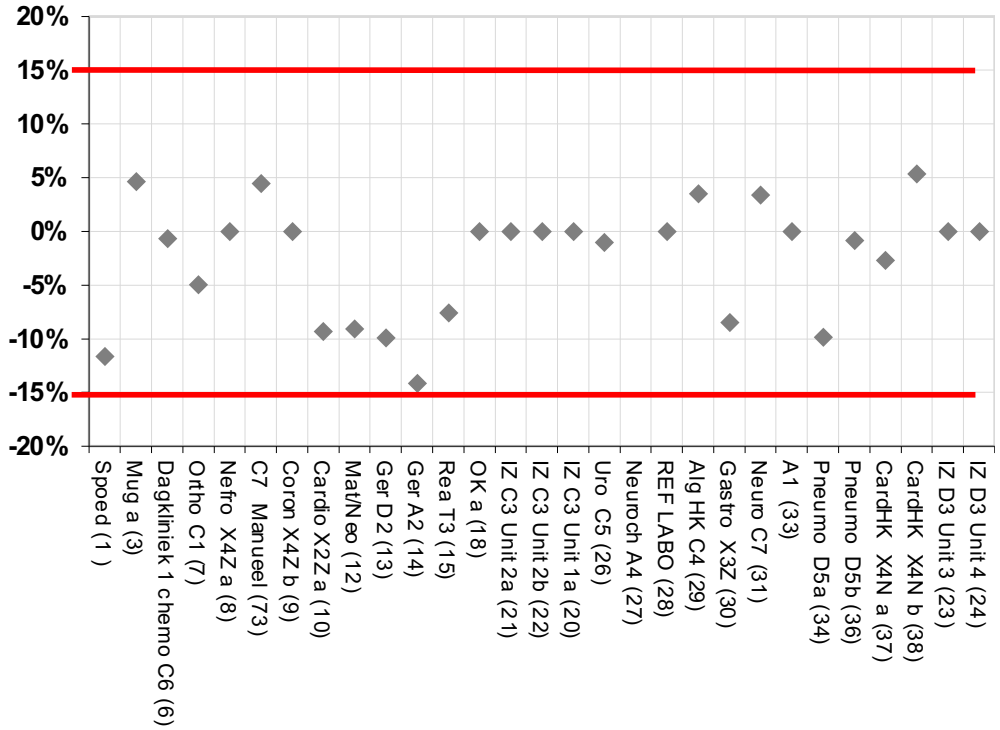
ADA. Diabetes Care 2025; 48: S27-S49

POCT glucose: analytical reliability

Weekly QC

- **Split sample**
  - Fasting patients
  - Capillary POCT glucose analysis
  - Venous fluoride blood sample
    hexokinase glucose analysis by central lab method

- **All hospital wards**
  - (Electronic) registration by POCT coordinator
  - Weekly follow up

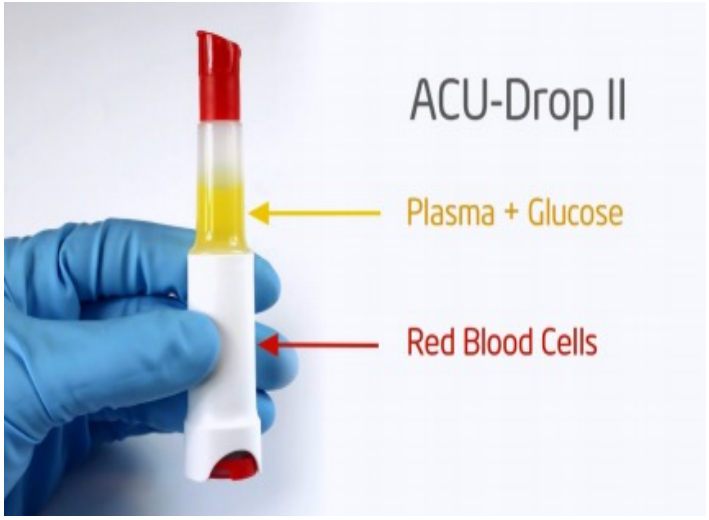


Nobels *et al*. Diabet Med 2004; 21: 1288-91

POCT glucose: analytical reliability

eQC Sciensano: 4-monthly

ACU-Drop II CueSee®



Whole blood (RBC + plasma) < bovine

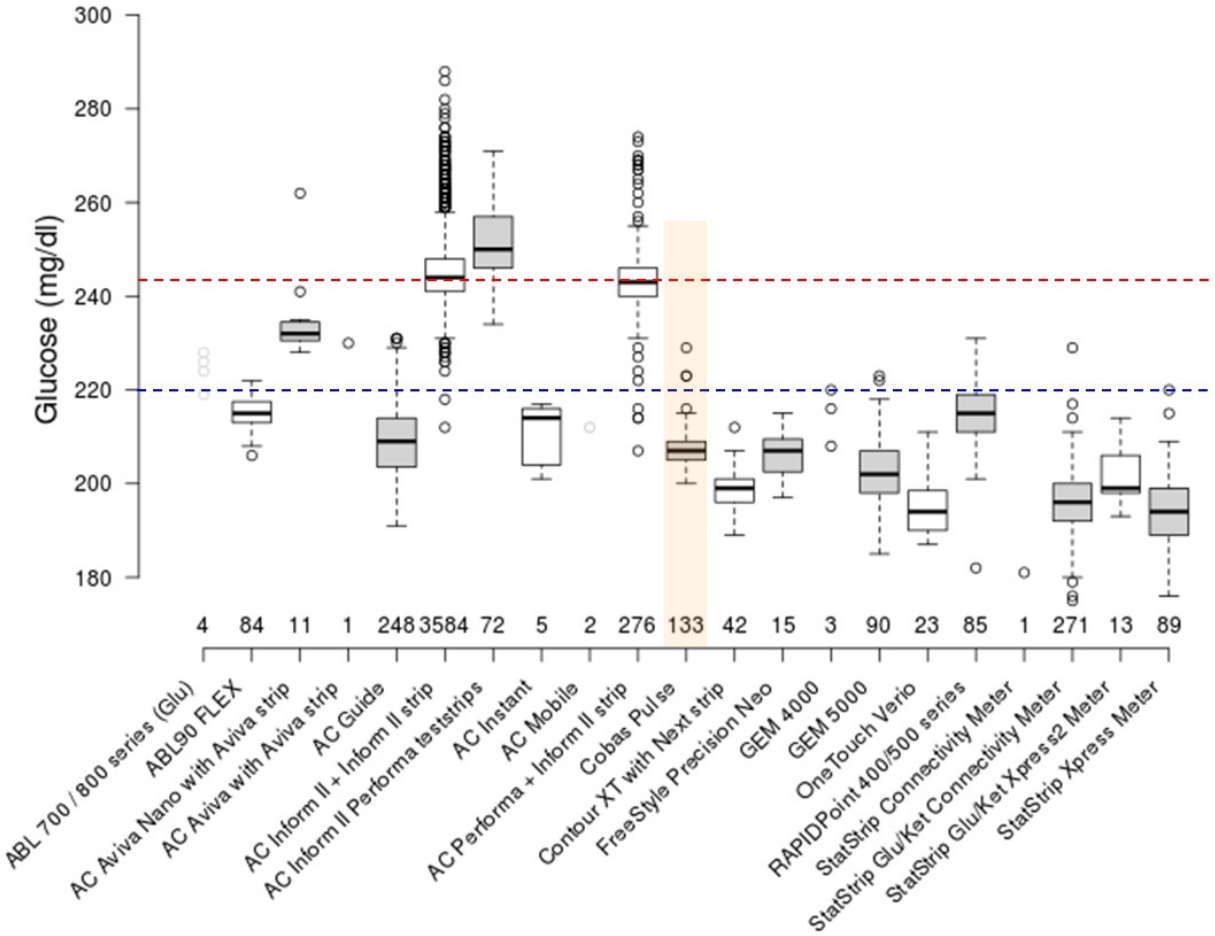
Glycolysis= not an issue

- stable for 8 weeks at 2-8°C
- stable for 4h after reconstitution at RT

https://www.eurotrol.com/products/pt-eqa/cuesee-glucose-eqas

POCT glucose: analytical reliability

eQC Sciensano: 4-monthly



POCT glucose: analytical reliability

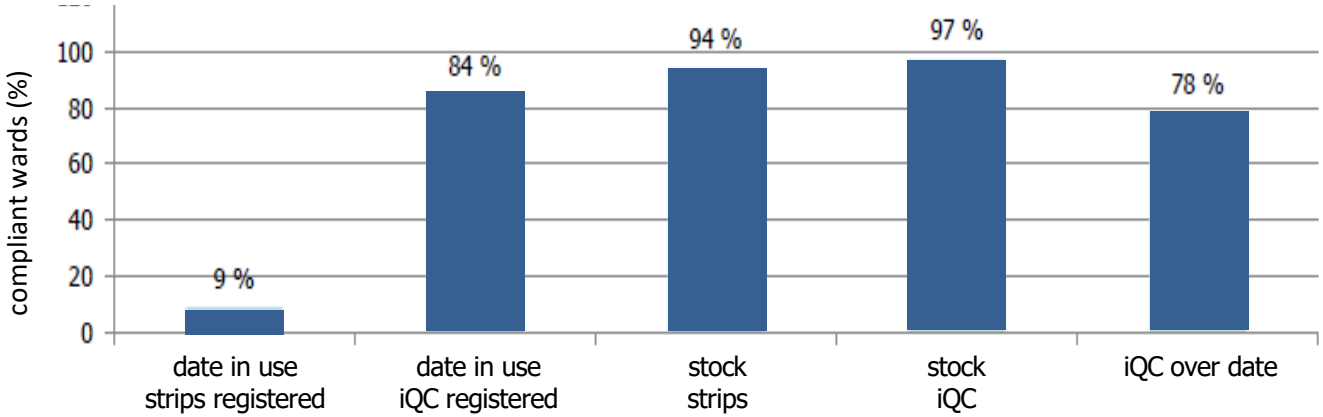
Lotvalidation: new strip lot

- **Lot restriction**
  - Lot reservation
  - Distribution of test strips by the POCT team

- **Lot validation**
  - Min. 2 lot numbers
  - **Relative difference** (CLSI EP09-A2)
    * Hexokinase (central lab method; CobasPro; hexokinase)
    * Current Cobas Pulse strip lotnumber (to validate accuracy at timepoint 'out')
    * Venous LiHep whole blood (StatStrip) – venous LiHep plasma (Cobas) (min. 40)
    * Measuring range distribution conform ISO 15197 (spiking vs CLSI POCT12-A3)
    * Deming regression, Bland-Altman plots
  - **Imprecision** (CLSI EP5-A3)
  - **Criteria** (cfr. Method validation)

