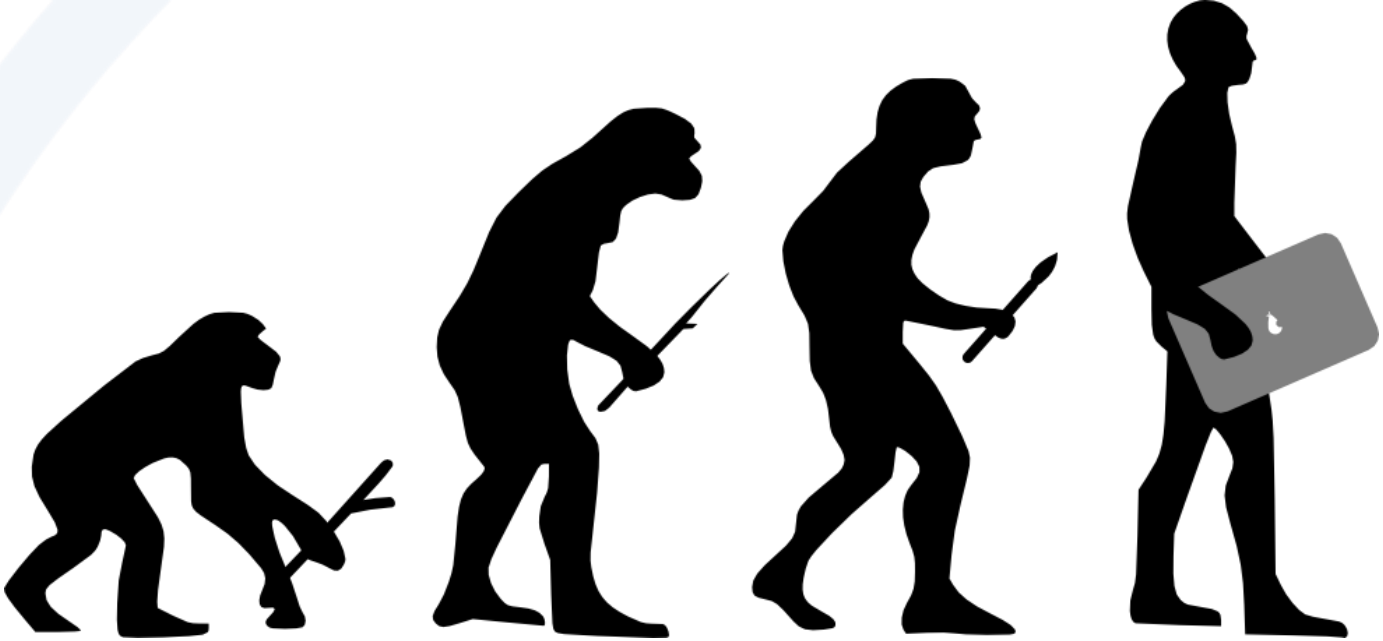
Les Jeudis de Fleurus

Point of Care testing:

