Point of Care in Critical Biochemistry

19/10/2026

Erasmus Hoge School, Brussel
Navorming POCT medewerker/coördinator

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Belgian corresponding member C-POCT, IFCC

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

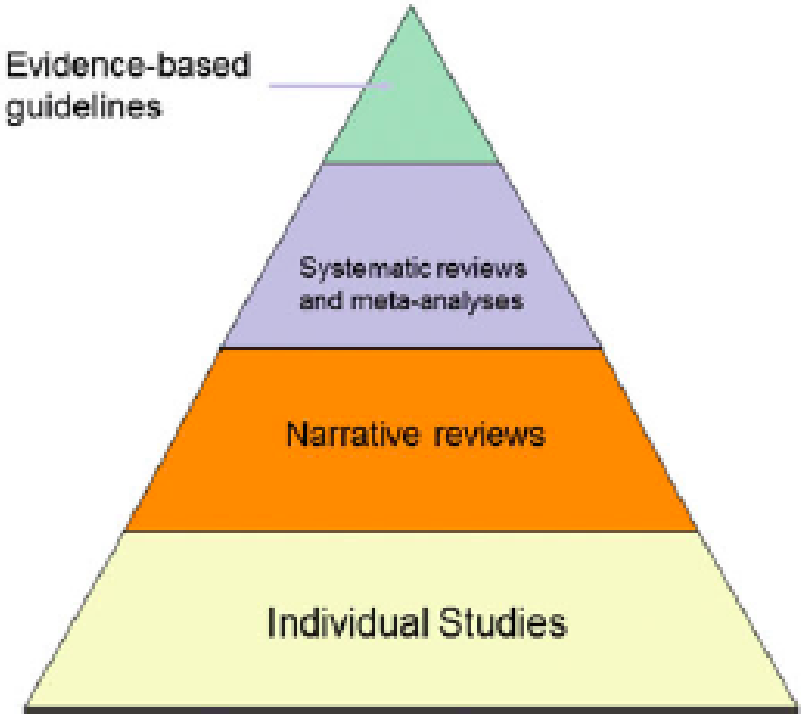


ISO 15189:2022
https://ifcc.org/ifcc-education-division/emd-committees/c-poct/

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



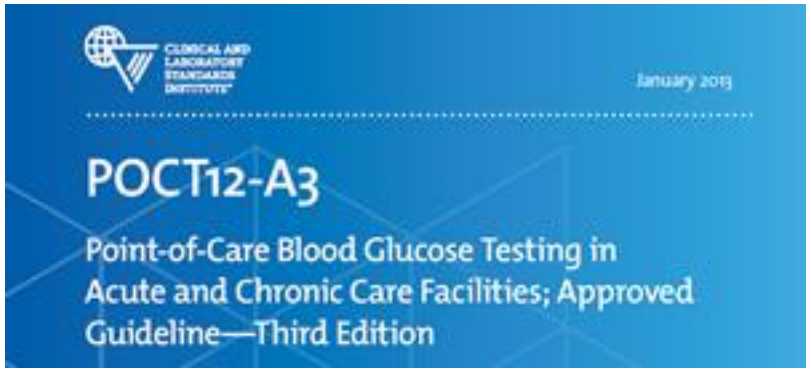
ISO 15189:2022
https://ifcc.org/ifcc-education-division/emd-committees/c-poct/

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)

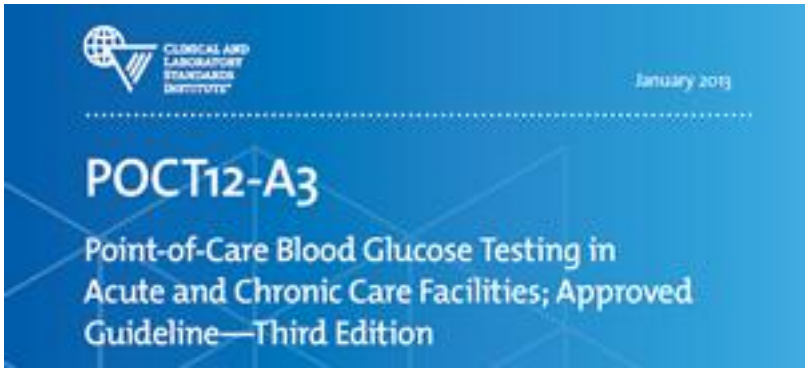
Intra- and perioperative management of blood glucose concentrations in surgical patients

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

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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

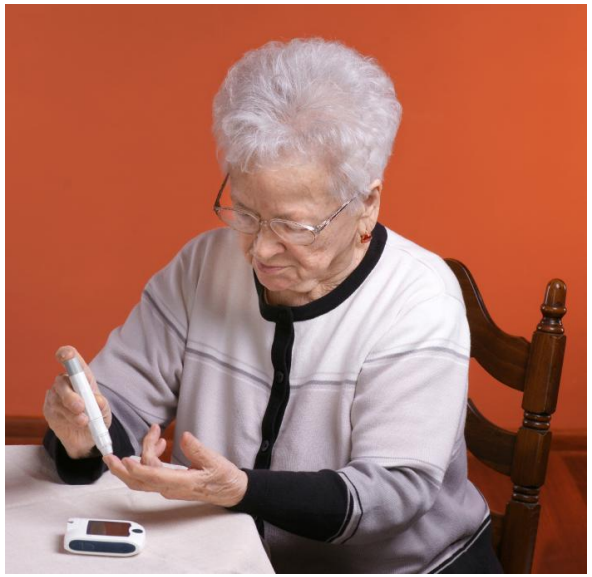
under discussion because of the risk of hypoglycemia

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

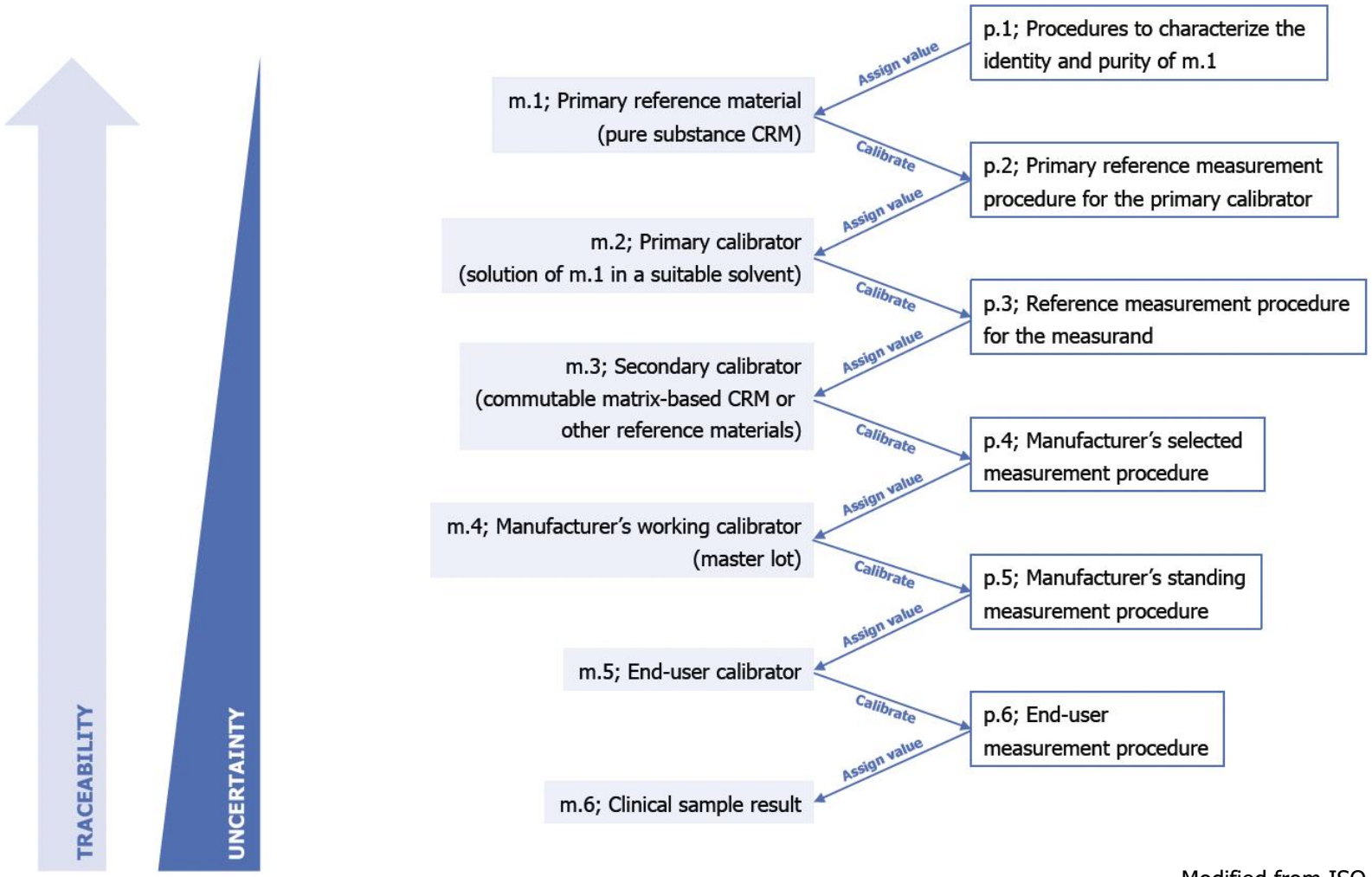
The laboratory method used for the comparison:
- imprecision ≤2.9%
- bias ≤2.2%
- total error ≤6.9%
- be traceable to a ID-GC/MS reference method