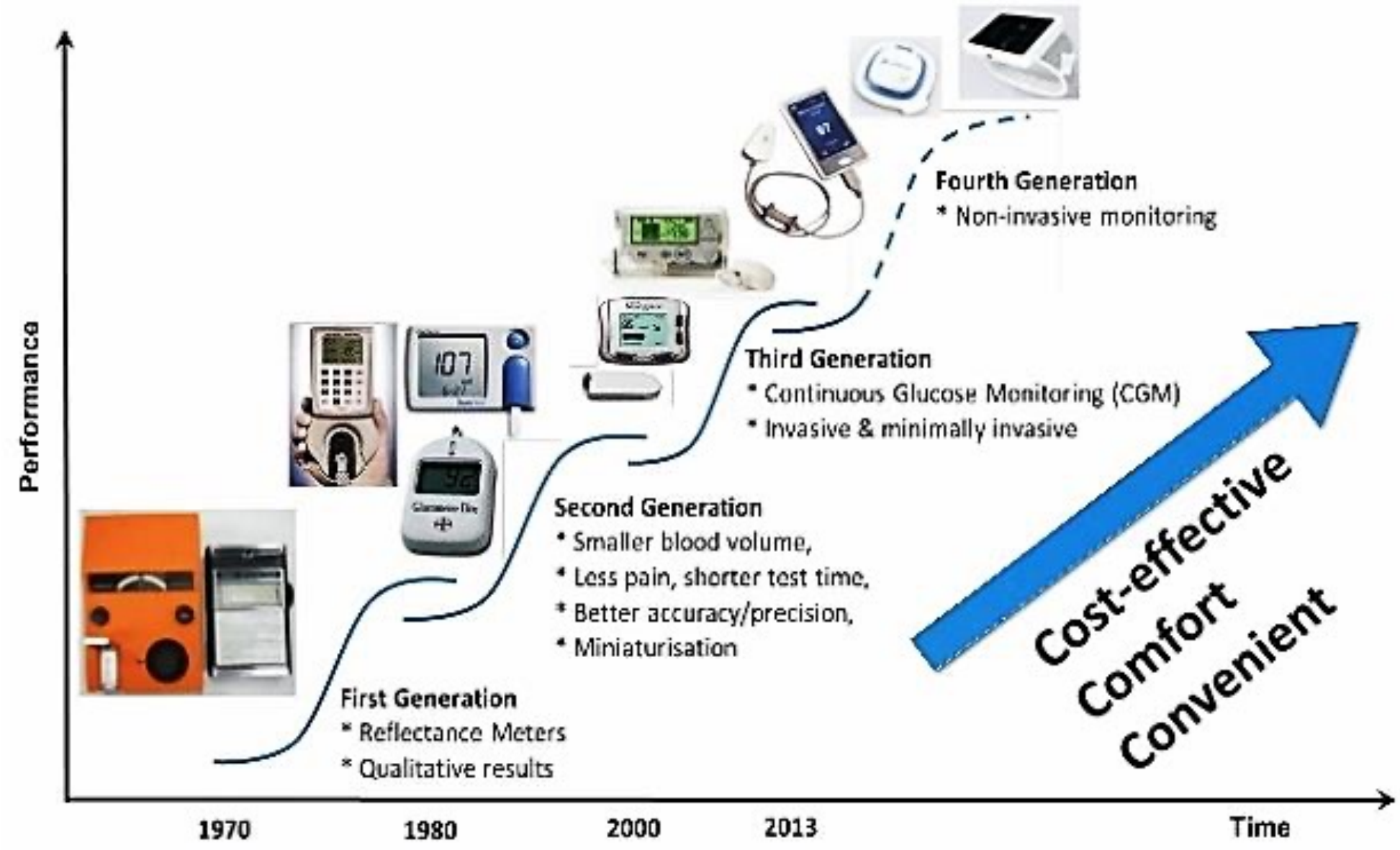
POCT glucose: analytical reliability

Yearly internal audit on the wards



- Trendanalysis/ward (< Management review)
- Feedback/ward
- Yearly feedback on general POCT AZORG meeting

POCT glucose: analytical reliability



POCT glucose: analytical reliability

Contineous Glucose Monitoring (CGM)

FreestyleLibre FLASH

Eversense CGM

MiniMed640G

Dexcom G5

MiniMed670G

- Contineous monitoring of glucose in **interstitial fluid**
- Belgian diabetic convention:
  type 1 DM: reimbursed
- **Glucose profiling**: added value

Glucose Pattern Insights

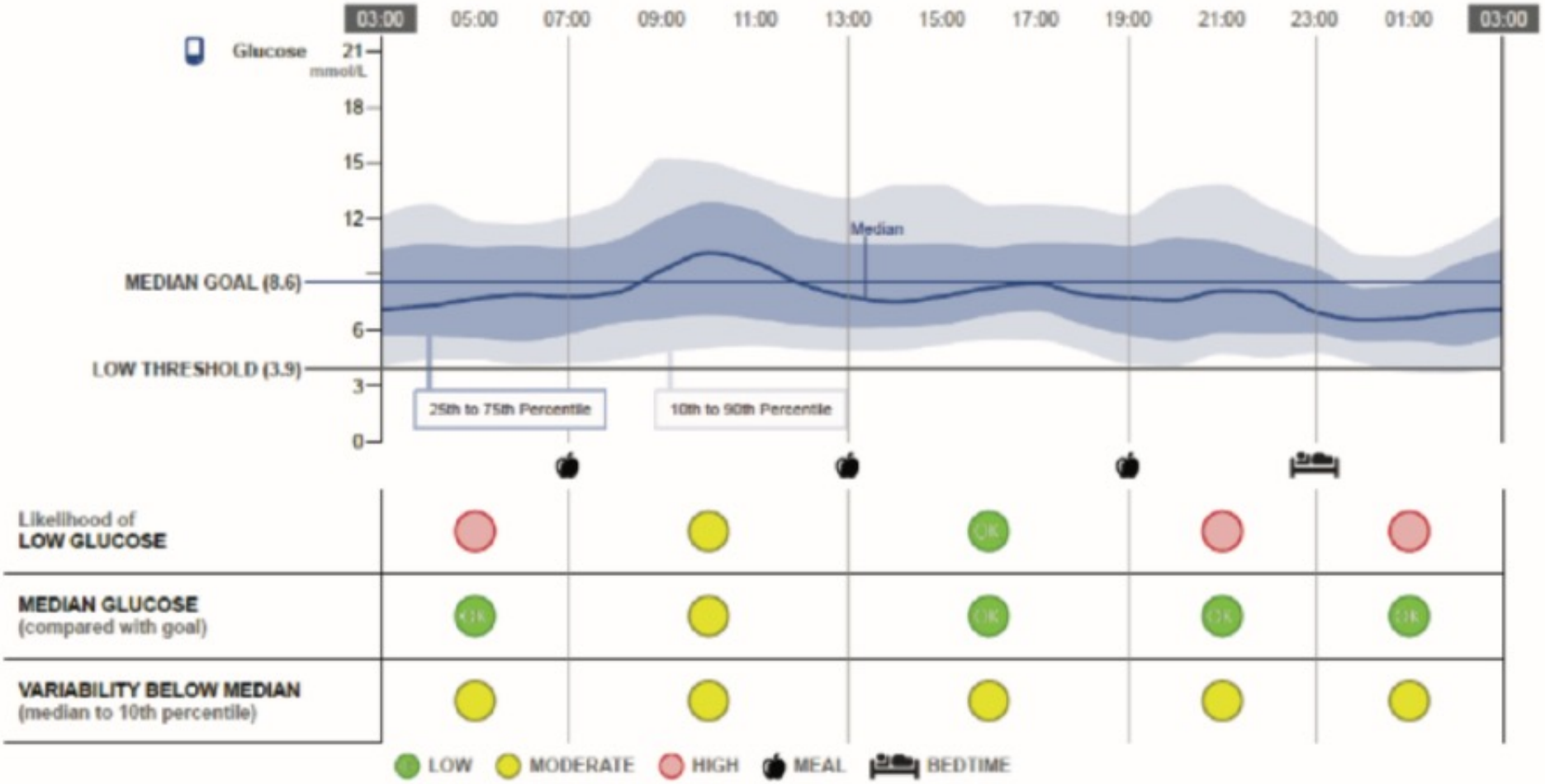
17 July 2015 - 16 October 2015 (92 days)

LOW-GLUCOSE ALLOWANCE SETTING: **Medium**

MEDIAN GOAL SETTING: **8.6 mmol/L (A1c: 7.0% or 53 mmol/mol)**

FreeStyle Libre

Estimated A1c 7.0% or 53 mmol/mol



POCT glucose: analytical reliability

Contineous Glucose Monitoring (CGM)