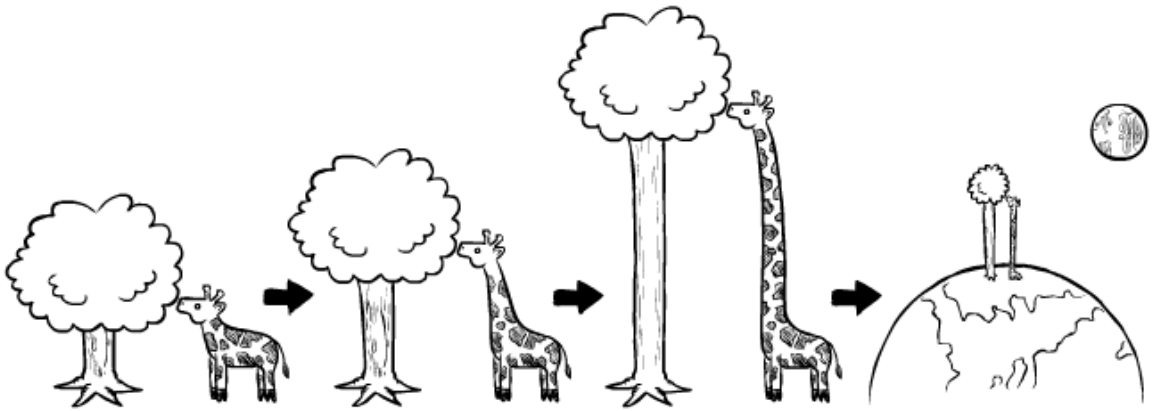
State of the art

Pr. D. Gruson
Pharm. Biol. – EurSpeLM, PhD
Department of Laboratory Medicine
UCL St-Luc, Brussels, Belgium

Cliniques universitaires
SAINT-LUC
UCL BRUXELLES



EVOLUTION



DefinitionS of POCT

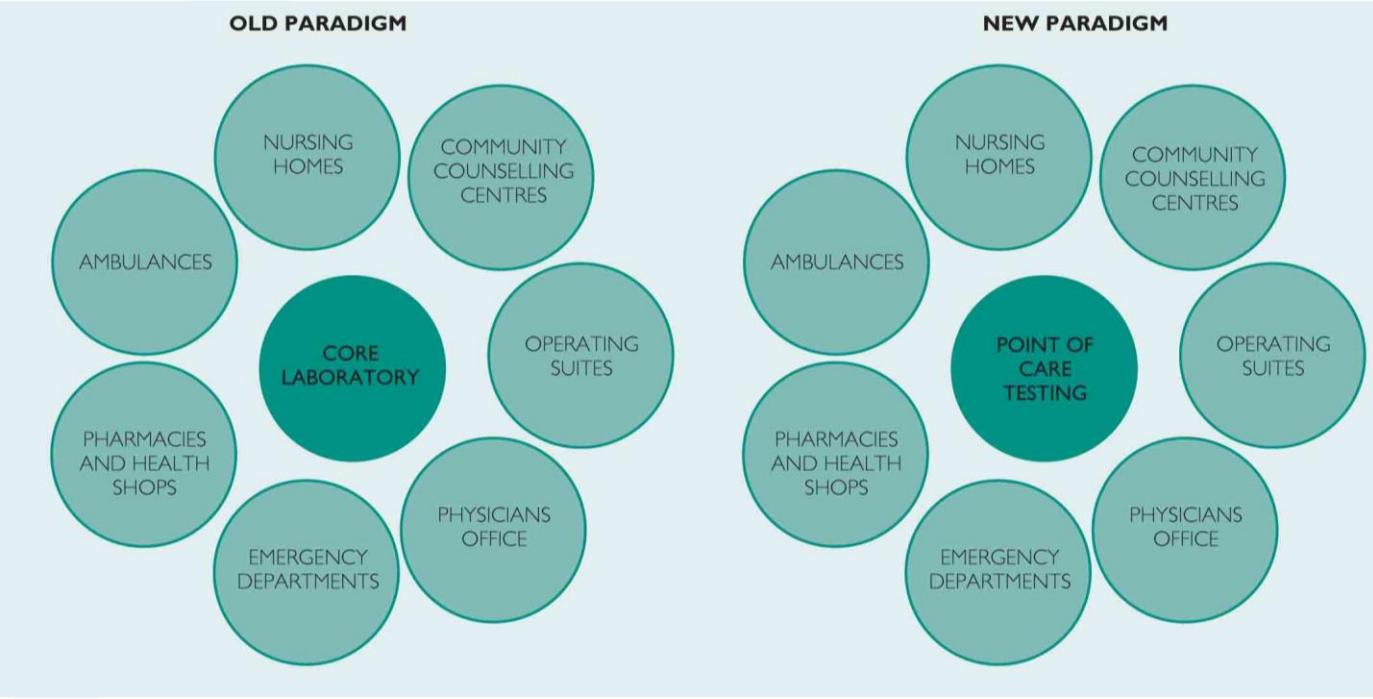
"… any analytical test performed for a patient by a healthcare professional outside the conventional laboratory."