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

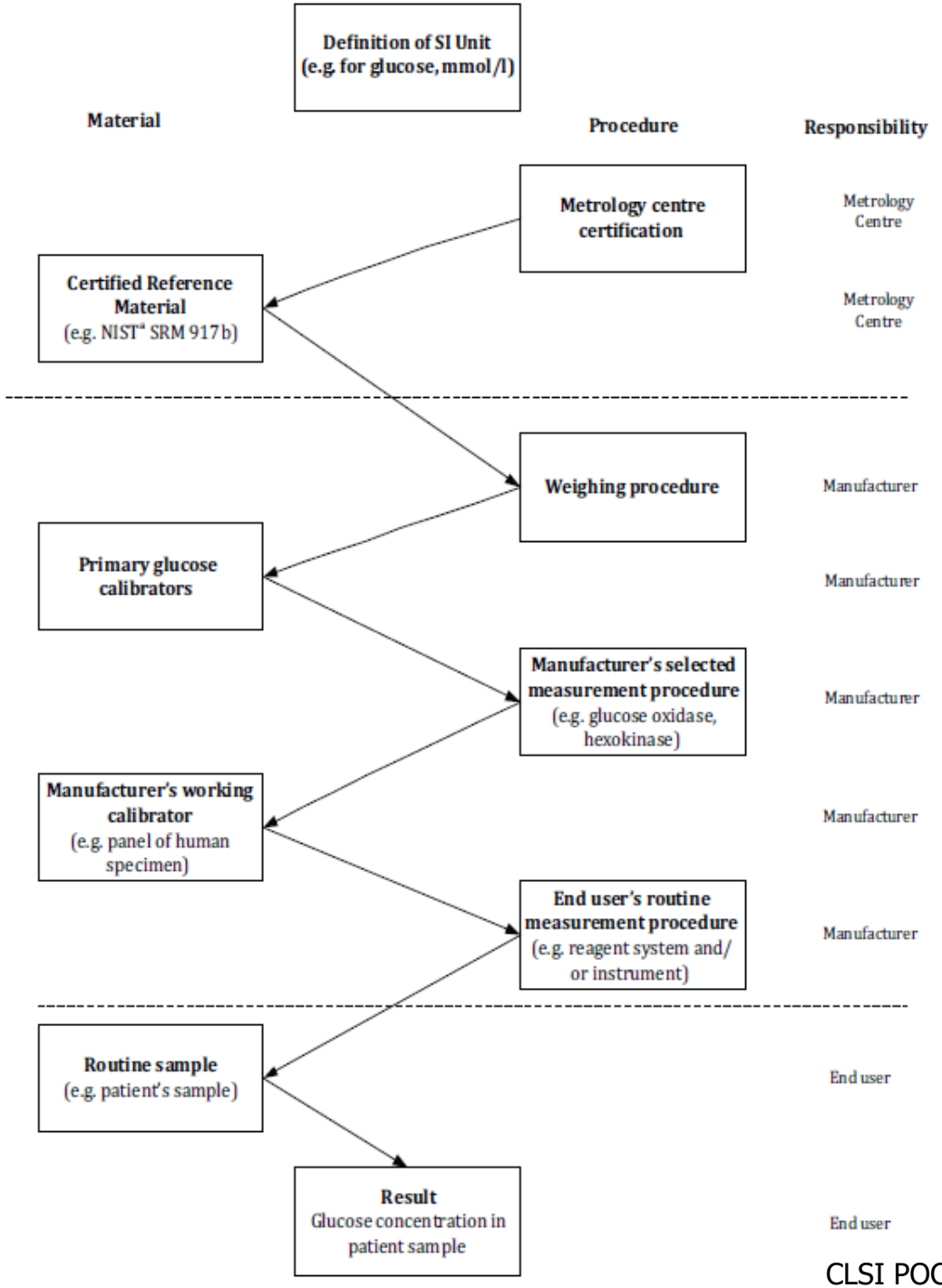


Modified from ISO 17511:2020

ID-GC/MS

Routine central lab glucose analysis (Hexokinase)

POCT glucose analysis

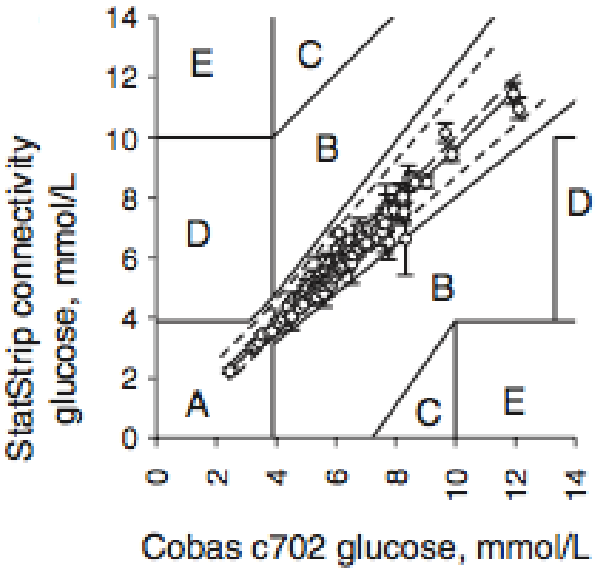


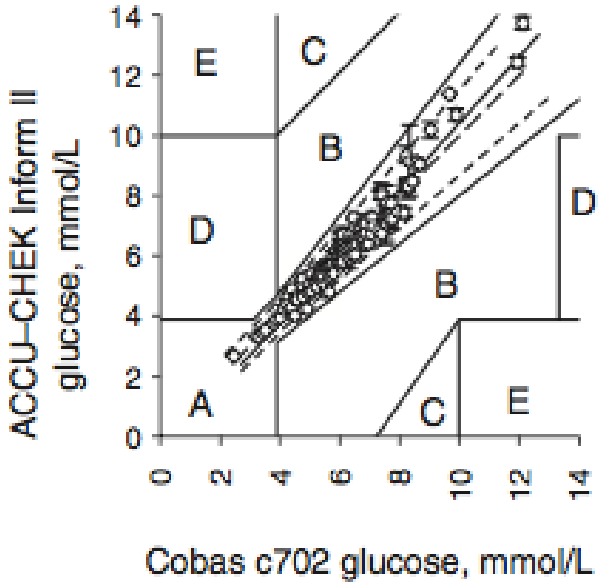
IFCC. CCLM 2013: 51: 943-952

CLSI POCT12-A3: 2013

POCT glucose: analytical reliability

Consensus error grid

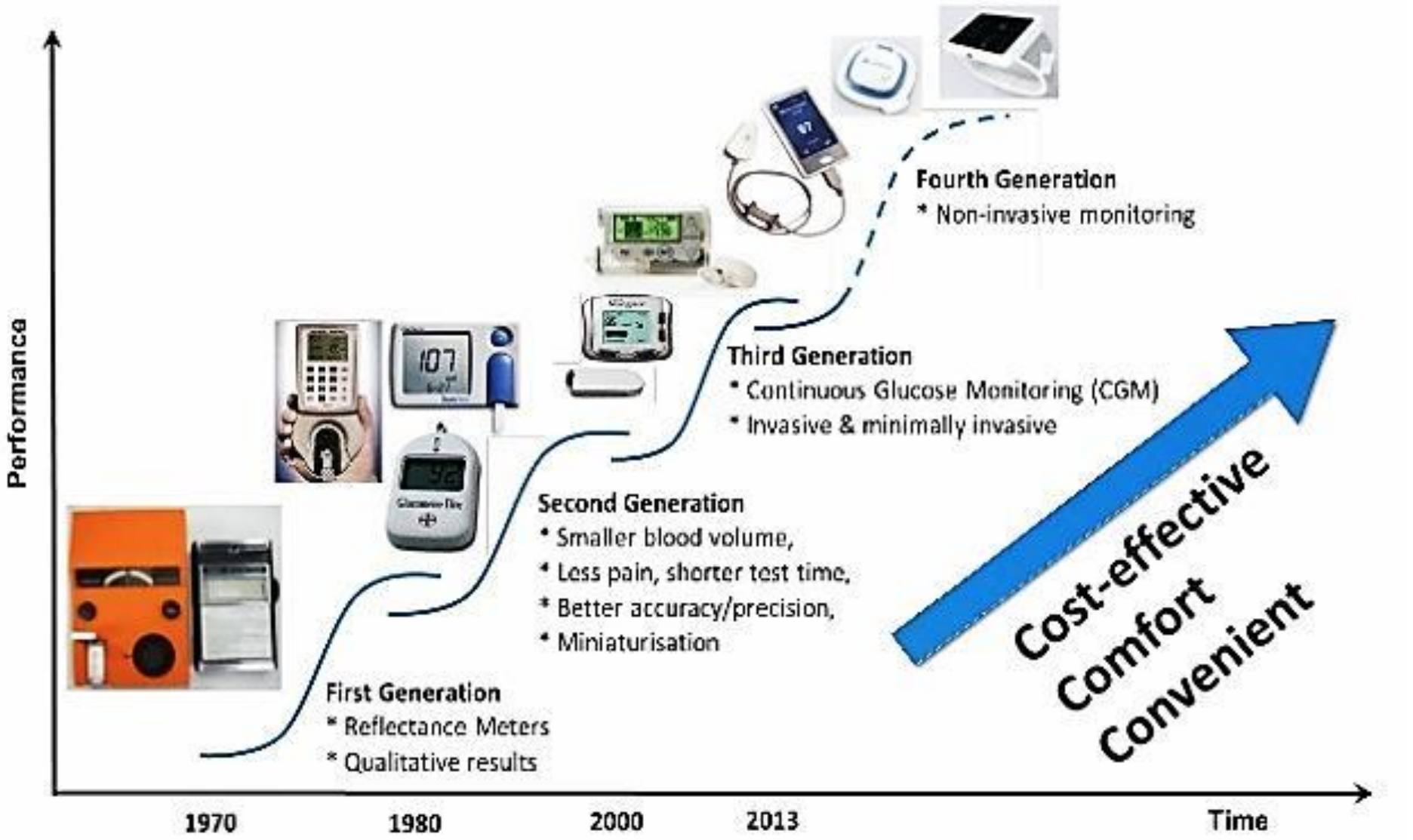




Risk level (CEG zone)	Risk to diabetic patient
A	No effect on clinical action.
B	Altered clinical action — little or no effect on clinical outcome.
C	Altered clinical action — likely to affect clinical outcome.
D	Altered clinical action — could have significant medical risk.
E	Altered clinical action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

Claerhout H *et al.* CCLM 2016; 54: 169-80

POCT glucose: analytical reliability



POCT glucose: analytical reliability

Contineous Glucose Monitoring (CGM)



FreestyleLibre



Accu-Chek



MiniMed780G

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



Dexcom G7

Glucose Pattern Insights

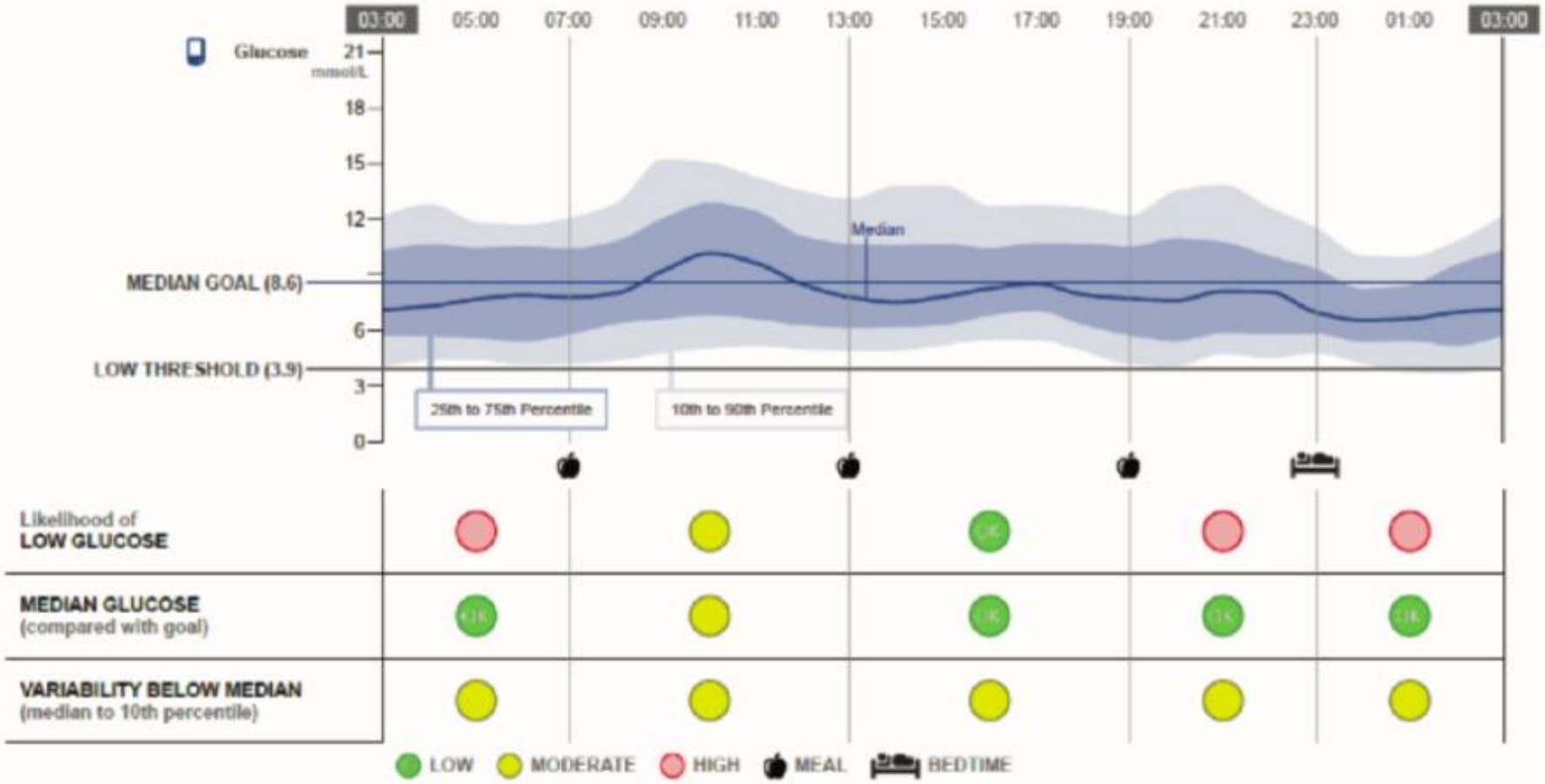
17 July 2015 - 16 October 2015 (92 days)