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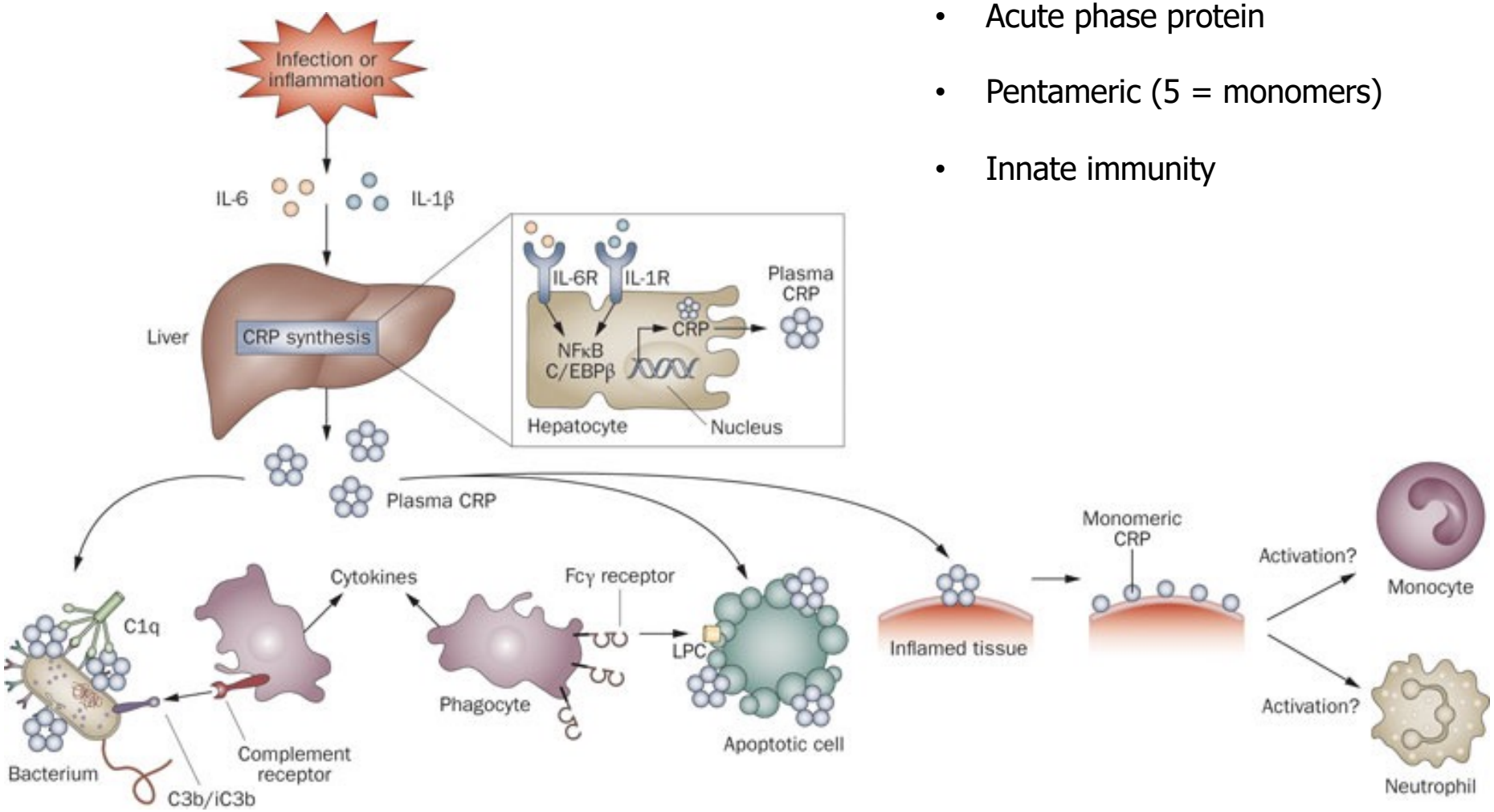
- Contineous monitoring of glucose in **interstitial fluid**
- Belgian diabetic convention:
  type 1 DM: reimbursed
- **Glucose profiling**: added value
- **Ambulatory care only**
  cfr. analytical requirements

Point of Care CRP

POCT CRP: guidelines

C-reactive protein

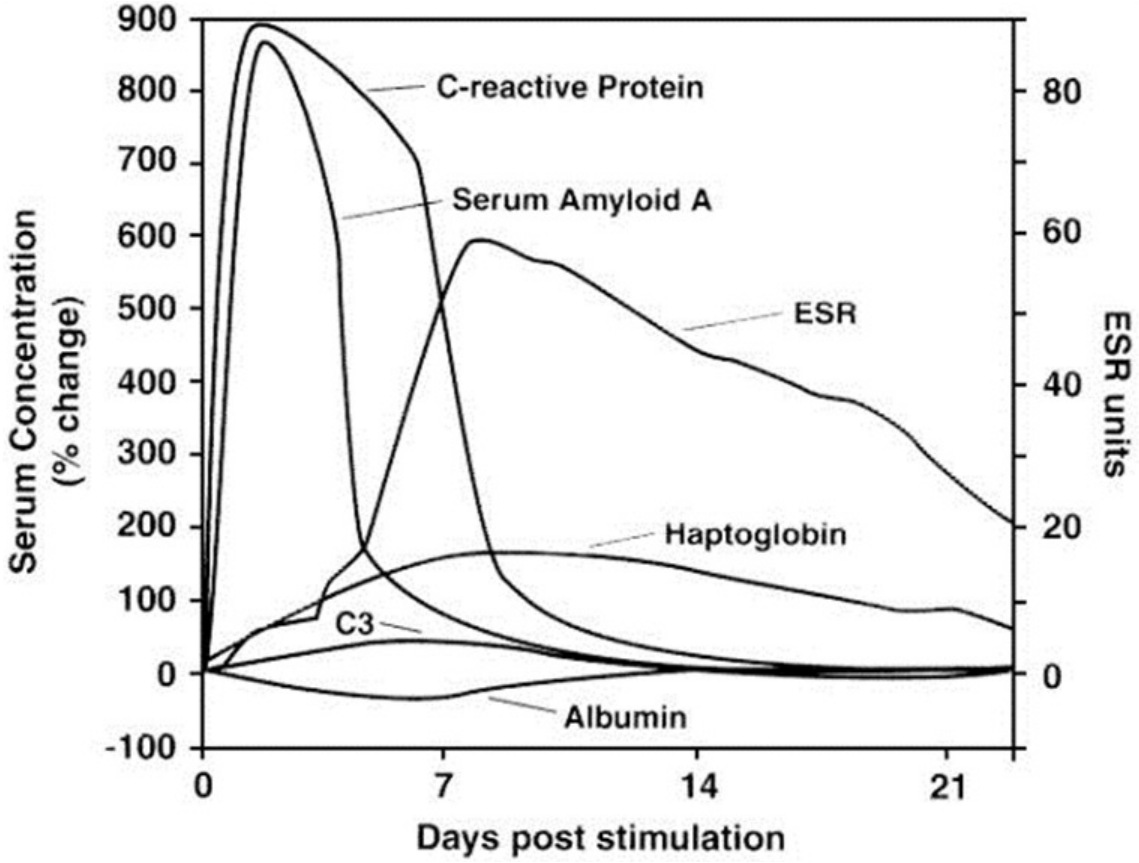


- Acute phase protein
- Pentameric (5 = monomers)
- Innate immunity

Rhodes et al. Nat Rev Rheumatol 2011; 7: 282-9

POCT CRP: guidelines

C-reactive protein

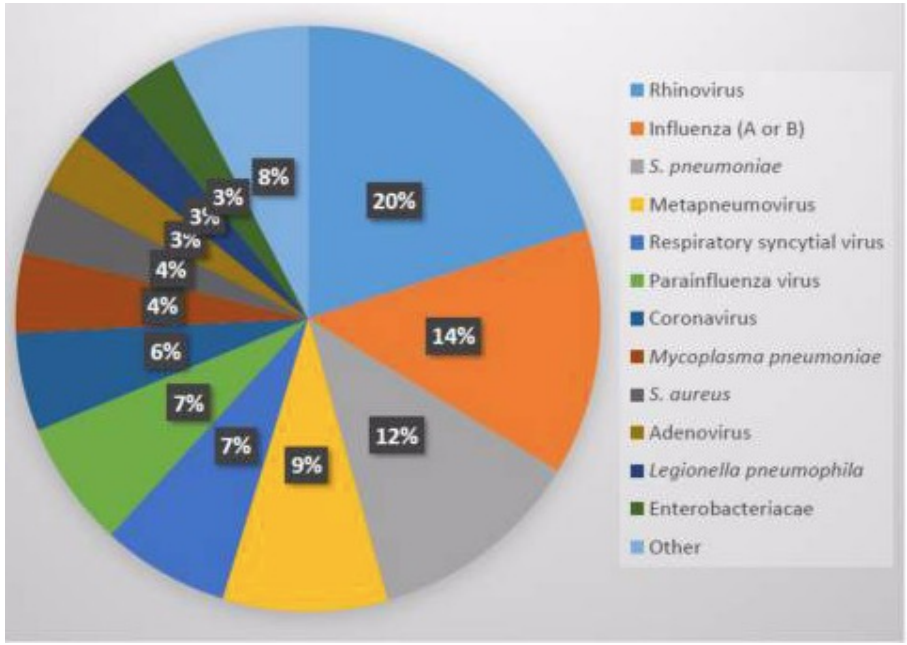


- Rapid increase of CRP, 4-6 hours after inflammation onset
- After 8 hours, doubling in concentration
  After 36-50h: peak
- $t_{1/2}$: 4-7 h

POCT CRP: guidelines

Diagnosis of bacterial LRTI

- Lower respiratory tract infections (LRTI) **leading infectious cause of death** and 6th leading cause of death overall worldwide
- Etiology of acute LRTI's is **mostly viral**
- **Antibiotic resistance** human threat worldwide
- **POCT CRP** for differention between viral and bacterial cause of LRTI and to guide AB prescription
- **Cost-effective** use: rapid and safe (EUnetHTA)
- Incorporated in **LRTI diagnostic recommandations** of The Netherlands, Norway, Sweden, Germany, Switzerland, Czech Republic, Estonia



Etiology of community acquired pneumonia: 62% viral
29% bacterial

Noviello et al. Diagnostics 2019: 9: 37
O'Brien et al. EUnetHTA Project ID: OTCA012. 31/01/2019

POCT CRP: guidelines

Diagnosis of bacterial LRTI

NICE National Institute for Health and Care Excellence

Search NICE...

NICE Pathways | NICE guidance | Standards and indicators | Evidence search | BNF | BNFC | CKS

Home > NICE Guidance > Conditions and diseases > Infections > Healthcare-associated infections

Pneumonia in adults: diagnosis and management

Clinical guideline [CG191] Published date: December 2014 Last updated: September 2019

1.1 Presentation with lower respiratory tract infection

1.1.1 For people presenting with symptoms of lower respiratory tract infection in primary care, consider a point of care C-reactive protein test if after clinical assessment a diagnosis of pneumonia has not been made and it is not clear whether antibiotics should be prescribed. Use the results of the C-reactive protein test to guide antibiotic prescribing in people without a clinical diagnosis of pneumonia as follows:

- Do not routinely offer antibiotic therapy if the C-reactive protein concentration is less than 20 mg/litre.
- Consider a delayed antibiotic prescription (a prescription for use at a later date if symptoms worsen) if the C-reactive protein concentration is between 20 mg/litre and 100 mg/litre.
- Offer antibiotic therapy if the C-reactive protein concentration is greater than 100 mg/litre.