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

"… any diagnostic test performed on a person by a competent individual, where a result that can be interpreted is provided before the person leaves."

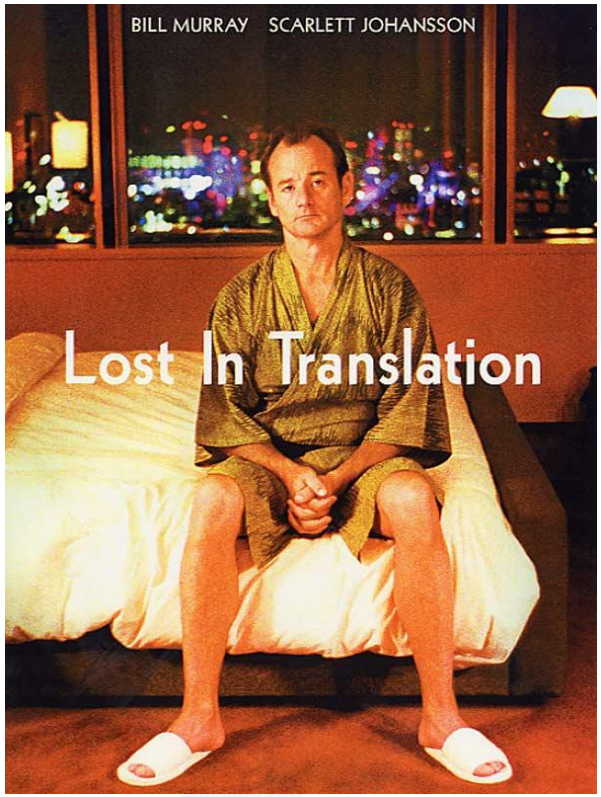
Campbell et al.

The paradigm is shifting?

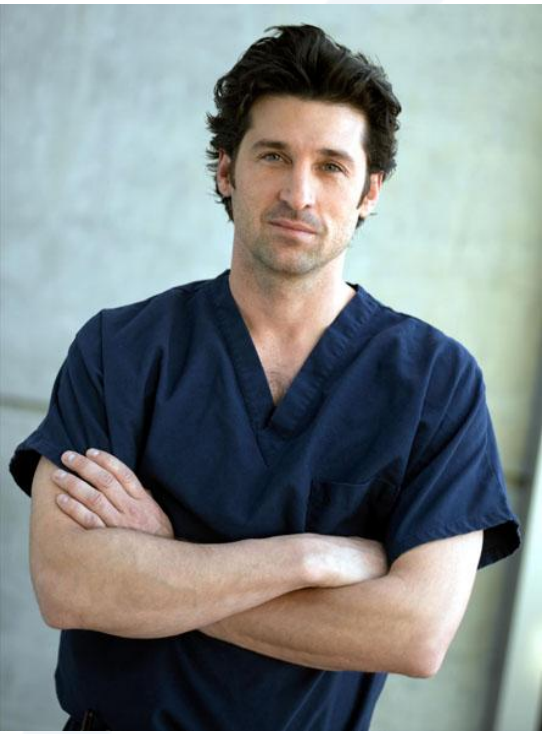


Sequeira et al. 2015

Being a laboratory manager…



"Automation and portable technologies have increasingly made diverse tests available at the point of care."