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)

7. Diabetes Technology: Standards of Care in Diabetes—2025

*American Diabetes Association Professional Practice Committee**

Diabetes Care 2025;48(Suppl. 1):S146–S166 | https://doi.org/10.2337/dc25-S007

Inpatient Care

Recommendations

7.31 In people with diabetes wearing personal CGM, the use of CGM should be continued when clinically appropriate during hospitalization, with confirmatory point-of-care glucose measurements for insulin dosing and hypoglycemia assessment and treatment under an institutional protocol. B

7.32 Continue use of insulin pump or AID in people with diabetes who are hospitalized when clinically appropriate, with confirmatory point-of-care blood glucose measurements for insulin dose decisions and hypoglycemia assessment and treatment. This is contingent upon availability of necessary supplies, resources, and training, ongoing competency assessments, and implementation of institutional diabetes technology protocols. C

POCT glucose: analytical reliability

Contineous Glucose Monitoring (CGM)

7. Diabetes Technology: Standards of Care in Diabetes—2025

*American Diabetes Association Professional Practice Committee**

Diabetes Care 2025;48(Suppl. 1):S146–S166 | https://doi.org/10.2337/dc25-S007

Diabetologia
https://doi.org/10.1007/s00125-026-06838-8

POSITION STATEMENT

Check for updates

An international position statement on practical approaches for inpatient continuous glucose monitoring, insulin pumps and automated insulin delivery systems in adults

Mikkel T. Olsen[1] · Elias K. Spanakis[2] · Hood Thabit[3,4] · Ketan Dhatariya[5,6] · Omar G. Mustafa[7] · Parizad Avari[8,9] · Alistair N. Lumb[10,11] · Katheleen Dungan[12] · Athena Philis-Tsimikas[13] · Kristen Kulasa[14] · David N. O'Neal[15] · Shashank R. Joshi[16] · Alexandros L. Liarakos[17,18] · Emma G. Wilmot[17,18] · Julie L. V. Shaw[19] · Roman Vangoitsenhoven[20] · Chantal Mathieu[20] · Irl B. Hirsch[21] · Priyathama Vellanki[22] · Francisco J. Pasquel[22] · Guillermo Umpierrez[22] · Rodolfo J. Galindo[23] · Ulrik Pedersen-Bjergaard[24,25] · Peter L. Kristensen[24,25] · Julia K. Mader[26] · Kirsten Nørgaard[1,25]

POCT glucose: analytical reliability

Contineous Glucose Monitoring (CGM)

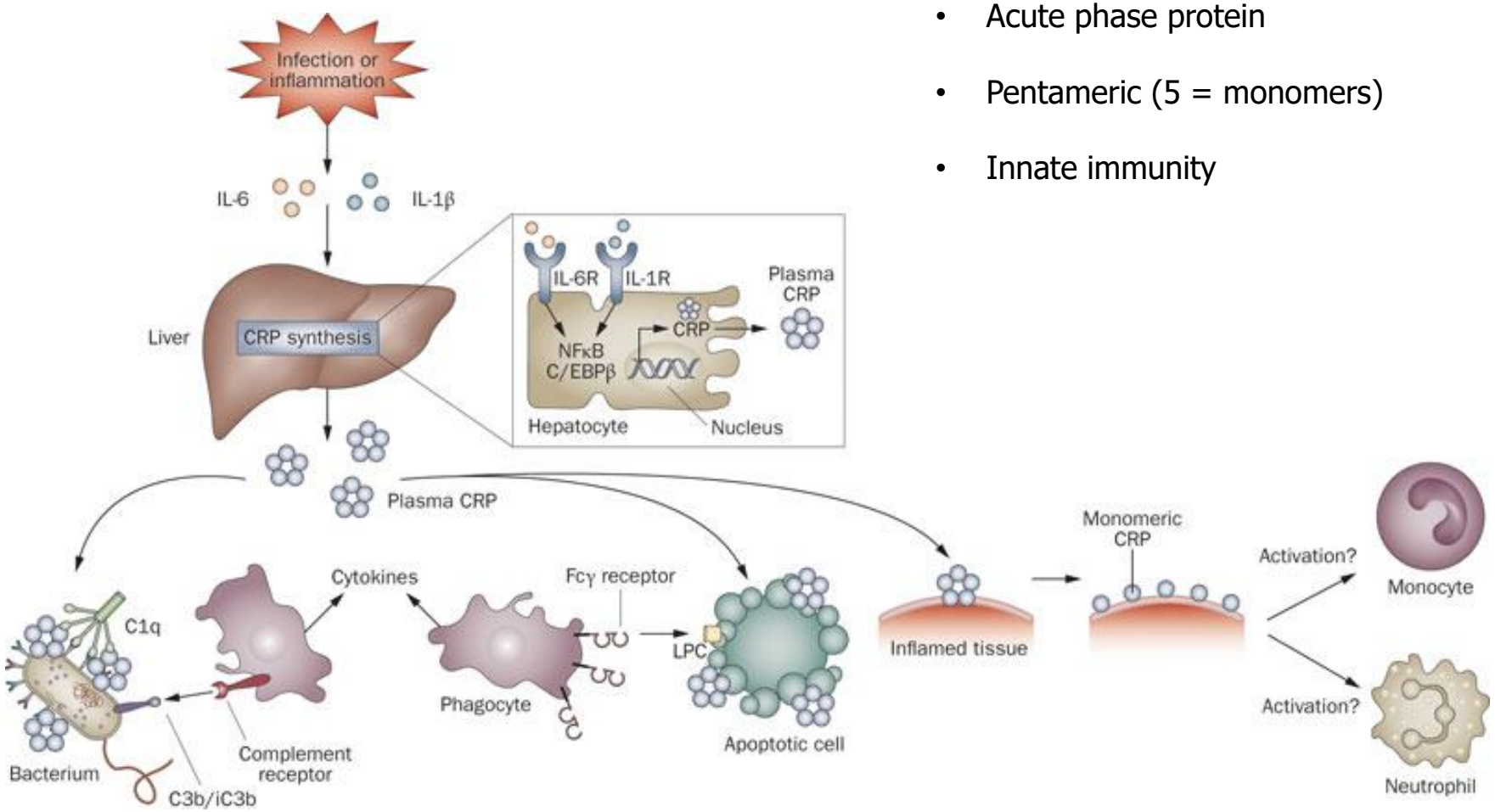
- Allowable on non-critical wards
- Verification based on comparison 3 pre-prandial results versus capillary POCT (pre-defined criteria in agreement with endocrinoly/treating physician)
- When alarm for hypo/hyper: always capillary POCT
- Cavé: interfering medicaiton (mainly acetaminophen): never use CGM results
- Restriciton on FDA approved CGM devices (< RIZIV): Abbott, Dexcom, Minimed, Roche

Specific hospital guidelines required (cfr. ADA guidelines)

Point of Care CRP

POCT CRP: guidelines

C-reactive protein

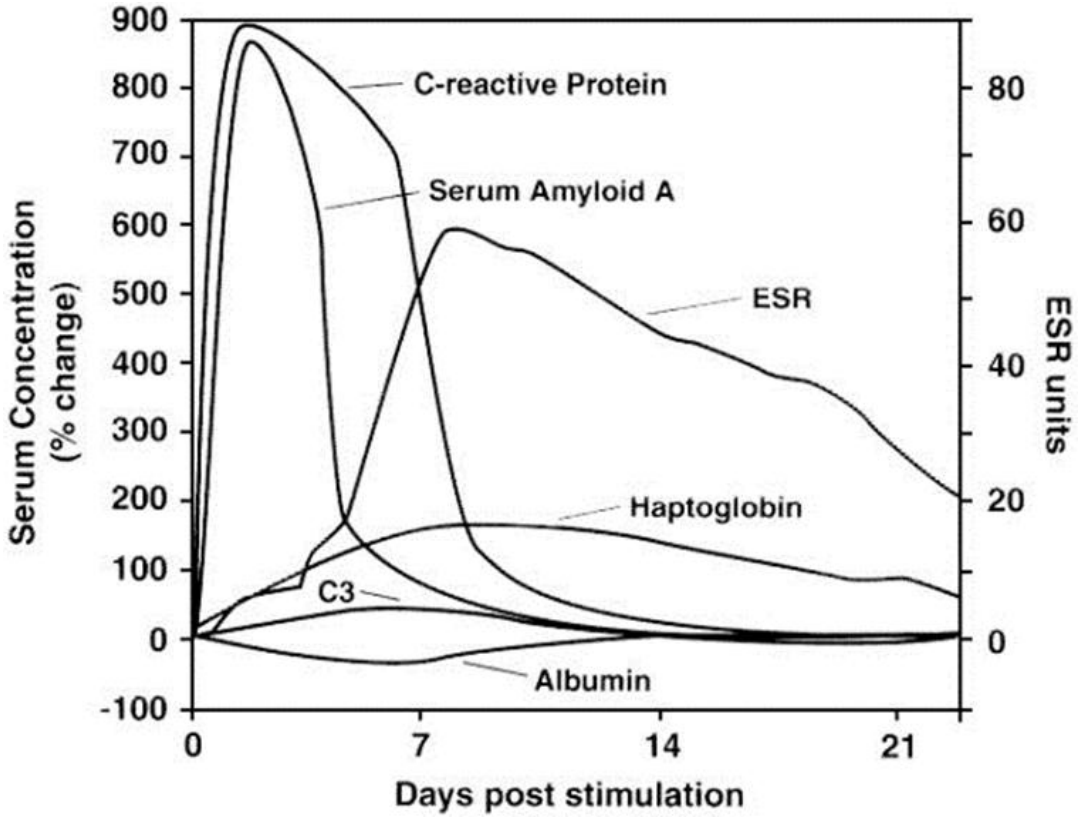


- Acute phase protein
- Pentameric (5 = monomers)
- Innate immunity

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

POCT CRP: guidelines

C-reactive protein

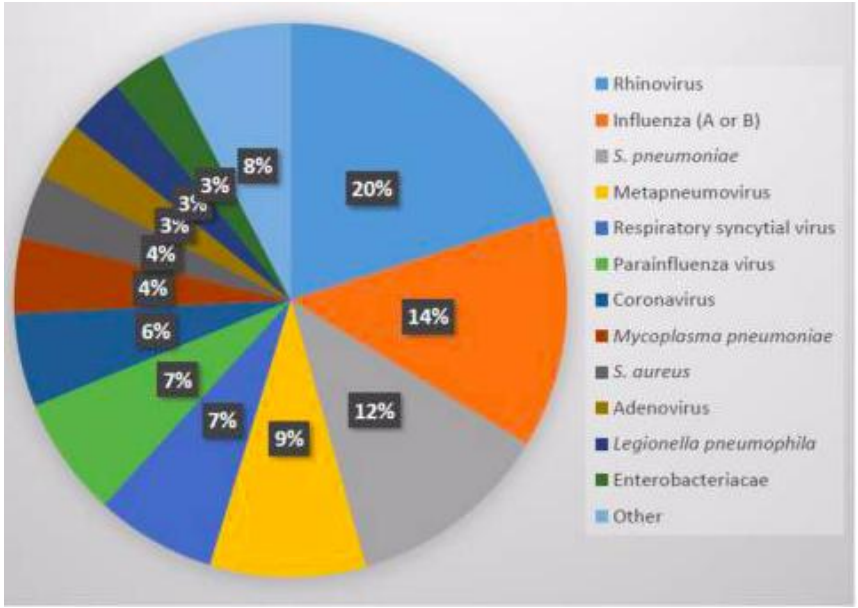


- Rapid increase of CRP, 4-6 hours after inflammation onset
- After 8 hours, doubling in concentration
  After 36-50h: peak
- $t_{1/2}$: 4-7 h