https://www.nice.org.uk/guidance/cg191

nhg Nederlands Huisartsen Genootschap

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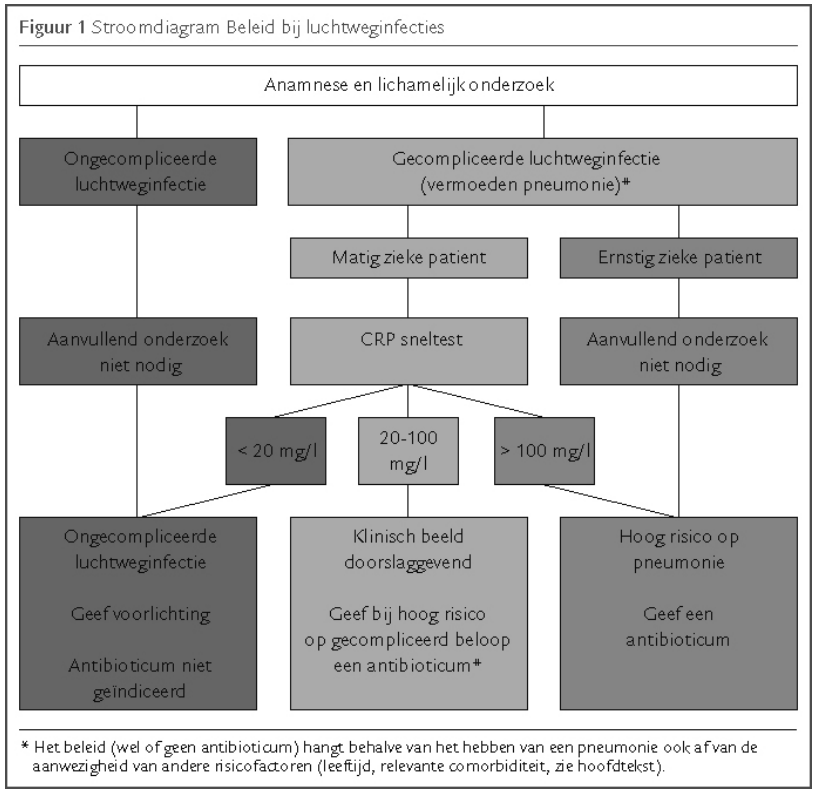
Home > Acuut hoesten

NHG-Standaard Acuut hoesten



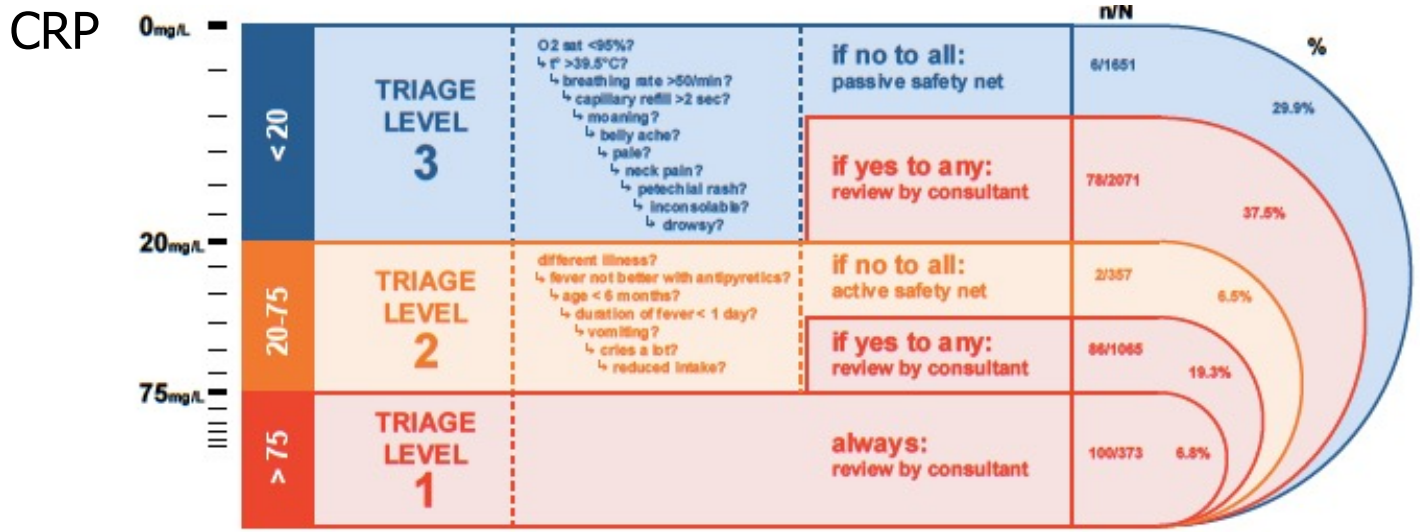
https://www.nhg.org/standaarden/volledig/nhg-standaard-acuut-hoesten

POCT CRP: guidelines

Diagnosis of bacterial LRTI

- Evidence in **pediatric departement** : ERNIE2 Trial
  Reduces clinician's uncertainty by ruling out **serious infection in children**

Lemiengre et al. BJGP 2018; 68: e204-e1(
Verbakel JY et al. BMC Pediatr 2014; 14: 207
https://kce.fgov.be/en/all-reports



Sens. 97,1%
NPV 99,6%

CRP POCT provides diagnostic value of ruling in or our serious bacterial infection in children

Van den Bruel et al. BMJ 2011; 342: d3082

CRP POCT decreases LOS in pediatric emergencies

Ivaska et al. PLoS One 2015; 10: e0129920
Nijman et al. Pediatr Emerg Care 2015; 31: 633-639
Hernandez-Bou et al. Eur J Clin Microbiol Infec Dis 2017; 36: 1205-1211

POCT CRP: guidelines

Reduction of antibiotic consumption

THE LANCET

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ARTICLES · Volume 406, Issue 10512, P1599-1610, October 11, 2025 Download Full Issue

A clinical decision tool including a decision tree, point-of-care testing of CRP, and safety-netting advice to guide antibiotic prescribing in acutely ill children in primary care in Belgium (ARON): a pragmatic, cluster-randomised, controlled trial

Jan Yvan Verbakel, PhD [a,b,†] · Ruben Burvenich, PhD [a,b,c,†] · Erinn D'hulster, MSc [a,b,e] · Liselore De Rop, MD [a,b] · Ann Van den Bruel, PhD [b] · Sibyl Anthierens, PhD [e,f] · et al. Show more

- 171 primary care practices in Belgium
- 6750 children (6m-12y)
- FU: 30 days
- 1st outcome: AB prescription

The clinical decision tool reduced antibiotic prescribing in children without causing harm. Our results support its broader dissemination and implementation to improve the management of acutely ill children in ambulatory care.

Verbakel *et al.* Lancet 2025; 406: 1599-1610

POCT CRP: guidelines

Reduction of antibiotic consumption

Cochrane Library

Cochrane Database of Systematic Reviews

Biomarkers as point-of-care tests to guide prescription of antibiotics in people with acute respiratory infections in primary care (Review)

Smedemark SA, Aabenhus R, Llor C, Fournaise A, Olsen O, Jørgensen KJ

Smedemark SA *et al.* CDSR 2022;10

POCT CRP: guidelines

Interest of physicians

Physicians agree that CRP POCT:

- increases diagnostic certainty
- provides reassurance for both clinicians and patients
- helps to manage patient expectations regarding AB
- facilitates shared decision making
- results in high patient satisfaction

- **Should not be used as a standalone diagnostic tool**

Jones *et al.* BMH Family Practice 2013; 14: 117
Hardy et al. BMJ Open 2017; 7

https://consultativebodies.health.belgium.be/sites/default/files/documents/fod_crp_poct_report-vjuly2025_0.pdf

POCT CRP: analytical reliability

POCT devices

QuikRead Go Easy
Mediphos Diagnostics BeLux
Renkum, The Netherlands

Alere Afinion 2
Abbott, Wiesbaden, Germany

Cobas b101
Roche Diagnostics, Mannheim, Germany

Lumira Dx
LumiraDx, Stirling, UK

Van Hoovels et al. CCA 2024; 119737

	QuikRead Go Easy (Mediphos Diagnostics BeLux, Renkum, Netherlands)	**Afinion 2** (Abbott, Wiesbaden, Germany)	**Cobas b101** (Roche Diagnostics, Mannheim, Germany)	**LumiraDx CRP** (LumiraDx, Stirling, UK)
Test principle	Immunoturbidimetric assay	Solid phase, sandwich-format, immunochemical assay	Immunoturbidimetric assay	Immunofluorescent assay
Required volume	10 µL	2.5 µL	12 µL	20 µL
Measurement range whole blood	1-200 mg/L	5-200 mg/L	3-400 mg/L	5-250 mg/L
Measurement range plasma/serum	1-120 mg/L	5-160 mg/L	3-400 mg/L	5-250 mg/L
Hematocrit correction	36%-41%	20%-60%	20%-60%	15%-55%
Traceability	**ERM DA 474/IFCC**	**ERM DA 474/IFCC**	**ERM DA 474/IFCC**	**ERM DA 474/IFCC**

POCT CRP: analytical reliability

Analytical performance criteria

Comparison method

- imprecision ≤2.9%
- Traceable to ERM DA 474/IFCC with maximum fit for purpose allowable measurement uncertainty ≤5.64%

Braga et al. CCLM 2020; 58: e263-265
Borrillo et al. CCLM 2023; 61: 1552-1557

CRP POCT*:

- Imprecision: <10 %
- Accuracy: > 95 % of the CRP results within +/- 20 % of the comparison method.
- Correlation:
  - a slope and intercept not significantly differing from 1.0 and 0.0
  - a Spearman's rank correlation rho ≥ 0.975

* Stavelin et al. Crit. Rev. Clin. Lab. Sci. 2023; https://doi.org/10.1080/10408363.2023.2262029
*https://skup.org

Van Hoovels et al. CCA 2024; 119737

POCT CRP: analytical reliability

Imprecision (CLSI EP5-A3)

	Low patient pool cobas c 503 (mg/L)	Mean (SD) (mg/L)	CV (%)
cobas b 101	18.6	20.6 (1.01)	4.91
Afinion 2		18.4 (1.39)	7.56
QuikRead go		18.1 (2.07)	11.5
LumiraDx		16.1 (1.45)	9.01
	High patient pool cobas c 503 (mg/L)	**Mean (SD) (mg/L)**	**CV (%)**
cobas b 101	98.6	93.1 (4.52)	4.86
Afinion 2		98.7 (7.59)	7.69
QuikRead go		88.8 (9.04)	10.2
LumiraDx		91.3 (4.44)	4.47