What did you expect?*

Speed

Reliability

Quality

Safety

Innovation

Data transmission

Counselling

Use of POCT

Table 2 Conditions for which respondents would like a point-of-care test to help them diagnose conditions: top 10 in each country

Australia (n=298)		Belgium (n=319)		The Netherlands (n=639)		UK (n=1109)		USA (n=405)	
Condition	Per cent (n)	Condition	Per cent (n)	Condition	Per cent (n)	Condition	Per cent (n)	Condition	Per cent (n)
Diabetes	57 (170)	PE/DVT	94 (300)	PE/DVT	106.5 (651)*	UTI	47 (521)	UTI	56 (225)
Acute cardiac disease	42 (126)	Acute cardiac disease	76 (241)	Acute cardiac disease	62.7 (383)	PE/DVT	43 (478)	Strep throat	54 (218)
UTI	32 (95)	Heart failure	24 (75)	Chest infection/ cough/LRTI	54.7 (334)	Diabetes	35 (385)	Diabetes	42 (169)
Pregnancy	26 (79)	Chest infection/ cough/LRTI	24 (75)	UTI	26.0 (159)	Acute cardiac disease	25 (282)	Influenza	40 (162)
Anaemia	18 (53)	Infections	23 (74)	Heart failure	22.9 (140)	INR/anticoagulation	18 (199)	Pregnancy	25 (103)
Chronic and acute renal conditions (excluding UTI)	15 (45)	UTI	19 (61)	Anaemia	20.0 (122)	Pregnancy	16 (178)	Infectious mono	14 (56)
INR/anticoagulation	17 (51)	Acute and chronic renal impairment	12 (39)	Diabetes	14.7 (90)	Anaemia	15 (162)	Anaemia	13 (52)
PE/DVT	13 (40)	Diabetes	12 (37)	Infections	13.1 (80)	Heart failure	11 (124)	STDs	7 (27)
Heart failure	12 (37)	Anaemia	8 (24)	Appendicitis	10.8 (66)	COPD/asthma	10 (116)	INR	7 (27)
COPD/asthma	12 (35)	STDs	7 (21)	STDs	9.0 (55)	Chest infection/ cough/LRTI	9 (102)	Acute cardiac disease	6 (23)

*>100% Since we combined PE and DVT. This is because some respondents in the Netherlands listed *both* PE and PE/DVT. In other countries we faced similar problems. Since it was impossible to split PE from DVT when respondents listed PE/DVT as a single condition, we lumped them together.
COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis; INR, international normalised ratio; LRTI, lower respiratory tract infection; PE, pulmonary embolism; STD, sexually transmitted disease; UTI, urinary tract infection.

Howick et al.; 2014

Use of POCT

Table 3 Point-of-care tests that at least 25% of respondents in at least one country reported currently using, ranked in descending order according to total percentage of general practitioners that reported using the tests

	Australia (n=298)	Belgium (n=319)	The Netherlands (n=639)	UK (n=1109)	USA (n=405)	Total (n=2770)
Urine pregnancy test	68% (203)	61% (193)	94% (603)	80% (887)	86% (350)	81% (2236)
Urine leucocytes or nitrite	NA	87% (275)	96% (611)	90% (993)	88% (355)	81% (2234)
Blood glucose	74% (221)	87% (278)	96% (616)	69% (760)	82% (334)	80% (2209)
INR	48% (144)	12% (37)	1% (6)	43% (476)	47% (189)	31% (852)
Haemoglobin	10% (29)	3% (8)	58% (371)	16% (174)	50% (202)	28% (784)
Faecal occult blood	6% (19)	18% (56)	2% (14)	13% (143)	83% (335)	20% (567)
Throat swab for group A streptococci	6% (19)	4% (12)	1% (4)	15% (164)	86% (348)	20% (547)
C reactive protein	3% (8)	3% (10)	48% (305)	15% (163)	10% (42)	19% (528)
Quantitative β-human chorionic gonadotropin	6% (18)	19% (59)	22% (138)	17% (193)	28% (112)	19% (520)
HbA1c	6% (17)	2% (6)	6% (38)	17% (183)	40% (162)	15% (406)
Nose/throat swab for influenza	7% (20)	1% (3)	0% (2)	6% (61)	60% (242)	12% (328)
Platelet count	4% (11)	0% (1)	1% (3)	15% (163)	28% (112)	10% (290)

HbA1c; glycated haemoglobin; INR, international normalised ratio; NA, not applicable.