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

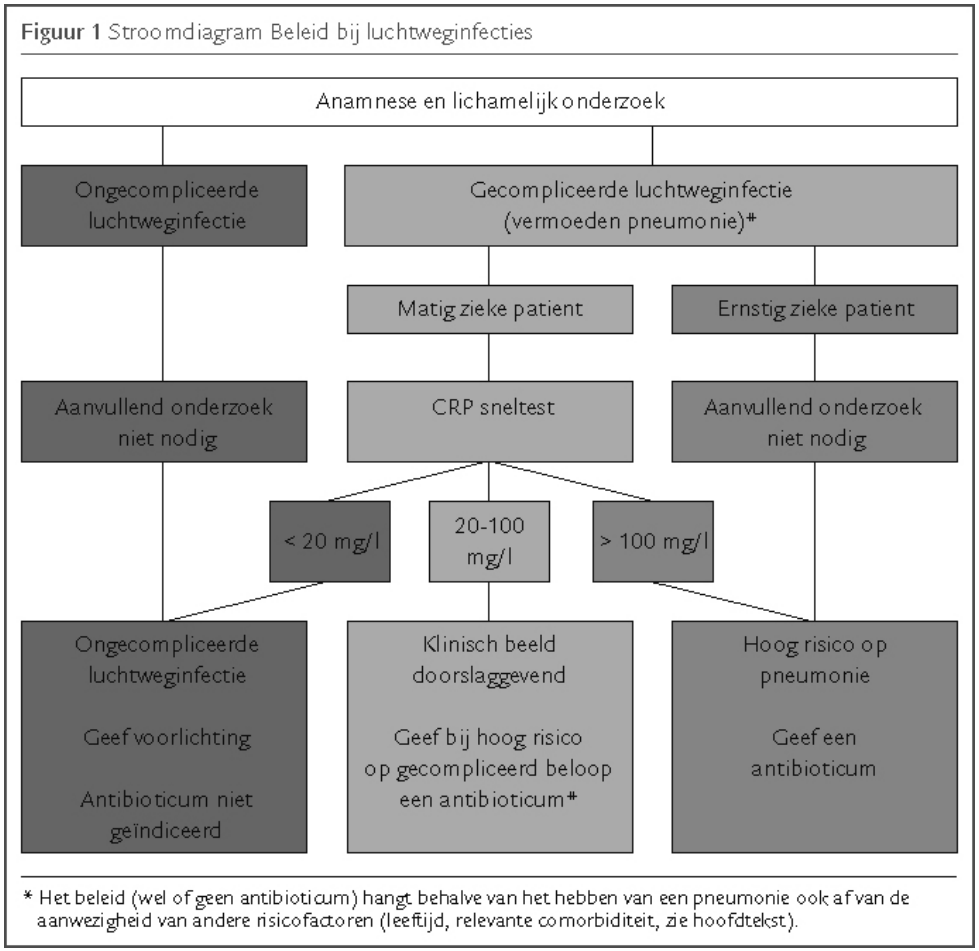
nhg Nederlands Huisartsen Genootschap

NHG-Standaard

Acuut hoesten (M78)

NHG-werkgroep:
De Bont EGPM, Greving JP, Kurver MJ, Van der Mooren FM, Van de Pol AC, Prins JM, Schot MJC, Verheij ThJM, Weersma RLS.

Versie 3.3, juli 2025



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

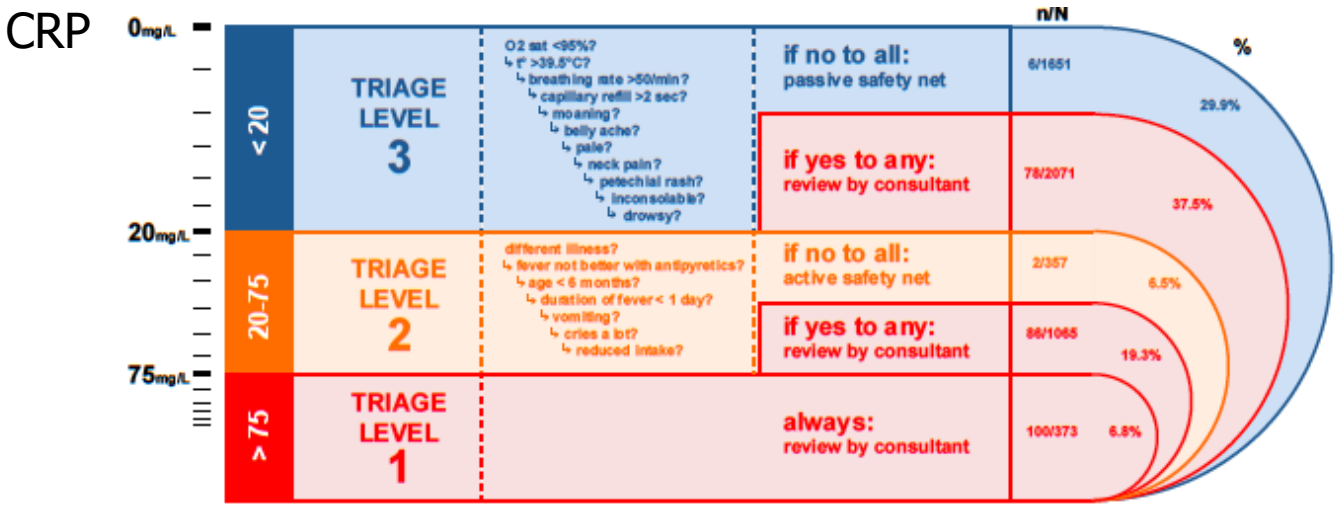
POCT CRP: guidelines

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-e10
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



EVALUATION OF THE ORGANIZATIONAL CHALLENGES IMPLEMENTING C-REACTIVE PROTEIN POINT-OF-CARE TESTING

IN PRIMARY CARE FOR ADULTS WITH ACUTE COUGH IN BELGIUM

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

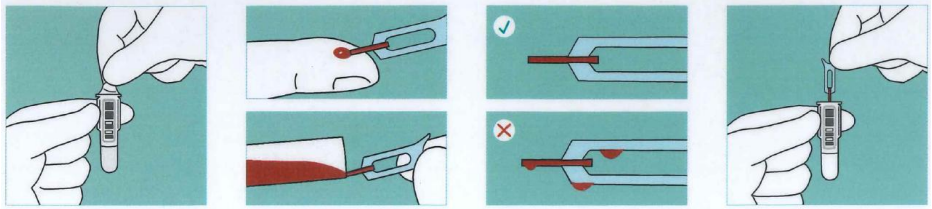
Van Hoovels et al. CCA 2024; 119737

POCT CRP: analytical reliability

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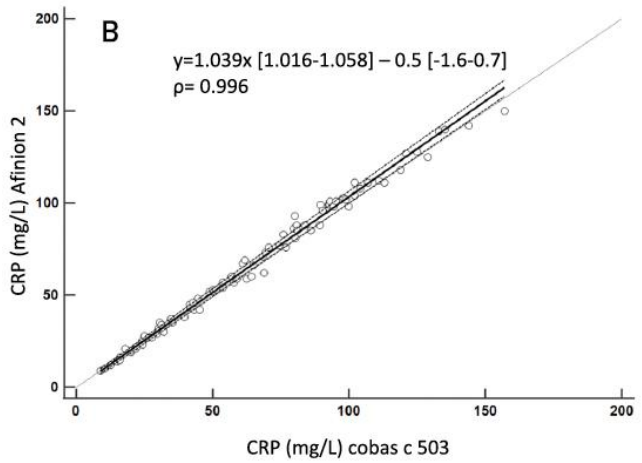


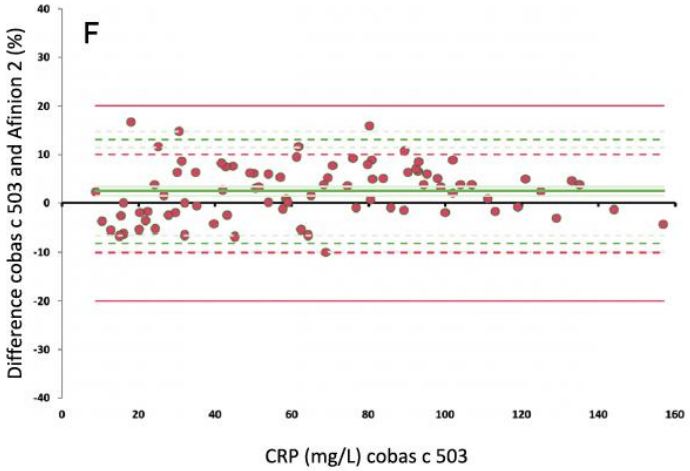
Imprecisie QuikRead na staalname met gecalibreerde pipet < 10%