Van Hoovels et al. CCA 2024; 119737

POCT CRP: analytical reliability

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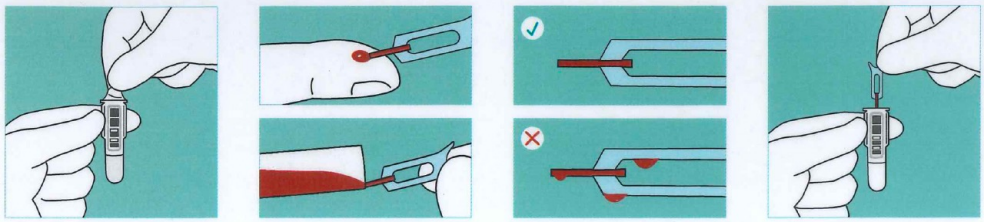
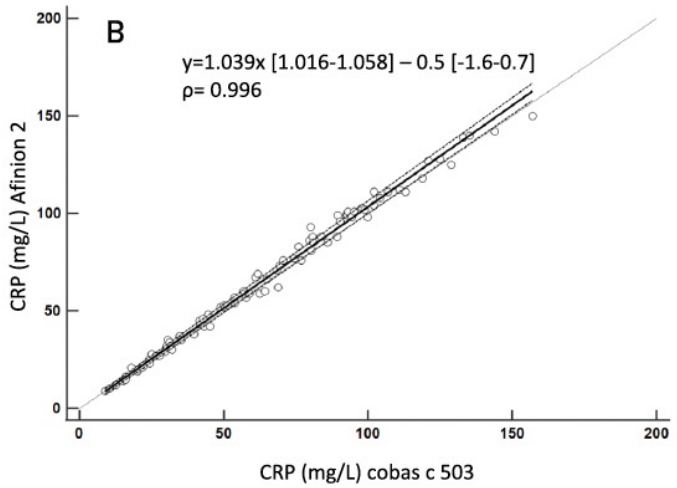


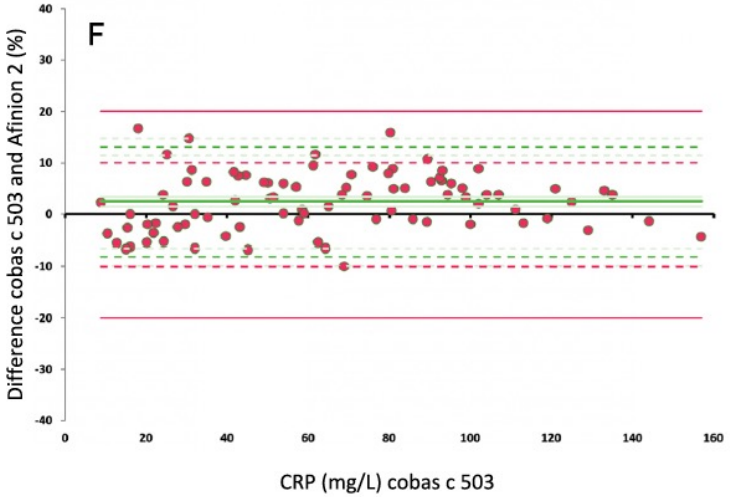
Imprecisie QuikRead na staalname met gecalibreerde pipet < 10%

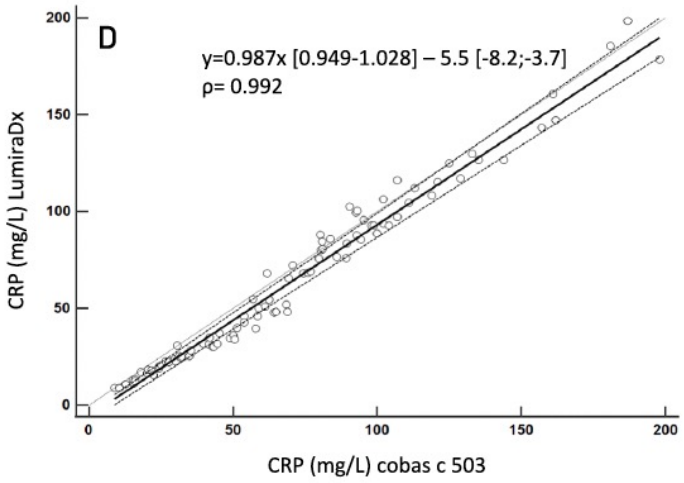
Van Hoovels et al. CCA 2024; 119737

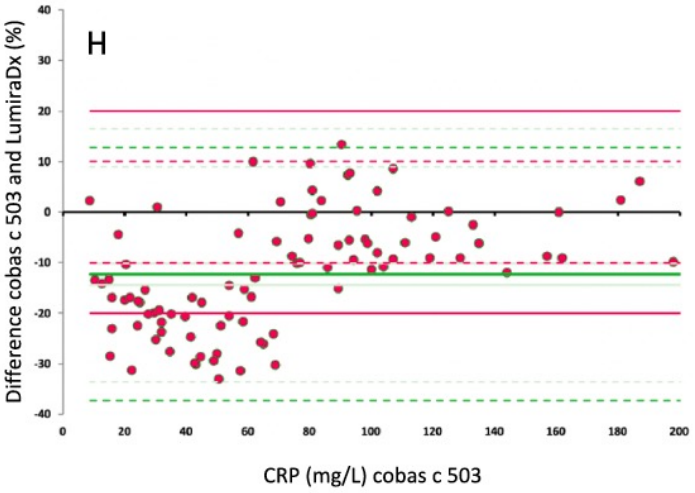
POCT CRP: analytical reliability

Method comparison (CLSI EP9-A2)









POCT CRP: analytical reliability

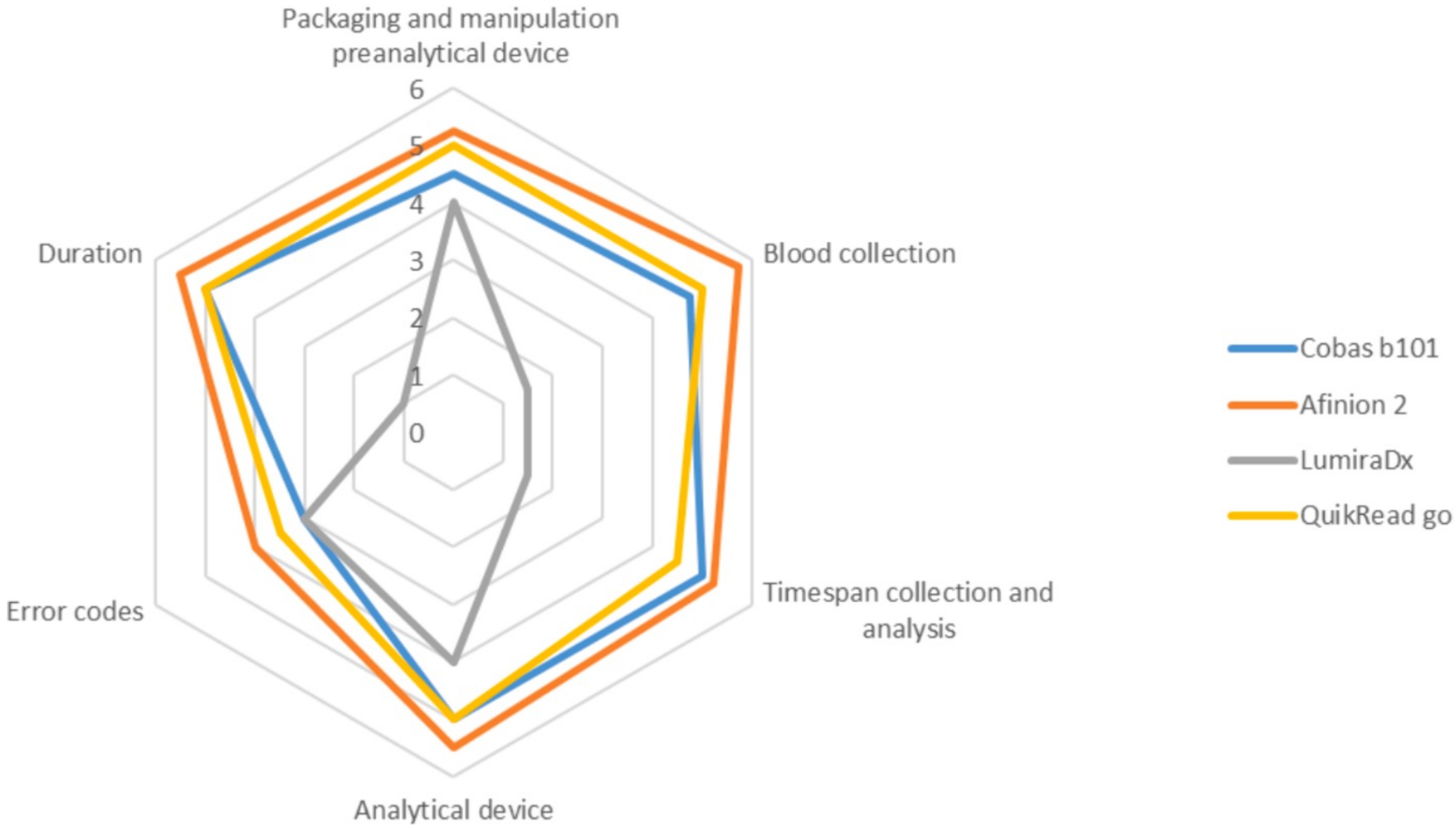
Method comparison (CLSI EP9-A2)

	Passing Bablok regression			Bland-Altman plot	% samples < +/- 20 % mean difference
	Slope [95 % CI]	Intercept [95 % CI]	Spearman's ρ [95 % CI]	Mean difference (%) [95 % CI]	
cobas b 101	0.954 [0.931–0.980]	0.4 [-0.7–1.7]	0.996 [0.994–0.997]	−2.58 [-17.19–12.04]	97.8
Afinion 2	1.039 [1.016–1.058]	−0.5 [-1.6–0.7]	0.996 [0.994–0.997]	2.53 [-8.21–13.28]	100.0
QuikRead go	0.904 [0.872–0.934]	1.5 [0.1–2.5]	0.991 [0.985–0.994]	−6.34 [–22.82–10.15]	97.5
LumiraDx	0.987 [0.949–1.028]	−5.5 [-8.2;-3.7]	0.992 [0.987–0.994]	−13.66 [-36.68–9.37]	66.3

Van Hoovels et al. CCA 2024; 119737

POCT CRP: analytical reliability

User friendliness



Van Hoovels et al. CCA 2024; 119737

https://consultativebodies.health.belgium.be/sites/default/files/documents/fod_crp_poct_report-vjuly2025_0.pdf

POCT CRP

Conclusion

1. Analytical Performance and linkage of devices (WP1): The study assessed the performance and user-friendliness of four POCT-CRP devices, focusing on analytical accuracy, precision, and traceability. Three out of four devices met the required criteria. The findings emphasized the need for strong quality assurance systems led by clinical laboratories to ensure reliable results.
2. End-user Training and Quality Assurance (WP2): Training of general practitioners and their staff was crucial for ensuring proper device usage. The report highlights the importance of ongoing quality assurance to maintain device accuracy and avoid negative public health consequences from incorrect usage.
3. Implementation Process and Stakeholder Engagement (WP3): A pilot implementation was conducted, and stakeholder feedback was gathered through interviews and focus group discussions. The findings revealed that the CRP tests were seen as valuable tools in clinical decision-making, particularly in reducing unnecessary antibiotic prescriptions. The study highlighted the importance of ease of use and proper integration into the clinical workflow for successful implementation.
4. Budget Impact Analysis (WP4): A budget impact analysis was conducted to estimate the financial consequences of implementing CRP POCT in Belgian general practice. The analysis projected an incremental cost of €12.8 million over five years compared to usual care, but it also highlighted the long-term benefits of reduced antibiotic use and improved AMR management.