Howick et al.; 2014

Use of POCT

Table 4 Point-of-care tests that at least 50% of respondents in at least one country would use, ranked in descending order according to total percentage of general practitioners that would use the tests

	Australia (n=298)	Belgium (n=319)	The Netherlands (n=639)	UK (n=1109)	USA (n=405)	Total (n=2770)
D-dimer	41% (121)	83% (265)	70% (448)	73% (811)	62% (251)	68% (1896)
Troponin	43% (129)	85% (271)	65% (418)	69% (765)	59% (238)	66% (1821)
Chlamydia	49% (145)	67% (212)	60% (382)	65% (721)	66% (267)	62% (1727)
B-type natriuretic peptide	28% (82)	51% (164)	62% (398)	66% (734)	60% (244)	59% (1622)
C reactive protein	38% (114)	75% (238)	47% (302)	61% (682)	45% (181)	55% (1517)
Gonorrhoea	34% (100)	56% (180)	51% (326)	58% (645)	65% (262)	55% (1513)
HbA1c	52% (156)	61% (195)	37% (239)	61% (679)	50% (202)	53% (1471)
White cell count	43% (127)	67% (212)	40% (256)	60% (661)	52% (212)	53% (1468)
Haemoglobin	47% (139)	47% (150)	26% (168)	72% (793)	39% (159)	51% (1409)
Potassium	33% (97)	47% (150)	33% (210)	61% (679)	57% (232)	49% (1368)
International normalised ratio	21% (63)	77% (244)	54% (347)	47% (517)	43% (176)	49% (1347)
Nose/throat swab for influenza	43% (128)	59% (187)	36% (231)	55% (609)	33% (134)	47% (1289)
Erythrocyte sedimentation rate	29% (86)	40% (128)	29% (183)	58% (645)	48% (194)	45% (1236)
Quantitative β-human chorionic gonadotropin	40% (120)	56% (177)	23% (149)	53% (586)	46% (187)	44% (1219)
Creatinine	34% (102)	41% (130)	28% (177)	53% (593)	53% (214)	44% (1216)
Thyroid stimulating hormone	32% (95)	33% (105)	27% (171)	53% (586)	62% (253)	44% (1210)
Throat swab for group A streptococci	35% (103)	60% (190)	33% (208)	53% (588)	11% (45)	41% (1134)
Uric acid	28% (82)	30% (94)	26% (167)	50% (549)	51% (205)	40% (1097)
Sodium	30% (88)	21% (66)	19% (122)	51% (571)	42% (172)	37% (1019)

HbA1c; glycated haemoglobin.

Howick et al.; 2014

« Planet of the POCT »

Broader menu of systems and tests

Market Sectors

Cardiac
Diabetes
Infectious diseases
Blood gas and electrolytes
Fertility
Coagulation
Haematology