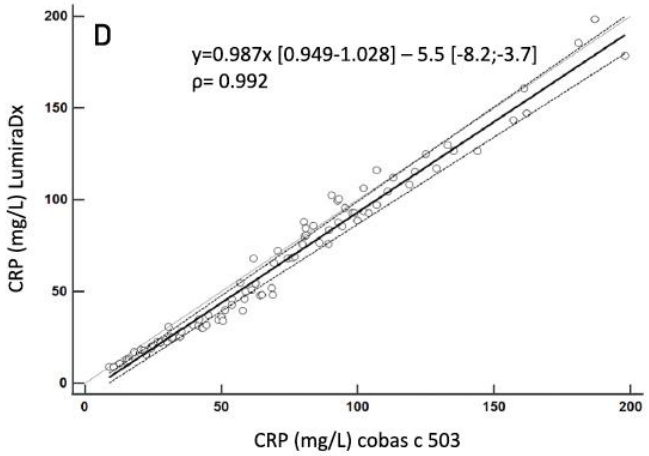
Van Hoovels et al. CCA 2024; 119737

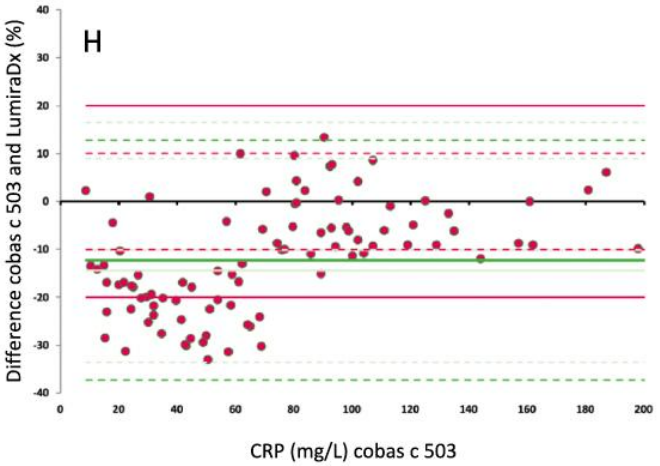
POCT CRP: analytical reliability

Method comparison (CLSI EP9-A2)









POCT CRP: analytical reliability

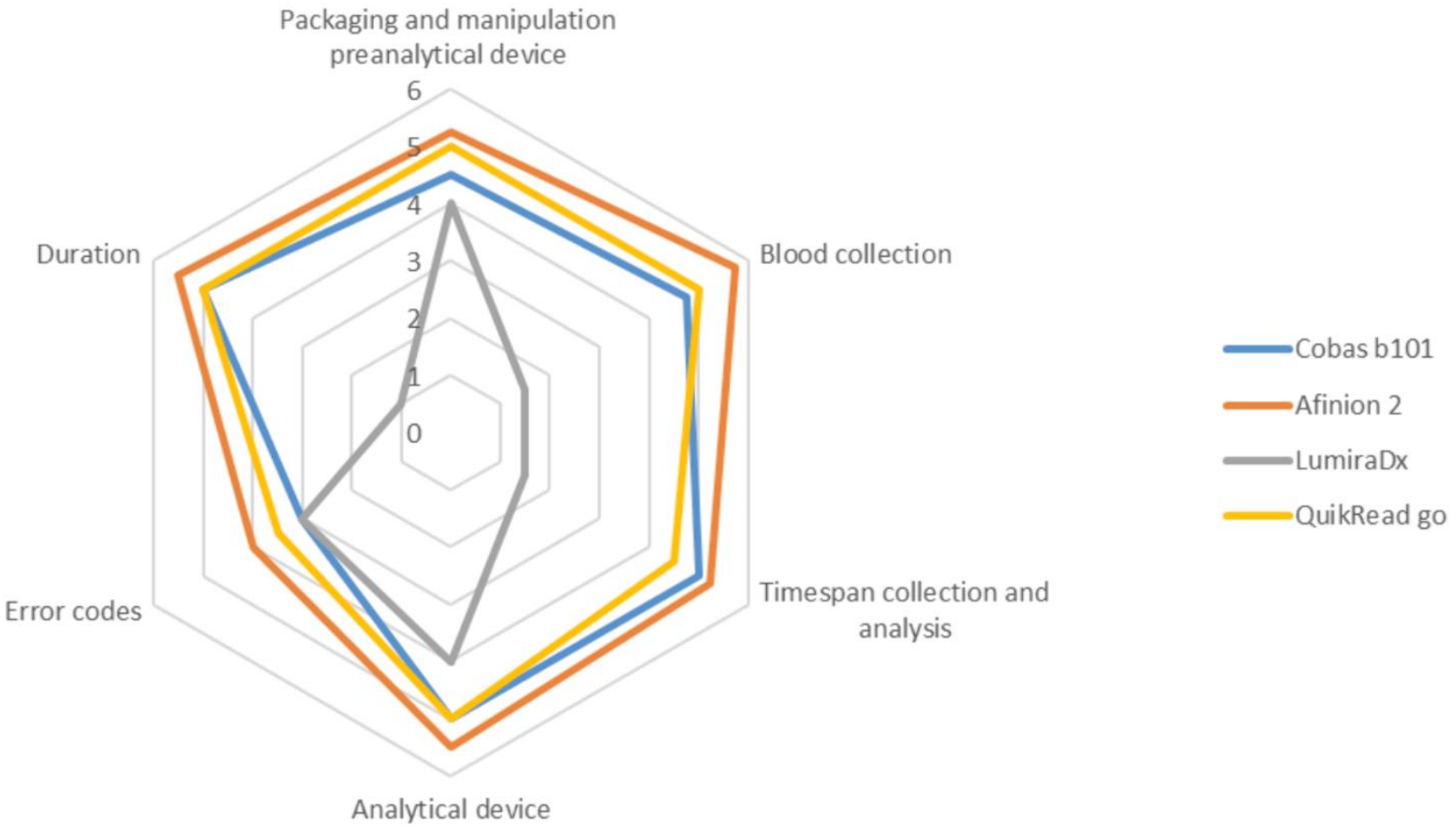
Method comparison (CLSI EP9-A2)

	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



EVALUATION OF THE ORGANIZATIONAL CHALLENGES IMPLEMENTING C-REACTIVE PROTEIN POINT-OF-CARE TESTING

IN PRIMARY CARE FOR ADULTS WITH ACUTE COUGH IN BELGIUM

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.

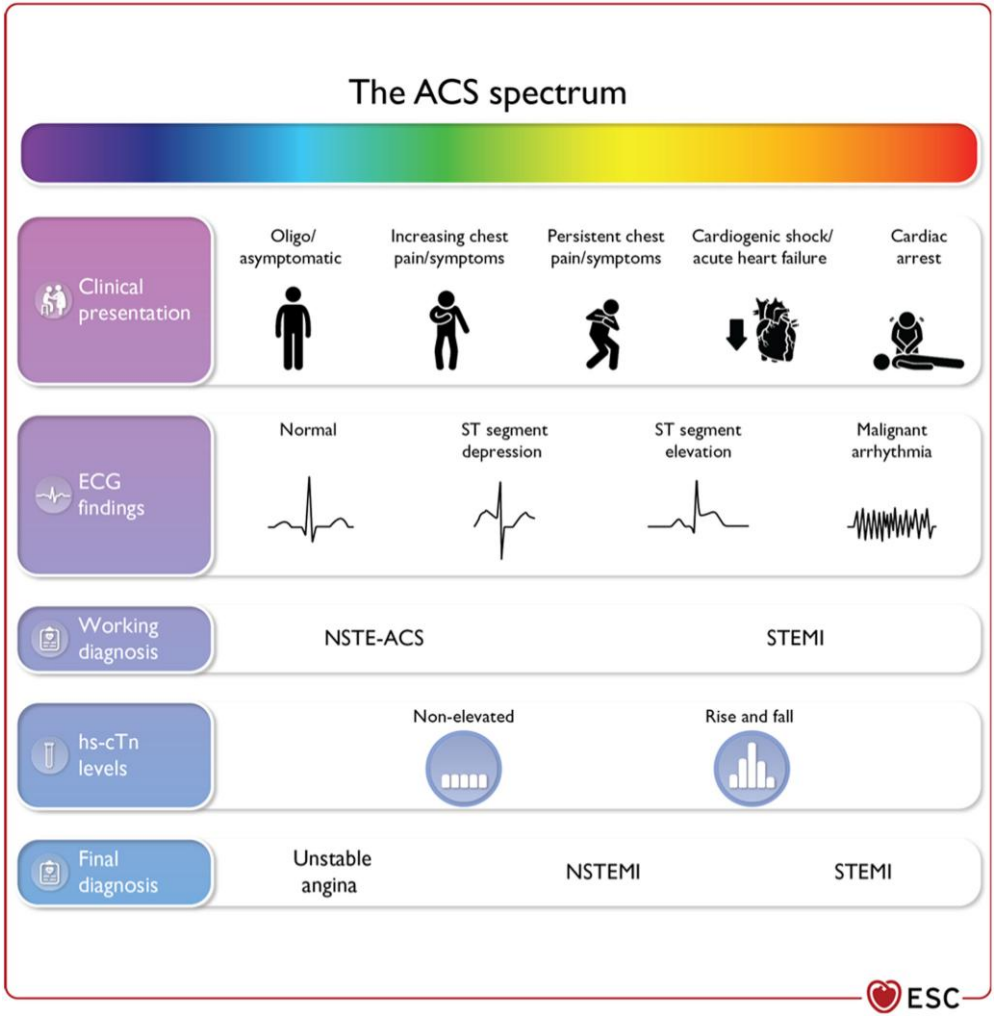
The study concludes that while the implementation of CRP POCT devices in Belgian general practice is promising, careful consideration of organizational, financial, and training aspects is essential for large-scale adoption. The findings offer policymakers valuable insights into balancing the costs of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

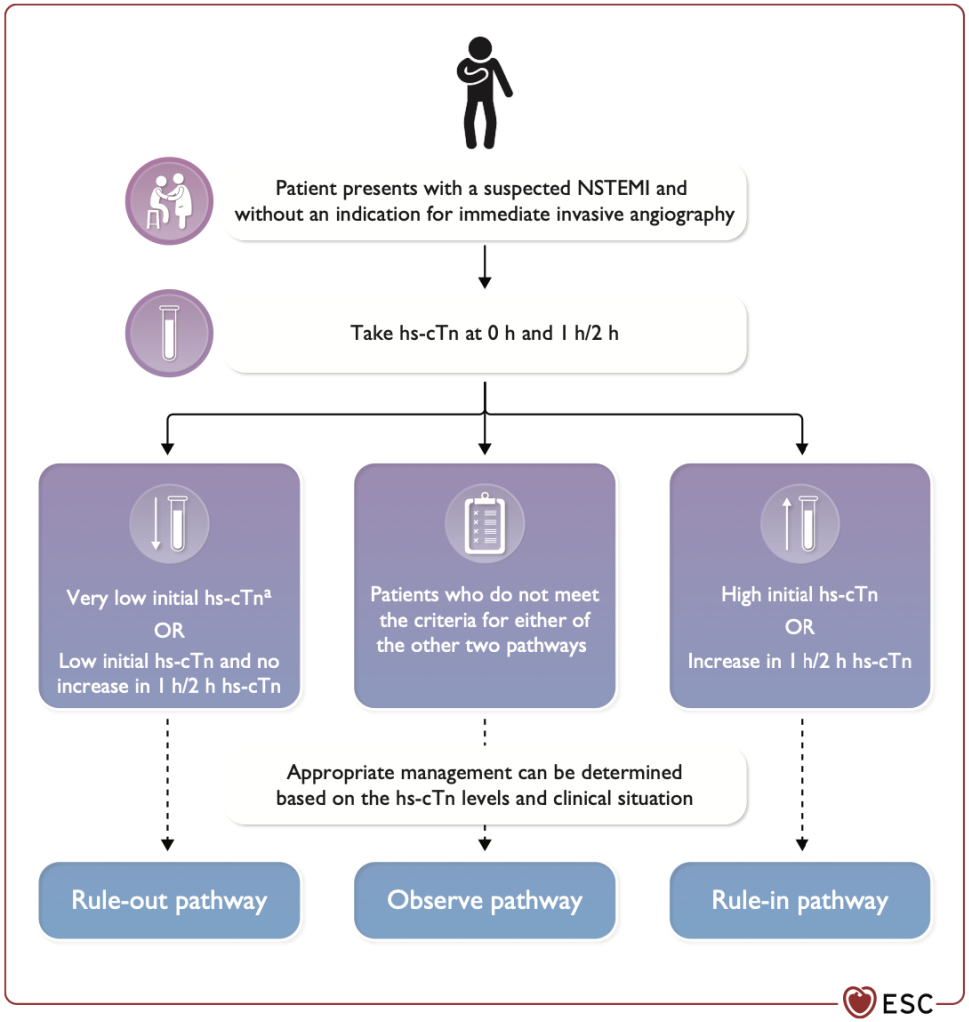
< 10 min

< 60 min

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

ACS: diagnostic guidelines

ESC guidelines ACS 2023



Hs cTn 0h and 1h/2h

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

POCT cTn: analytical reliability

Analytical performance criteria

Clinical Chemistry 64:4
645-655 (2018)