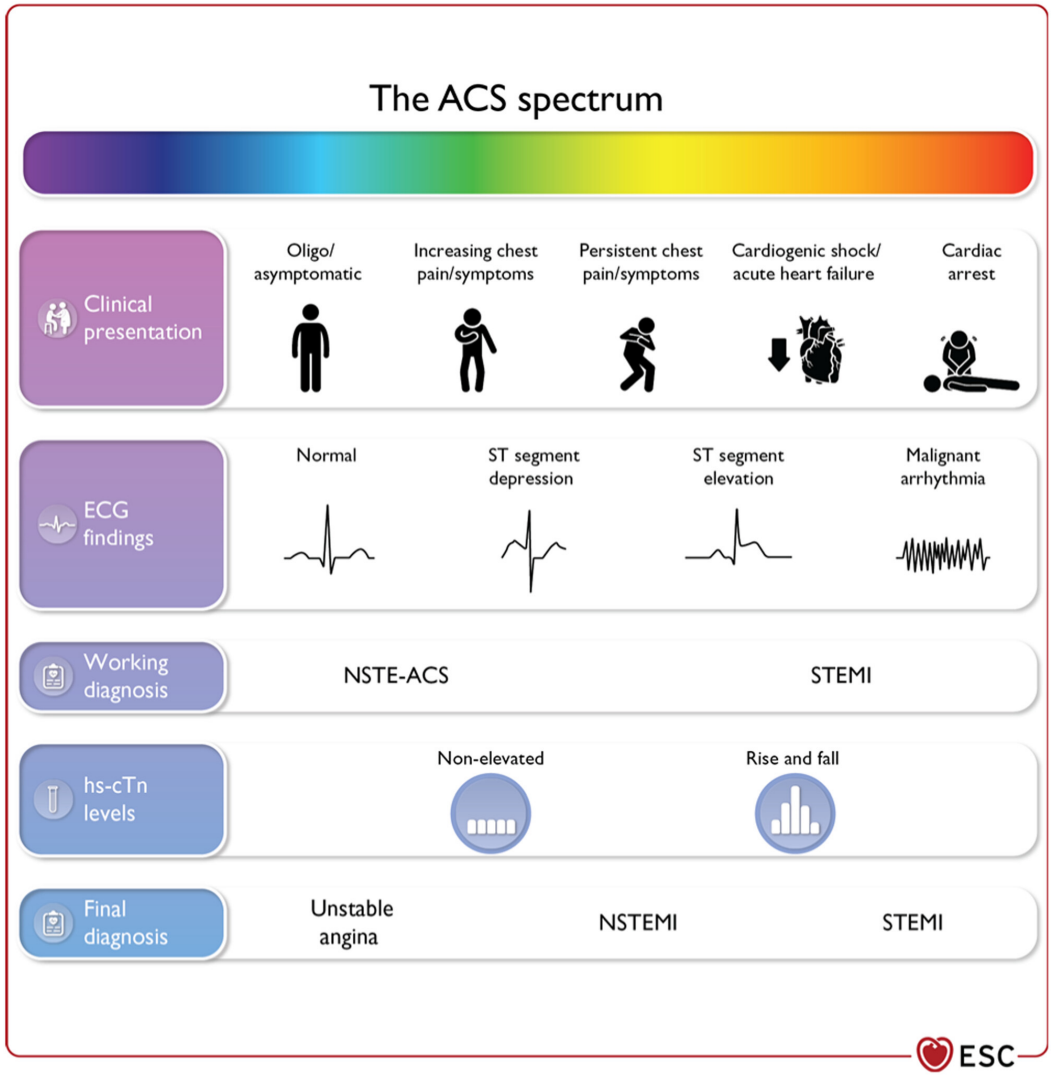
The study concludes that while the implementation of CRP POCT devices in Belgian general practice is promising, careful consideration of organizational, financial, and training aspects is essential for large-scale adoption. The findings offer policymakers valuable insights into balancing the costs of implementation with the public health benefits of reducing AMR.

https://consultativebodies.health.belgium.be/sites/default/files/documents/fod_crp_poct_report-vjuly2025_0.pdf