POCT performances and reliability

✓ T.A.T

✓ Whole blood / less volume

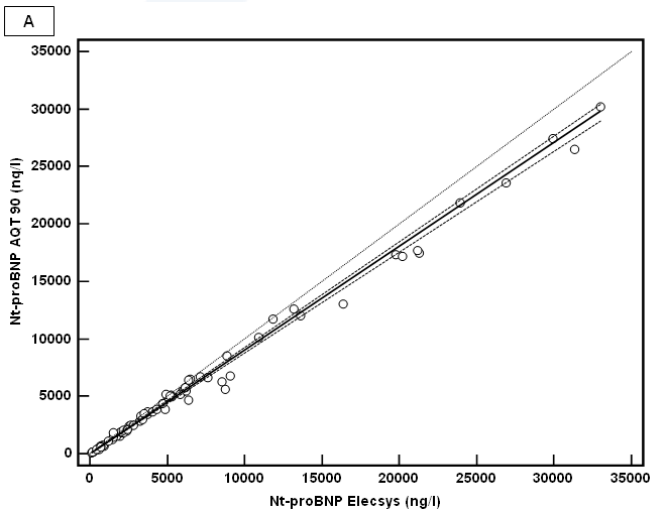
✓ Analytical performances

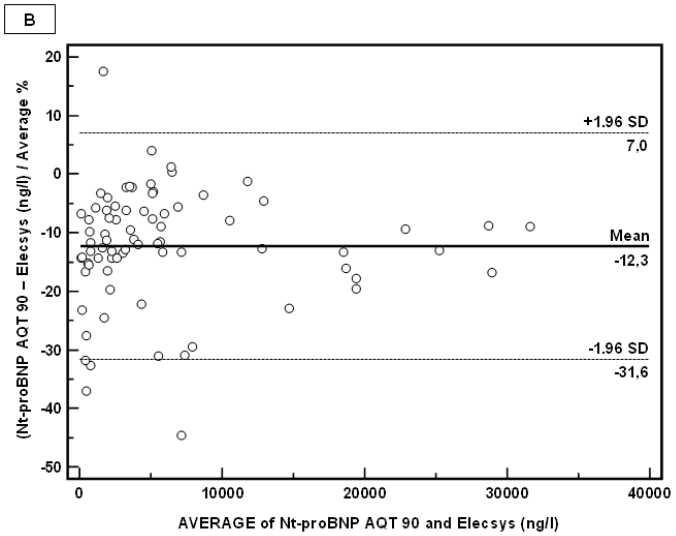
Between-run coefficients of variation (n=9) with the AQT90 TPNI assay.

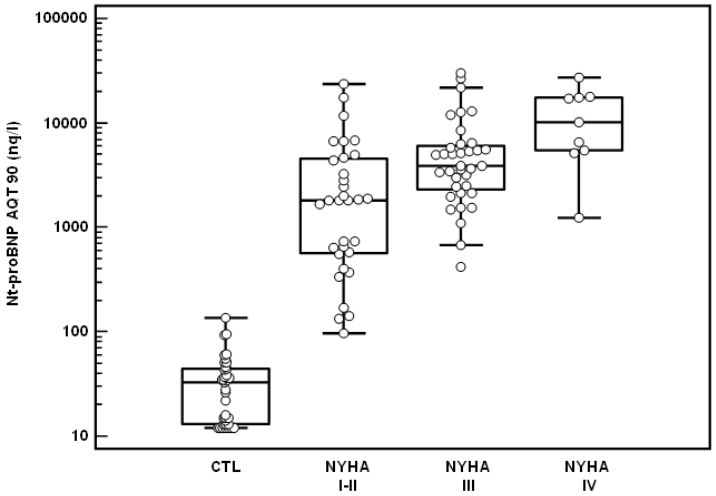
Troponin I levels (ng/mL)	0,036	0,321	1,543
Coefficient of variation (%)	5,6	3,4	26

Gruson et al.; AACC 2013

POCT performances and reliability





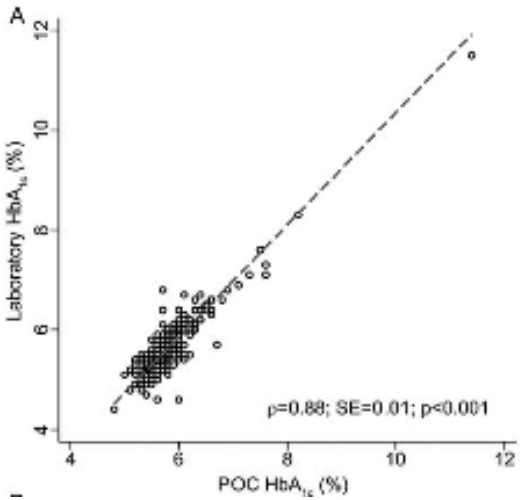


Measurement Nt-proBNP circulating concentrations in heart failure patients with a new point-of-care assay.