Special Report

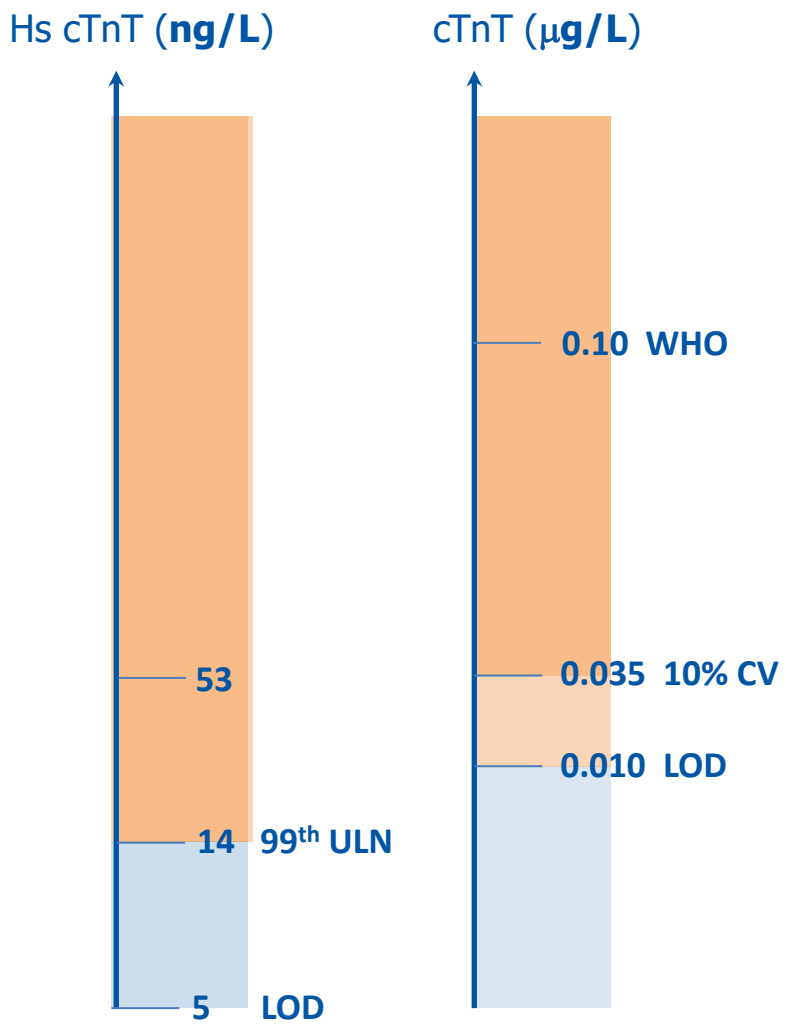
Clinical Laboratory Practice Recommendations for the Use of Cardiac Troponin in Acute Coronary Syndrome: Expert Opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-Markers of the International Federation of Clinical Chemistry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

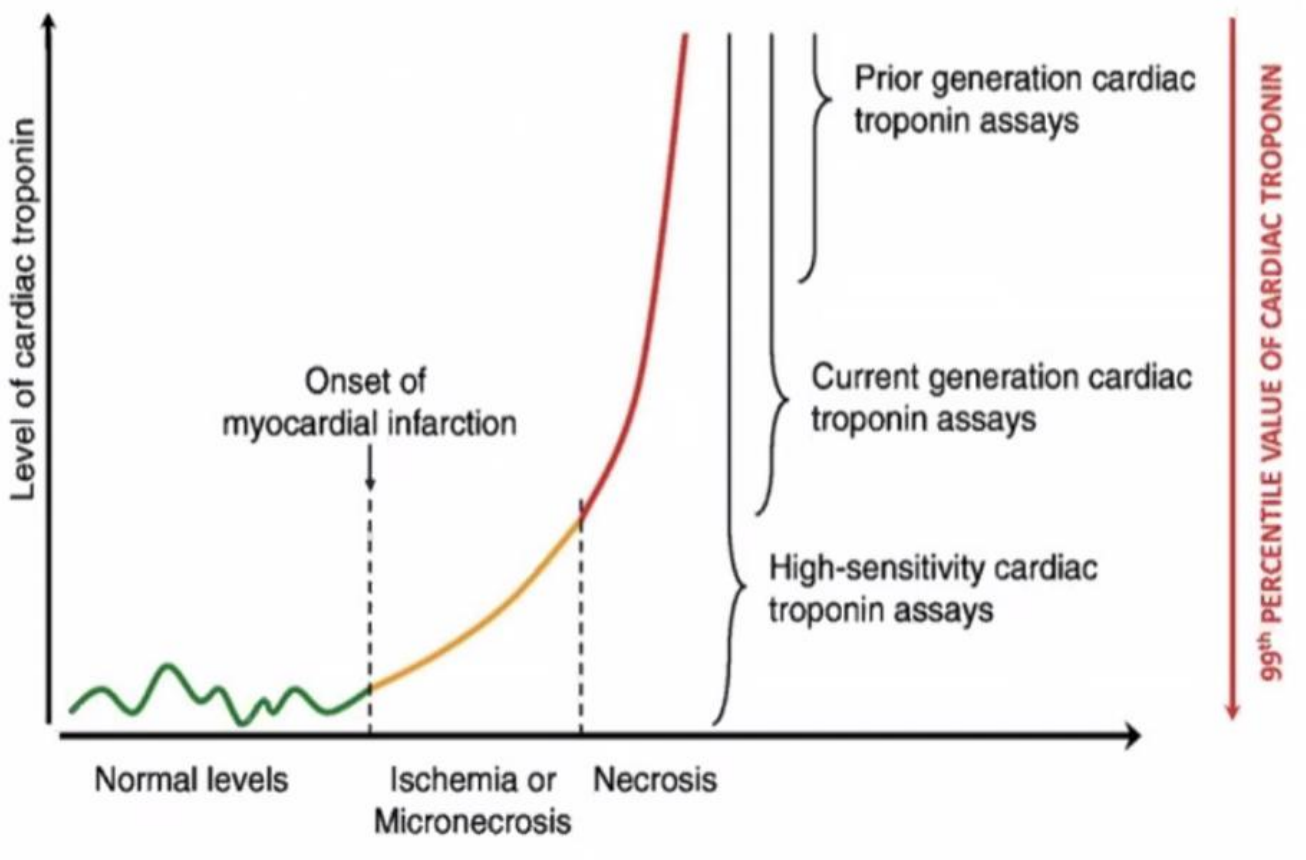
Pathogenic
Likely pathogenic
Likely normal

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

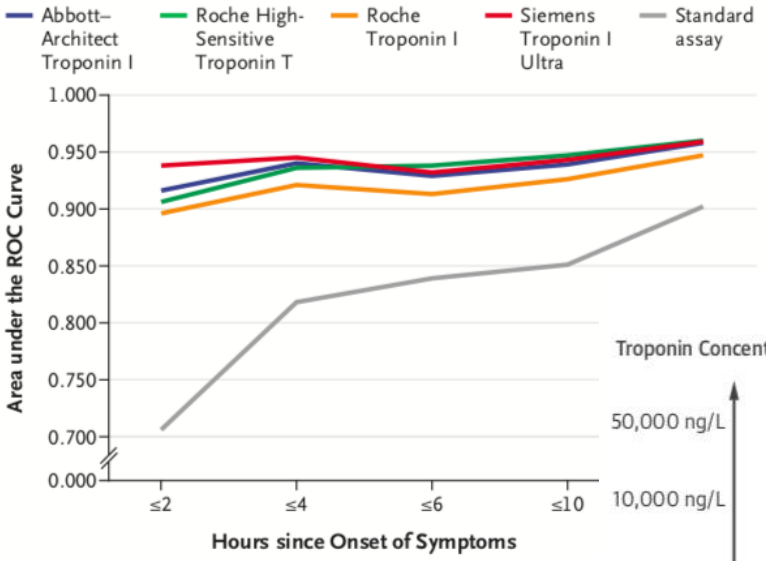
ACS: diagnostic guidelines

Analytical performance criteria

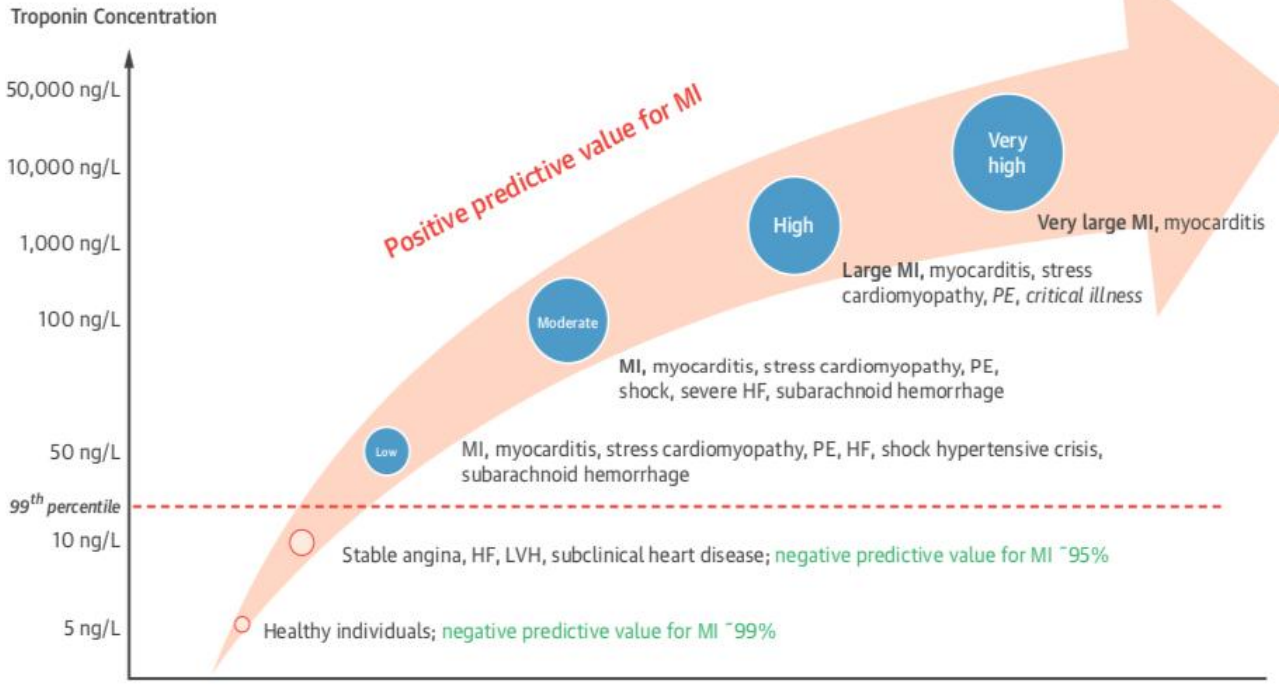


ACS: diagnostic guidelines

Analytical performance criteria



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

POCT cTn: analytical reliability

ESC guidelines ACS 2023



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 sus-

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

!! cTn methods are not interchangeable

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

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
- When several cTn assays are used within one institution, the laboratory information system should use **different labels for requesting and reporting** and the relevant **cut-off** should be communicated for each assay. **Serial measurements** should be performed on one assay.