Cardiac Troponin

ACS: diagnostic guidelines

ESC guidelines ACS 2023



Clinical presentation

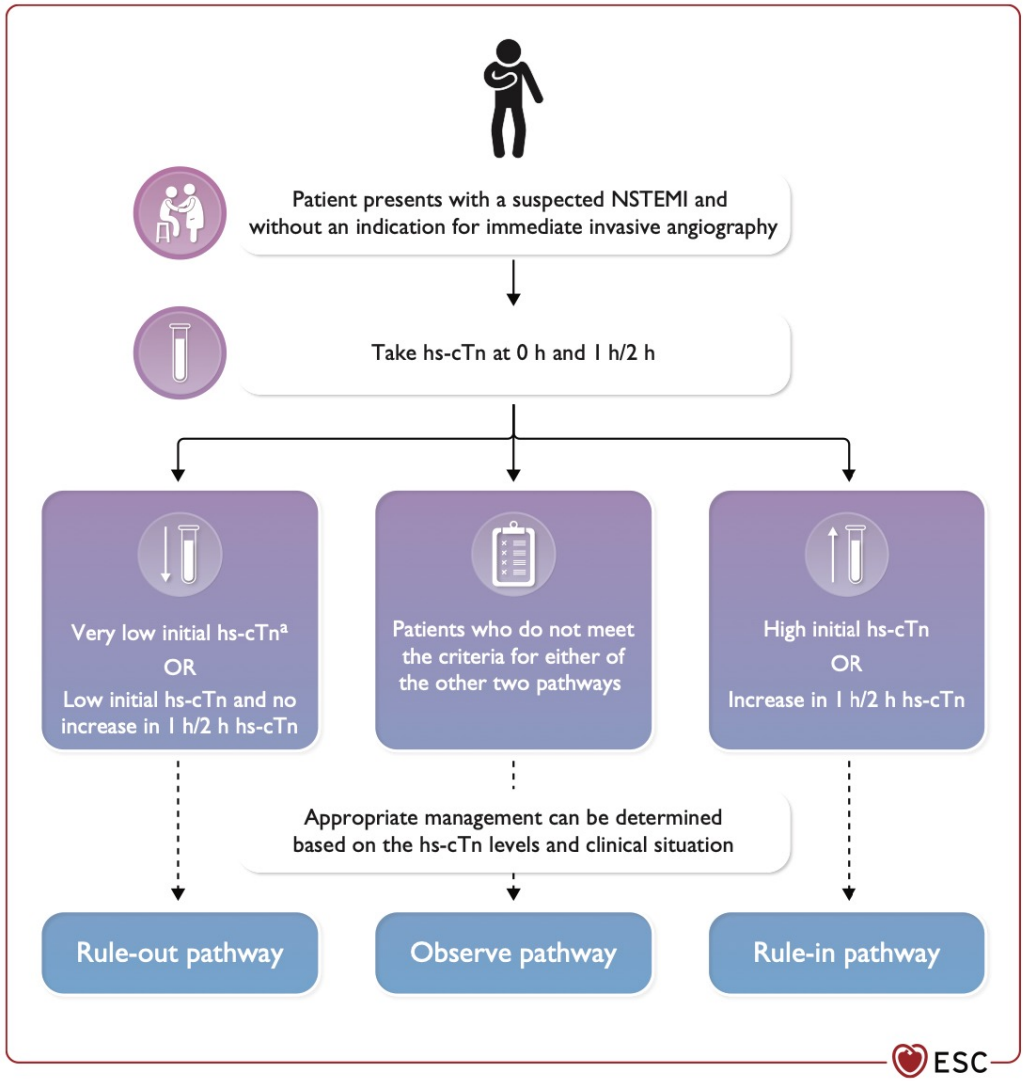
< 10 min

< 60 min

Byrne *et al*. Eur Heart J 2023; 44: 3720-3826

ACS: diagnostic guidelines

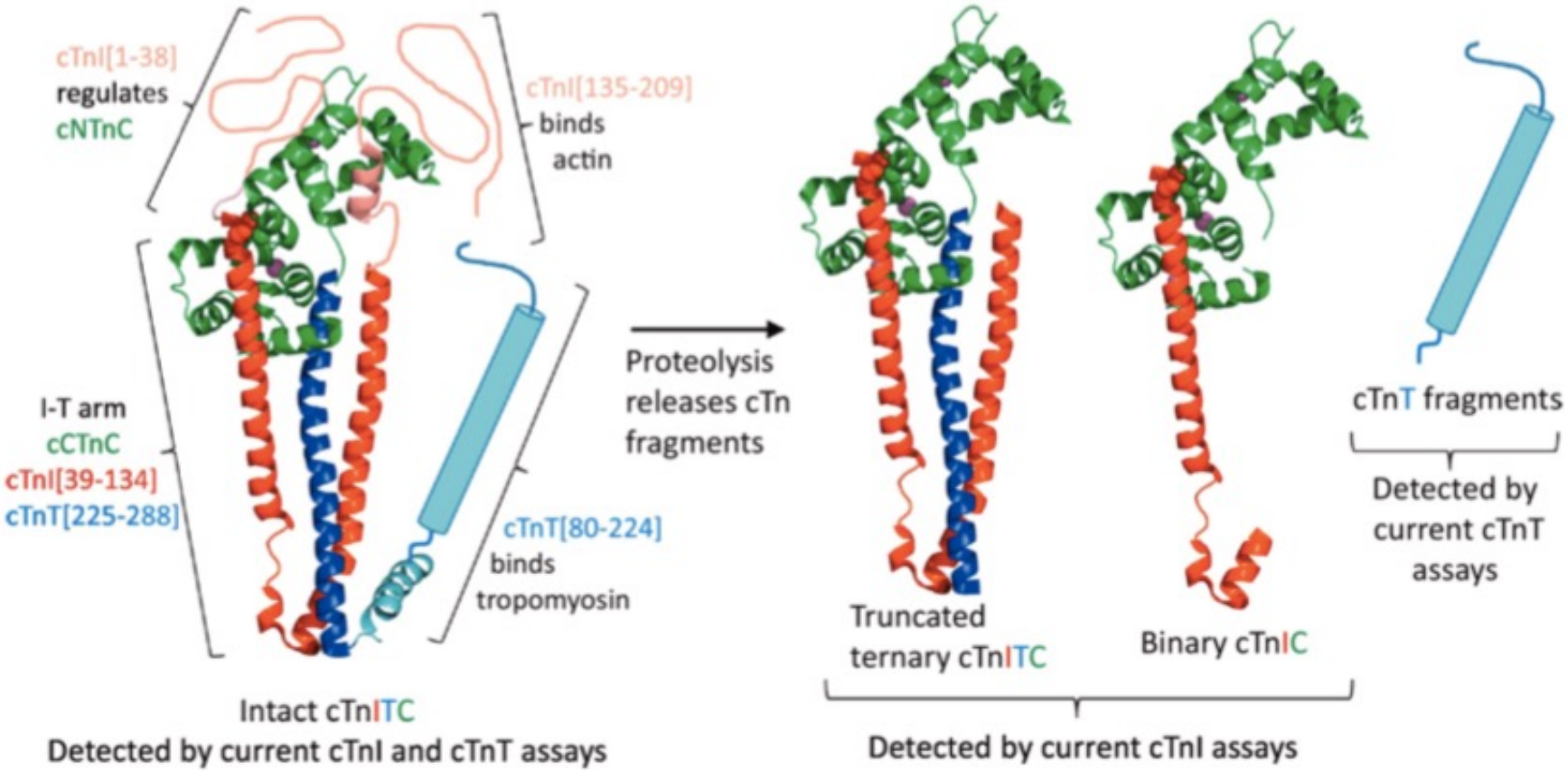
ESC guidelines ACS 2023



Byrne *et al*. Eur Heart J 2023; 44: 3720-3826

ACS: diagnostic guidelines

Cardiac troponin



Hwang et al. Clin Biochem 2019; 73: 32-34

POCT cTn: analytical reliability

Analytical performance criteria

Clinical Chemistry 64:4
645–655 (2018)

Special Report

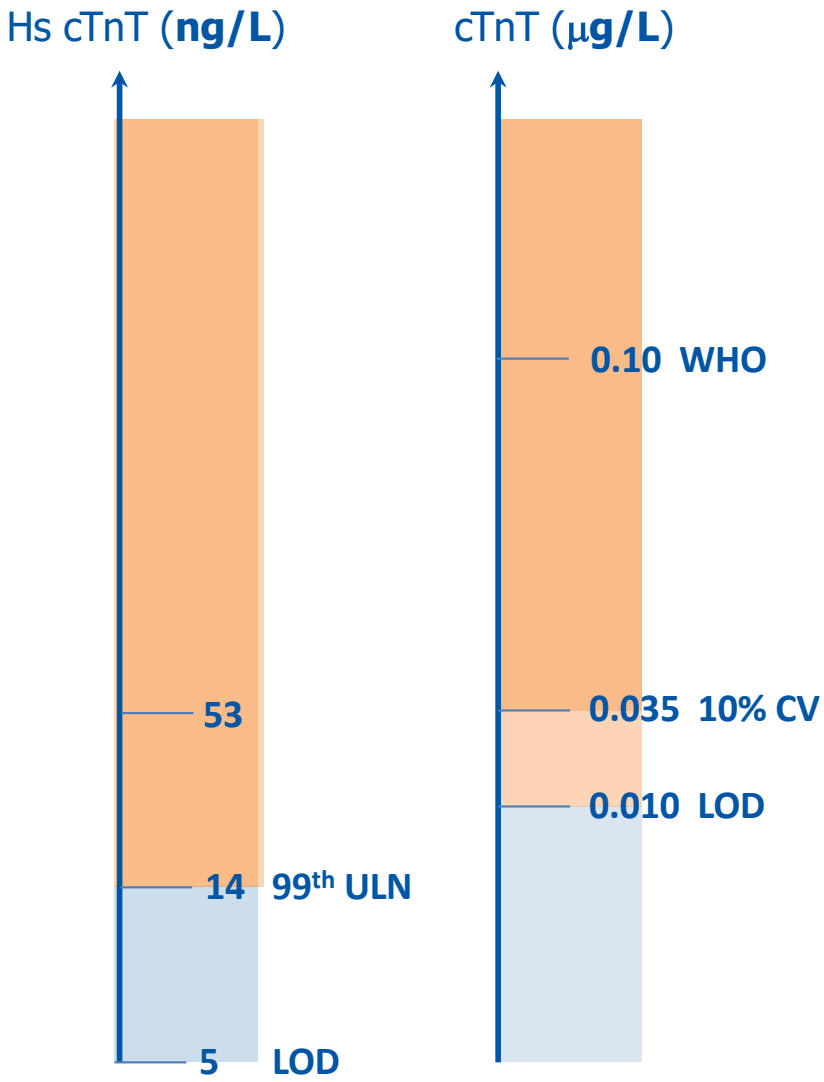
Clinical Laboratory Practice Recommendations for the Use of Cardiac Troponin in Acute Coronary Syndrome: Expert Opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-Markers of the International Federation of Clinical Chemistry and Laboratory Medicine

Alan H.B. Wu,[1*] Robert H. Christenson,[2] Dina N. Greene,[3] Allan S. Jaffe,[4] Peter A. Kavsak,[5] Jordi Ordonez-Llanos,[6] and Fred S. Apple[7]

Wu et al. Clin Chem 2018; 64: 645-655

ACS: diagnostic guidelines

Analytical performance criteria



Definition hs cTn:

- CV% ≤ 10% bij 99th ULN
- > 50% healthy individuals (F&M) cTn > LOD

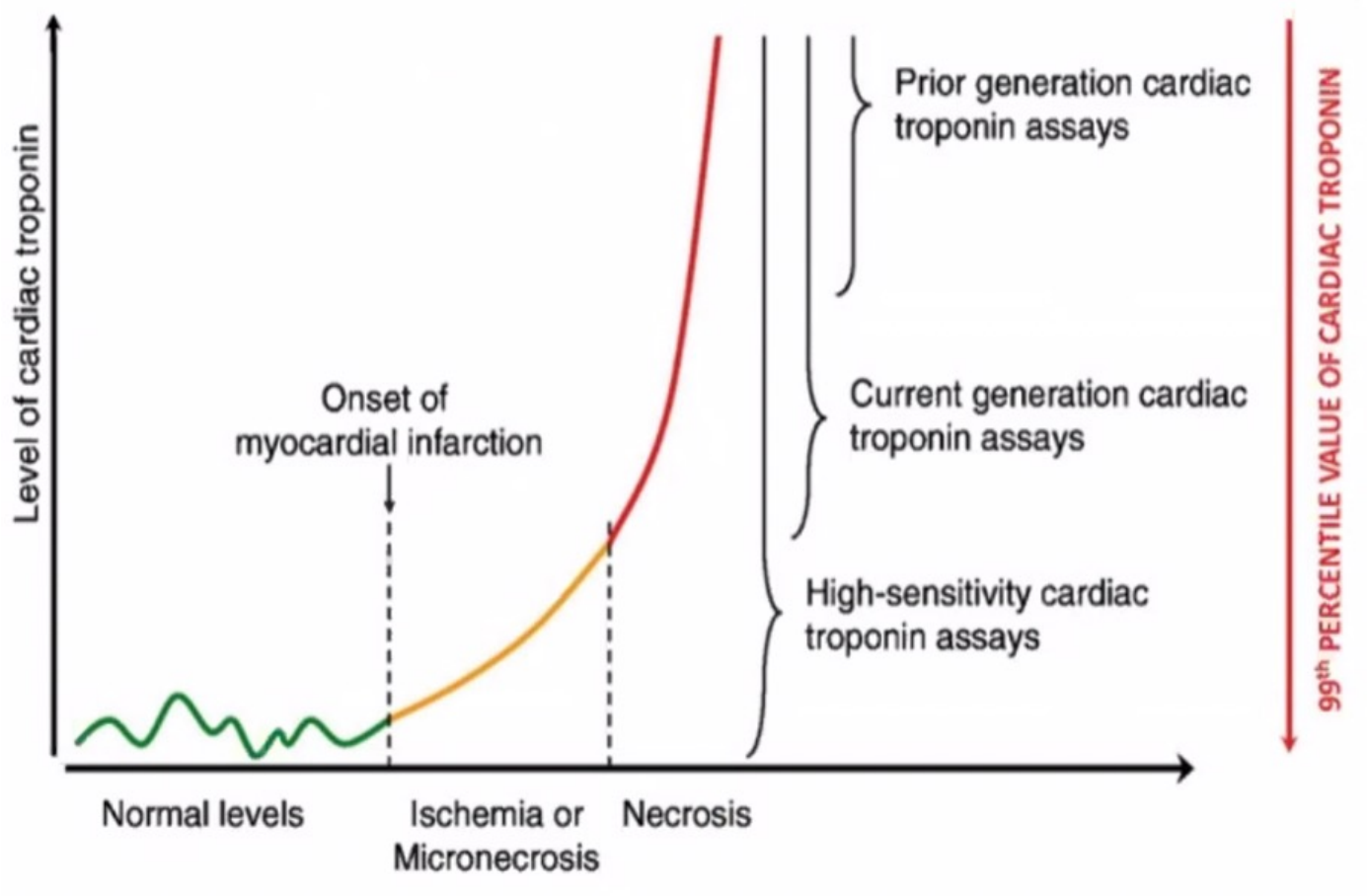
Pathogenic
Likely pathogenic
Likely normal

Twerenbold et al. Eur Heart J 2012; 72: 2231-64

Twerenbold *et al*. Eur Heart J 2012; 72: 2231-64
Alan *et al*. Clin Chem 2018; 64: 645-655