Lepoutre T, Rousseau MF, Ahn SA, Gruson D.

Clin Lab. 2013;59(7-8):831-5.

POCT performances and reliability



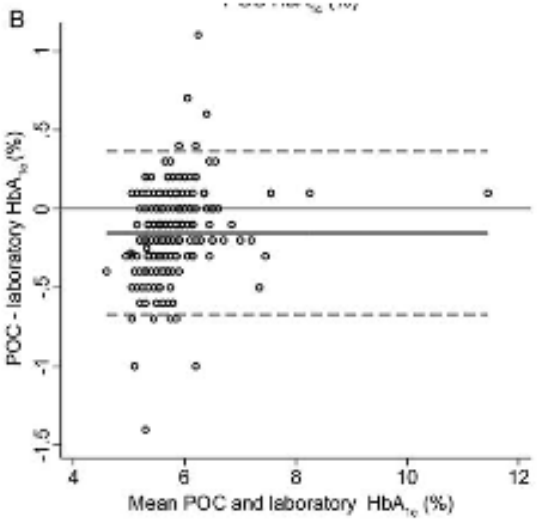


Table 2 Sensitivity, specificity, predictive values and classification by point-of-care (POC) glycated haemoglobin (HbA_{1c}) testing for diagnosing diabetes and screening for participants (n=241) with diabetes or a high risk of developing diabetes

	Diagnosis*	Screening†
Sensitivity (95% CI, %)	73.7 (48.6 to 89.9)	**91.0 (81.8 to 96.0)**
Specificity (95% CI, %)	**98.2 (95.1 to 99.4)**	76.7 (69.3 to 82.9)
Positive predictive value (%)	77.8	65.1
Negative predictive value (%)	97.8	94.7
Correctly classified (%)	96.3	81.3

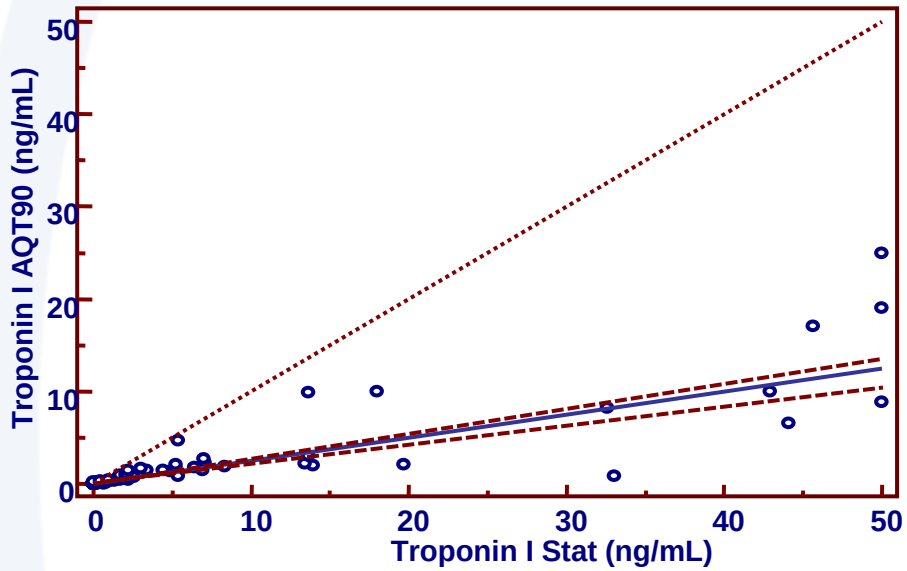
Bold typeface indicates the main criteria for selecting a cut point.
*Diagnosis based on laboratory HbA_{1c} ≥6.5%, 48 mmol/mol using a POC cut point of 6.5%, 48 mmol/mol.
†Screening based on laboratory HbA_{1c} ≥6.0%, 42 mmol/mol using a POC cut point of 5.7%, 39 mmol/mol.