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

DE GRUYTER Clin Chem Lab Med 2026; aop

Review

Paul Collinson, Leo Lam, John W. Pickering, Robert Christenson, Lieve Van Hoovels, Lena Jafri, Louise Cullen, Allan S. Jaffe, Fred S. Apple, Ola Hammarsten, Torbjørn Omland, Yader Sandoval, Nicholas L. Mills, Martin Than, Vanessa Buchan, Sverre Sandberg and Kristin M. Aakre*

Considerations and pragmatic strategies for implementation of point of care testing for high sensitivity cardiac troponin into the acute care setting

Cooperation between IFCC-C-CB and IFCC-C-POCT

Collison et al. CCLM 2026; doi.org/10.1515/cclm-2026-0210

Point of Care Creatinine

POCT creatinine: guidelines

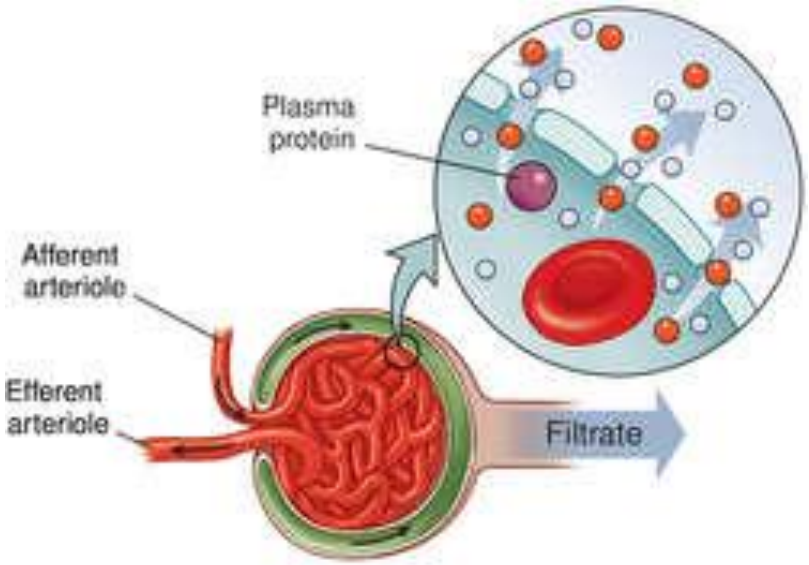
Definition glomerular filtration rate

GFR= (U x V)/P

U= urine concentration

P= plasma concentration

V= volume



Perfect marker:

- Stabile concentration plasma
- Free filtration through glomeruli
- No secretion, reabsorption, metabolisation … in kidney

POCT creatinine: guidelines

Calculation of GFR

Cockcroft-Gault

$$GFR = \frac{(140 - age) * weight}{72 * [creatinin]_{plasma}} * 0{,}85 \text{ if women}$$

MDRD

$$GFR = 170 * [creat]_{plasma}^{-0.999} * age^{-0.176} * [BUN]^{-0.170} * [Albumin]^{0.318}$$

$$* 0{,}762 \text{ if women} * 1{,}180 \text{ if Afro-Am}$$

= Modification of Diet in Renal Disease

CKD-EPI

men

[creatinine] $_{plasma}$

< 0.9 mg/dL $CKD\text{-}EPI = 141 \times (cr_s/0.9)^{-0.411} \times 0.993^{leeftijd}$

>= 0.9 mg/dL $CKD\text{-}EPI = 141 \times (cr_s/0.9)^{-1.209} \times 0.993^{leeftijd}$

women

[creatinine] $_{plasma}$

< 0.7 mg/dL $CKD\text{-}EPI = 144 \times (cr_s/0.7)^{0.329} \times 0.993^{leeftijd}$

>= 0.7 mg/dL $CKD\text{-}EPI = 144 \times (cr_s/0.7)^{1.209} \times 0.993^{leeftijd}$

POCT creatinine: guidelines

Contrast and acute kidney injury

PC-AKI

Post-contrast acute kidney injury (any AKI <48-72h)

CA-AKI

Contrast-associated acute kidney injury (any AKI <48h)

CI-AKI

Contrast-induced acute kidney injury (causal link)

KDIGO AKI Staging	
Stage	Serum Creatinine Criteria
1	1.5–1.9 times baseline serum creatinine
	OR
	Increase in serum Cr ≥ 0.3 mg/dL (≥26.5 umol/l)

American College of Radiology™

NATIONAL KIDNEY FOUNDATION®

POCT creatinine: guidelines

Risk of CA-AKI

- **Older studies:**
  - ~5% (general)
  - Up to 30% (renal dysfunction)
- **Recent studies:**
  - 0–2% (general)
  - Up to 17% (severe renal dysfunction)

eGFR (mL/min/1.73 m²)	CA-AKI Risk
≥60	~5%
45 - 59	~10%
30 - 44	~15%
<30	~30%

→ Risk of AKI↑ if kidney function↓

- **Conflicting evidence:**
  - No CI-AKI at any CKD stage
  - Risk of GFR↓↓↓
- No risk: eGFR ≥45 mL/min/1,73m²
- Uncertainty: eGFR <30 mL/min/1,73m²

eGFR (mL/min/1.73 m²)	CI-AKI Risk
≥45	~0%
30 - 44	0% - 2%
<30	0% - 17%

Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. Kidney Int. 2024;105(4S):S117-S314
Davenport, Matthew S et al. Kidney Med. 2020;2(1):85-93

POCT creatinine: guidelines

Prevention of CA-AKI



ESUR Contrast Media Safety Commitee Guidelines 2025

Guidelines 2025

Contrast Media Safety Committee

European Society of Urogenital Radiology

Measurement of renal function

Measure eGFR before administering intravascular iodine-based contrast medium either
(a) in all patients, or
(b) in patients who have a history of

- Renal disease (eGFR < 60 ml/min/1.73 m2, but not in patients receiving dialysis treatment, compare note above)
- Kidney surgery
- Proteinuria
- Hypertension
- Hyperuricemia
- Diabetes mellitus

Estimated glomerular filtration rate (eGFR), calculated from the serum creatinine (sCr), is the recommended method to estimate renal function before contrast agent administration.

→ Adults: CKD-EPI
→ Children: revised Schwartz

Guidelines 2025

Contrast Media Safety Committee

European Society of Urogenital Radiology

Patient-related risk factors

- eGFR less than 45 ml/min/1.73 m² before intra- arterial contrast medium administration with first pass renal exposure or in ICU patients.
- eGFR less than 30 ml/min/1.73 m² before intravenous contrast medium or intra-arterial contrast medium administration with second pass renal exposure.
- Known or suspected acute renal failure.

Procedure-related risk factors

- Large doses of contrast medium given intra-arterially with first pass renal exposure.
- Multiple contrast medium injections within 48-72 hours.

At-risk patients (see above)

- Consider an alternative imaging method not using iodine-based contrast media.
- Intravenous saline and bicarbonate protocols have similar efficacy for preventive hydration.

Timing of eGFR measurement

- Within 7 days before contrast medium administration in patients with an acute disease, an acute deterioration of a chronic disease, or who are hospital inpatients.
- Within 3 months before contrast medium administration in all other patients.

Guidelines 2025

Contrast Media Safety Committee

European Society of Urogenital Radiology

What if there is no recent eGFR available?

Emergency examinations

Identify at-risk patients (see above) if possible:

- Determine eGFR if the procedure can be deferred until the result is available without harm to the patient.
- If eGFR cannot be obtained, follow the protocols for patients with eGFR less than 45 ml/min/1.73 m2 for intra-arterial administration with first pass renal exposure and eGFR less than 30 ml/min/1.73 m2 for intravenous administration and intra-arterial administration with second pass renal exposure as closely as clinical circumstances permit.

→ Potential for indirect harm related to delayed diagnosis and misdiagnosis

POCT creatinine: guidelines



NICE guidelines. POCT creatinine before CT imaging with IV contrast. November 2019

POCT creatinine: analytical reliability

1 Recommendations

1.1 Point-of-care creatinine devices ABL800 FLEX, i–STAT Alinity and StatSensor, which calculate estimated glomerular filtration rate (eGFR), are recommended to assess kidney function to guide decisions on whether to use intravenous contrast during an outpatient CT scan in adults. They should only be used when current practice is that a recent eGFR result must be available before a person has a CT scan with intravenous contrast and if all the following apply:

- a person presents for a CT scan without a recent eGFR result
- the person has risk factors for acute kidney injury
- clear governance structures for point-of-care testing are in place.

1.2 Take age, sex and ethnicity into account when assessing risk of acute kidney injury using a questionnaire-based tool (see section 4.13).

1.3 Point-of-care creatinine devices ABL90 FLEX PLUS, Dri–chem NX500, epoc Blood Analysis System, and Piccolo Xpress are not recommended to assess kidney function to guide decisions on whether to use intravenous contrast during an outpatient CT scan. This is because there are insufficient data to assess their diagnostic accuracy.

1.4 Further research is recommended to:

- better understand the level of risk of contrast-induced acute kidney injury (see section 5.1)
- identify the most appropriate tool for identifying risk factors (see section 5.2)
- monitor the effect of implementation on patient experience and efficiency in radiology departments (see section 5.3).

NICE guidelines. POCT creatinine before CT imaging with IV contrast. November 2019

POCT creatinine: analytical reliability

Beverly Snaith*, Martine A. Harris, Bethany Shinkins, Marieke Jordaan, Michael Messenger and Andrew Lewington

Point-of-care creatinine testing for kidney function measurement prior to contrast-enhanced diagnostic imaging: evaluation of the performance of three systems for clinical utility

Background: Acute kidney injury (AKI) can occur rarely in patients exposed to iodinated contrast and result in contrast-induced AKI (CI-AKI). A key risk factor is the presence of preexisting chronic kidney disease (CKD); therefore, it is important to assess patient risk and obtain kidney function measurement prior to administration. Point-of-care (PoC) testing provides an alternative strategy but there remains uncertainty, with respect to diagnostic accuracy and clinical utility.