ACS: diagnostic guidelines

Analytical performance criteria



ACS: diagnostic guidelines

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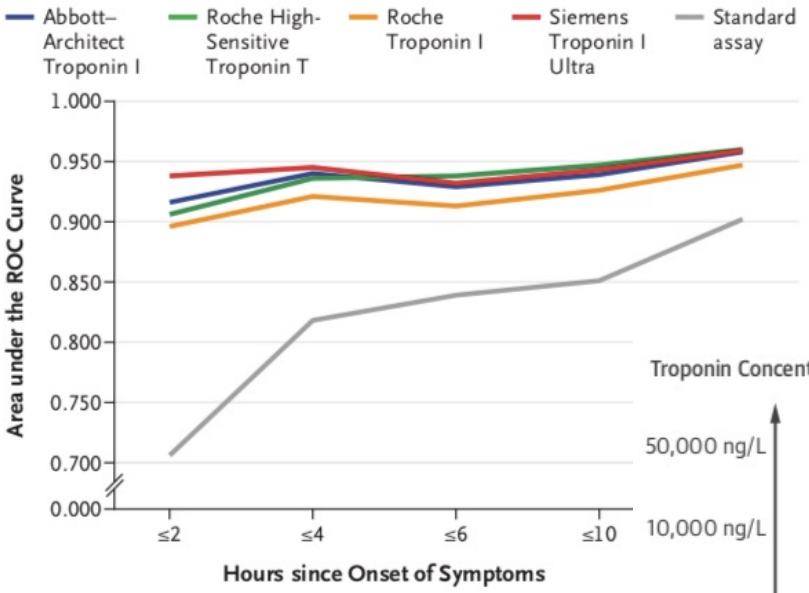
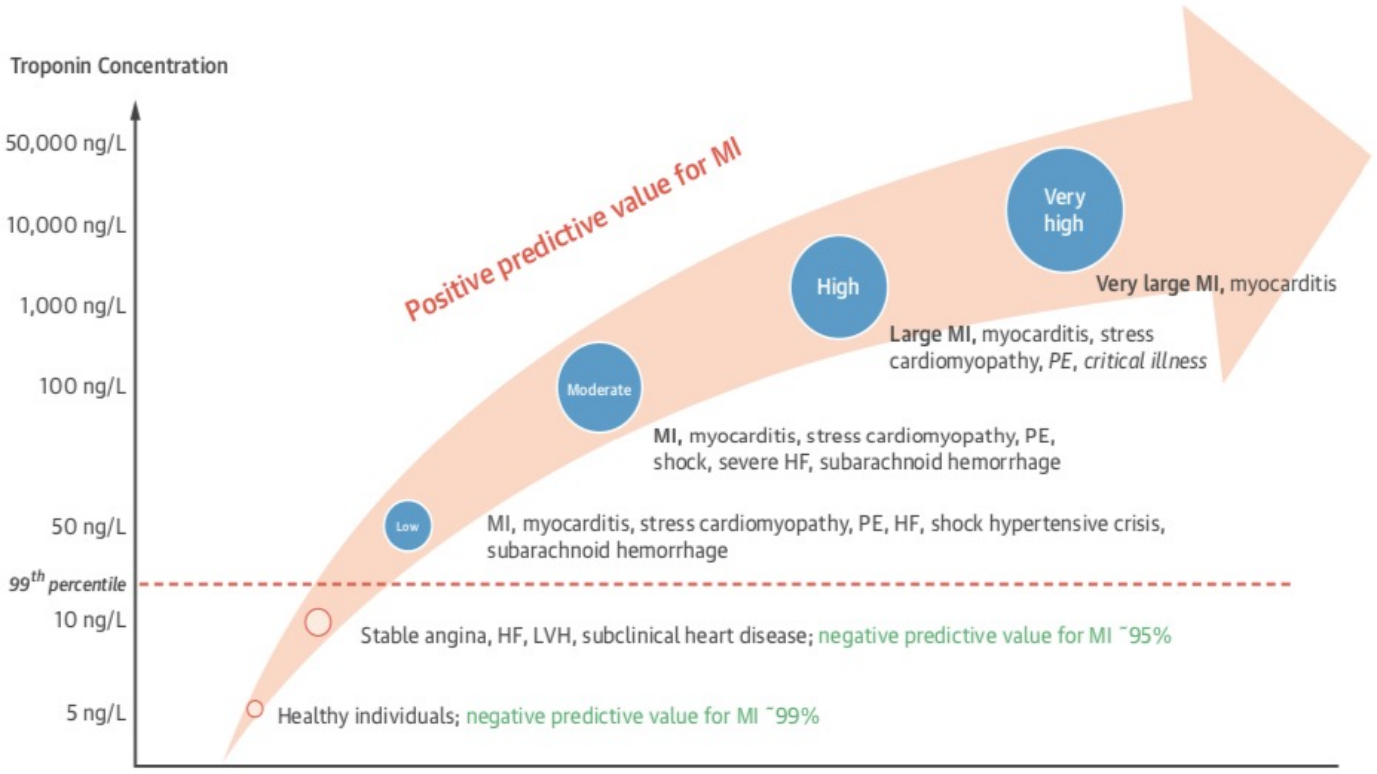


Reichlin et al. NEJM 2009; 361:858-67



Januzzi et al. J Am Coll Cardiol 2019; 73: 1059-1077

POCT cTn: analytical reliability

ESC guidelines ACS 2023

Different cTn method specific **cut-offs** defined

!! cTn methods are not interchangeable

3.3.2. Central laboratory vs. point of care

The vast majority of cTn assays that run on automated platforms in the central laboratory are sensitive (i.e. allow for the detection of cTn in ~20–50% of healthy individuals) or high-sensitivity (i.e. allow for the detection of cTn in ~50–95% of healthy individuals) assays. High-sensitivity assays are recommended over lower-sensitivity assays, as they provide higher diagnostic accuracy at an identical low cost.[1,12,15,25–27,57,63]

The majority of currently used point-of-care (POC) tests cannot be considered high-sensitivity assays.[64] The advantage of POC tests is a shorter turnaround time. However, this is counterbalanced by lower sensitivity, lower diagnostic accuracy, and lower negative predictive value (NPV). A randomized trial in low-risk chest pain patients with suspected NSTE-ACS and onset of symptoms ≥2 h before ambulance presentation reported that the use of a pre-hospital rule-out strategy (with a single POC conventional troponin T test) resulted in a significant reduction of 30-day healthcare costs and a comparable major adverse cardiovascular event (MACE) rate in comparison to an ED rule-out strategy (with evaluation as per standard local practice).[65]

Overall, automated assays have been more thoroughly evaluated than POC tests and are currently preferred.[1,12–15,26,34,35,53,55–58] However, this is a rapidly developing field and it will be important to re-evaluate this preference when more extensively validated high-sensitivity POC tests are clinically available.[66–68]

Byrne *et al*. Eur Heart J 2023; 44: 3720-3826

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

Information not available, NA; ethylenediaminetetraacidic acid, EDTA; surface plasmon-field enhanced fluorescence spectroscopy, SPFS; lower limit of detection, LoD; coefficient of variation, CV; upper reference limit defined as the 99th percentile among healthy, URL; female, F; male, M;, and minutes, min.

Reported numbers are from package inserts of assay manufacturers and of publications where available. All listed assays measure cardiac troponin I. The availability of the listed assays depends on local regulatory approval. Please see the IFCC Biomarkers Reference Tables online for contemporary information. More assays are currently in development.

POCT cTn: analytical reliability

Central laboratory versus POCT hs cTn

Table 2 Advantages and disadvantages of point-of-care vs central laboratory high-sensitivity cardiac troponin testing

	Point of care	Central laboratory
Advantages	Actionable results in real-time	Single platform for testing in all settings reduces the risk of confusion where patients move from one setting to another for serial measurements
	Feasible for use in a broad range of settings New opportunities for biomarker-guided care in outpatient settings, prehospital settings, primary care and other healthcare settings	Utilizes existing laboratory infrastructure, staff, training and quality controls
	May facilitate earlier diagnosis and treatment	Lower cost of testing
	May reduce the time to further testing or cardiac investigation in those where the diagnosis remains uncertain	
	May avoid unnecessary additional central laboratory tests	
Disadvantages	Failed test rate higher using whole blood	Longer time for availability of results
	Staff training in operation and quality control	Lack of real-time access to results
	Risk of missed diagnosis if results not integrated into laboratory information system/patient record system	Delays in diagnosis, investigations and treatment
	Potential for greater diagnostic uncertainty where findings are discordant between POC and central laboratory	Unnecessary repeat testing in serial protocols where the results are not available within 1 h
	Need to establish new baseline on the central laboratory platform for high-risk patients requiring admission for serial measurements	Requires central laboratory infrastructure, staffing, equipment and training on a 24 h basis
	Potential additional cost to the local healthcare system	Limited to larger healthcare settings
		Encourages transfer of patients to Emergency Department who could be evaluated in a community or outpatient setting

Cullen et al. Eur Heart J 2025; 00: 1-11

Table 3 **Considerations prior to implementation of high-sensitivity cardiac troponin assays at the point of care**

Laboratory	ED or hospital setting	Other settings
Analytical performance evaluation	Clinical performance and safety in specific clinical environment	
Accreditation requirements, regulatory oversight, and quality assurance processes		
Maintenance, calibration and ongoing verification of instrument performance		
Training	Training, education and staff competency	
Integration with laboratory information systems, data and results monitoring.	Documentation and integration within electronic health records	Documentation and integration with electronic health records
Operational integration: workflow, contingency planning	Operational integration: workflow and turnaround times, efficiency and peak demand planning, avoidance of bottlenecks, and contingency planning.	
	Device placement and accessibility, location, power, portability, storage of cartridges, number of devices, space requirements	
	Scalability and flexibility with patient volume and clinical demands	
	Local patient assessment and management pathways	Setting-specific assessment and management pathways
	Clinical management and interpretation of results	
Interference and errors: Knowledge and management		
	Evaluation of impact of additional testing and investigations required. Mitigation of other patient delays	
Workforce impact, POC operators, staffing levels		
Staff adaptation to change and new technology		
	Environmental challenges—movement	Environmental challenges—heat, vibration, movement
Impact assessment—laboratory flow	Impact assessment—patient safety and outcomes, patient flow, disposition	
Cost evaluation—Initial investment, long-term costs, cost-benefit		
	Infection control	
Environmental considerations: Waste management and sustainability		

Point of care, POC; emergency department, ED.

cTn: analytical reliability

cTn in POCT?

- TAT cTn = ≤ 60 min.
- Type of cTn: cTnT versus cTnI
- Sample type: whole blood
  Cavé **hemolysis**: cTnI ↑ and cTnT ↓
- Contemporary versus high sensitive with proven clinical effectivity

- POCT contemporary cTn not recommended
  Exception: TAT core lab cTn > 60 min
- Not interchangeably with routine central lab method
- Cavé: hemolysis

Overall conclusion

"Diagnostic testing that is performed **near to or at the site** of the patient care with the result leading to possible **change in the care** of the patient"

- ✓ **Proven effectivity** on direct medical acting
- ✓ **Analytical reliability** of the POCT as compared to the central lab test
- ✓ **User friendly** without increasing workload

ISO 15189:2022
https://ifcc.org/ifcc-education-division/emd-committees/c-poct/

Acknowledgments

Thank you!

Colleagues Clinical Biologists AZORG

Members POCT committee AZORG

24/24 POCT team AZORG (all sites)

Expert commission POCT Sciensano

Co-chair of POCT expert working group of National Commission Clinical Biology

IFCC POCT working group

On behalf of the working group on POCT of the Belgian Commission on Clinical Biology and in cooperation with Sciensano and RBSLM

5th NATIONAL POCT POINT OF CARE TESTING SYMPOSIUM

Transforming healthcare: advances and innovations in Point-Of-Care Testing

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www.rbslm.be/2026/poct-symposium