StatSensor
(Nova Biomedical, USA)



iSTAT
(Abbott, USA)



ABL800 FLEX PLUS
(Radiometer, Netherlands)

Snaith B et al. Clin Chem Lab Med. 2018;56(8):1269-1276

POCT creatinine: analytical reliability

Beverly Snaith*, Martine A. Harris, Bethany Shinkins, Marieke Jordaan, Michael Messenger and Andrew Lewington

Point-of-care creatinine testing for kidney function measurement prior to contrast-enhanced diagnostic imaging: evaluation of the performance of three systems for clinical utility

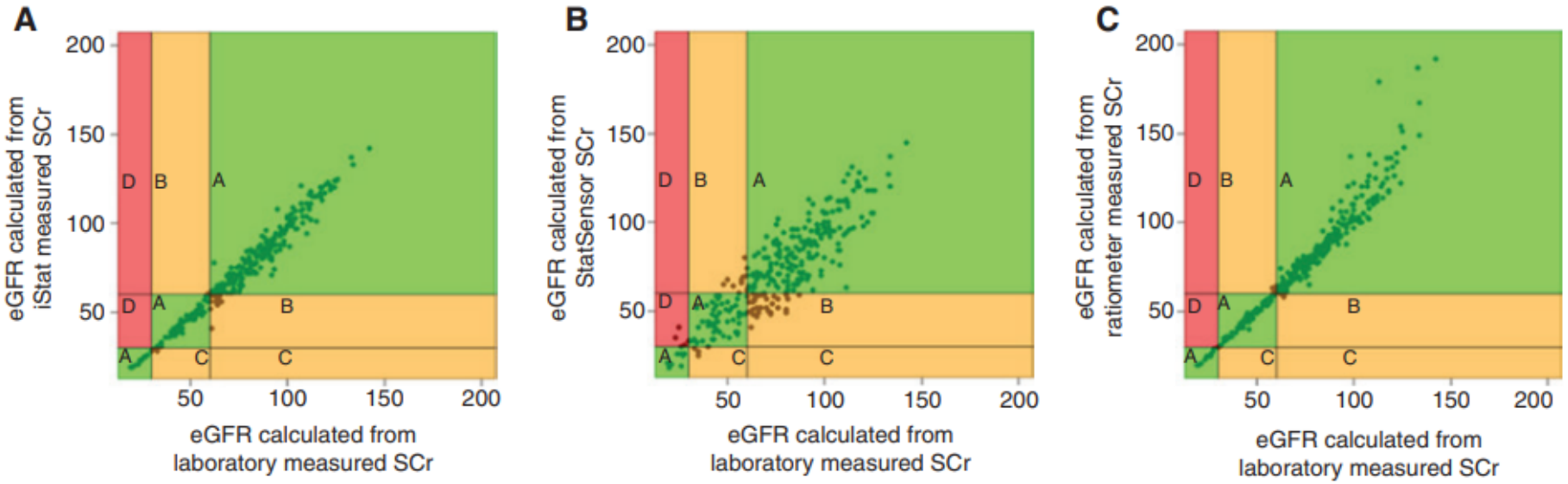
Table 2: Descriptive and method comparison statistics for patient creatinine values (PoC devices compared with the laboratory reference standard).

	Mean (SD)	Range	*r*	Mean bias (95% CI)	95% Limits of agreement		Passing-Bablok		Total analytical error
					Lower (95% CI)	Upper (95% CI)	Constant Error (95% CI)	proportional error (95% CI)	
Laboratory reference standard, µmol/L	92 (34)	38–302	–	–	–	–	–	–	–
iSTAT, µmol/L	96 (36)	35–323	0.985	3.88 (3.14 to 4.62)	−8.8 (−10.06 to −7.54)	16.6 (15.30 to 17.82)	−3.289 (−5.029 to −1.572)	1.079 (1.060 to 1.098)	−6.80 to 14.56
StatSensor, µmol/L	95 (35)	44–330	0.891	3.56 (1.75 to 5.37)	−27.7 (−30.80 to −24.60)	34.8 (31.72 – 37.92)	0.778 (−6.103 to 6.217)	1.022 (0.957 to 1.103)	−22.75 to 29.87
ABL800 FLEX, µmol/L	91 (33)	37–304	0.991	−0.86 (−1.37 to −0.35)	−9.6 (−10.52 to −8.78)	7.9 (7.06 to 8.81)	−0.046 (−1.000 to 1.538)	0.992 (0.975 to 1.000)	−8.26 to 6.54

Snaith B et al. Clin Chem Lab Med. 2018;56(8):1269-1276

Table 4: Patient management implications of concordance between eGFR risk stratification based on UK guidelines during data collection [1].

Zone	Implication on management decision	i-STAT no (%)	StatSensor no (%)	ABL800 FLEX no (%)
A	Correct risk classification – appropriate management	282 (94.0)	250 (83.3)	297 (99.0)
B	Incorrectly classified, but no implication for clinical management	16 (5.3)	42 (14.0)	3 (1.0)
C	Incorrect classification, potential for unnecessary prophylaxis or with-holding of contrast	2 (1.0)	4 (1.3)	0
D	Incorrect classification and potential for increased risk of CI-AKI due to insufficient prophylaxis	0	4 (1.3)	0



Snaith B et al. Clin Chem Lab Med. 2018;56(8):1269-1276

POCT creatinine: analytical reliability

Evaluation of POCT equipment



iSTAT
(Abbott, USA)



StatSensor
(Nova Biomedical, USA)



STAT Profile Prime+



epoc
(Siemens, UK)



ABL90 Flex Plus
(Radiometer,
Netherlands)

Reference technique:



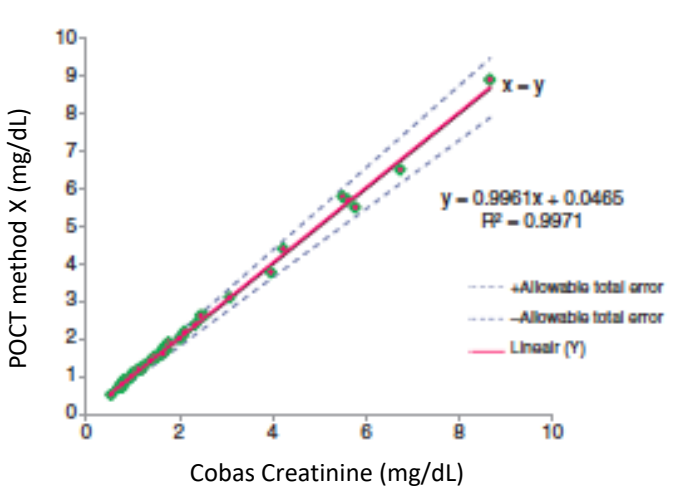
Creatinine (Enzymatic)
on Cobas ®c501 (Roche, Germany)

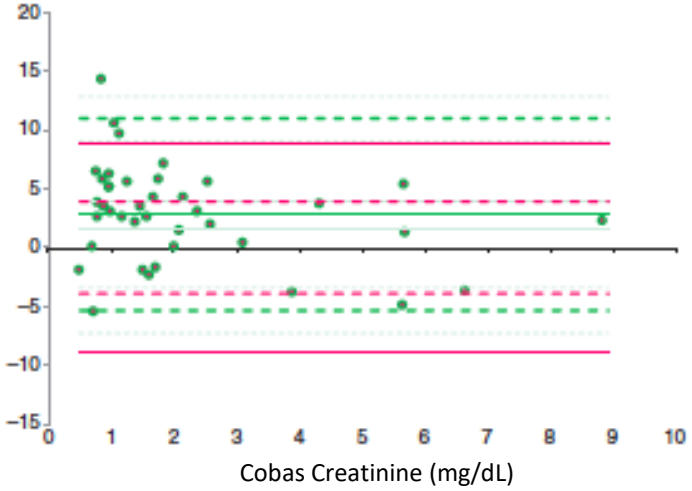
Bogaert L et al. CCLM 2019; 57(9):e214-e217

POCT creatinine: analytical reliability

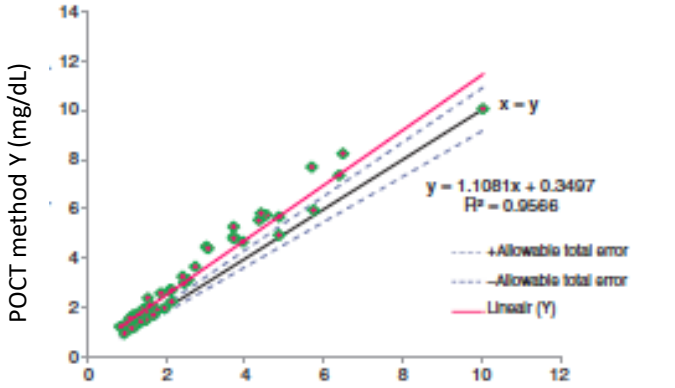
Evaluation of POCT equipment

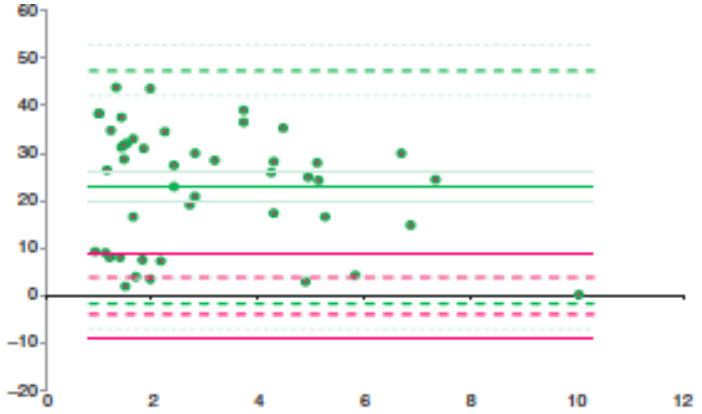
Method comparison (n=40; APS TEa < 8.9%)





Mean Δ= 2.8%





Mean Δ= 22.8%

Bogaert L et al. CCLM 2019; 57(9):e214-e217

POCT creatinine: analytical reliability

Evaluation of POCT equipment

Hematocrit interference

- Increased Hct (60%) = increased creatinin for Statsensor (18%), epoc (18%), and STAT Profile (20%); no effect of iSTAT or ABL90

Results: eGFR calculation

Kappa (95% C.I.)	iSTAT (Abbott)	StatSensor (Nova Biomedical)	Epoc (Siemens)	ABL90 Flex Plus (Radiometer)	STAT Profile Prime+ (Nova Biomedical)
50-year-old male	0.93 (0.84-1.00)	0.69 (0,52-0.86)	0.85 (0.71-0.99)	0.96 (0.89-1.00)	0.85 (0.71-0.99)
80-year-old woman	0.88 (0.75-1.00)	0.32 (0.12-0.52)	0.58 (0.36-0.81)	0.95 (0.86-1.00)	0.22 (0.05-0.38)

Bogaert L et al. CCLM 2019; 57(9):e214-e217



Impact of lower specificity devices on the workflow of a radiology department.

POCT creatinine

Point of care creatinine testing in diagnostic imaging: A feasibility study within the outpatient computed tomography setting

Beverly Snaith[a,b,*], Martine A. Harris[a], Bethany Shinkins[c], Michael Messenger[c], Andrew Lewington[d], Marieke Jordaan[a], Nicholas Spencer[a]

- Screening eGFR
- Scan-day eGFR (POCT)

Table 1
Patient management implications of concordance between baseline (pre-scan) eGFR laboratory result and scan-day eGFR laboratory result.

Zone	Implication if management based on pre-scan eGFR result	No (%)
A	Same risk category – appropriate management	281 (93.7)
B	Changed from low risk to moderate risk, or vice versa. No impact on management (if all patients orally pre-hydrated as standard).	17 (5.7)
C	Changed from being at high risk to either moderate or low risk, potential for unnecessary prophylaxis or withholding of contrast	1 (0.3)
D	Incorrect classification and potential for increased risk of PC-AKI due to insufficient prophylaxis	1 (0.3)

→ In support of POC creatinine to allow efficient workflow and rapid TAT

ESUR Contrast Media Safety Commitee Guidelines 2025
Snaith B, et al. Eur J Radiol. 2019;112:82-87

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/

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Point of Care in Critical Biochemistry

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IFCC International Federation of Clinical Chemistry and Laboratory Medicine