POC HbA1c testing is sufficiently accurate to be a useful component in screening for, and diagnosing, diabetes in remote communities. Limited local training is adequate to produce results comparable to laboratory results and accreditation processes need to reflect this

Marley et al.; BMJ 2014

Assays reliability

« We are Still Fighting »



Point of care (POC) and Over The Counter (OTC)

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Qualitative point-of-care and over-the-counter urine hCG devices differentially detect the hCG variants of early pregnancy

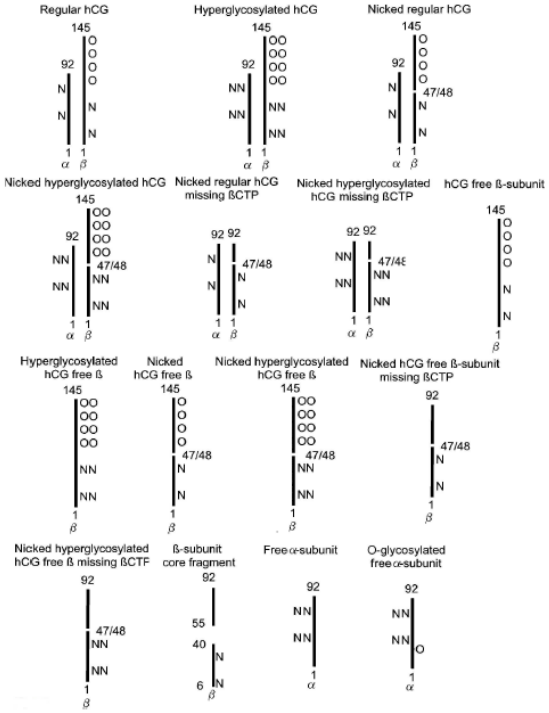
Mark A. Cervinski [a], Christina M. Lockwood [a], Angela M. Ferguson [a], Randall R. Odem [b], Ulf H. Stenman [c], Henrik Alfthan [c], David G. Grenache [d], Ann M. Gronowski [a,*]

[a] Department of Pathology and Immunology, Washington University School of Medicine St. Louis, MO, United States
[b] Department of Obstetrics and Gynecology, Washington University School of Medicine, St. Louis, MO, United States
[c] Department of Clinical Chemistry, Helsinki University Central Hospital, Helsinki, Finland
[d] Department of Pathology, University of Utah Health Sciences Center, Salt Lake City, UT, United States

How low should we go?

	Median Concentration (IU/L) 3/3 devices test positive (n=11 patients)	
POC Device		
Clinitest	12.5	POC
Osom	18.8	
Quick-Vue	25	
hCG Combo	25	
ICON II	25	
SureVue	25	
OTC Device		
First Response	2.4	OTC
Answer	3.1	
Target Early Result	6.3	
EPT Certainty	6.3	
Clearblue Easy	12.5	
Wal-Mart Equate	12.5	

Point of care (POC) and Over The Counter (OTC)



Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Qualitative point-of-care and over-the-counter urine hCG devices differentially detect the hCG variants of early pregnancy

Mark A. Cervinski [a], Christina M. Lockwood [a], Angela M. Ferguson [a], Randall R. Odem [b], Ulf H. Stenman [c], Henrik Alfthan [c], David G. Grenache [d], Ann M. Gronowski [a,*]

[a] Department of Pathology and Immunology, Washington University School of Medicine St. Louis, MO, United States
[b] Department of Obstetrics and Gynecology, Washington University School of Medicine, St. Louis, MO, United States
[c] Department of Clinical Chemistry, Helsinki University Central Hospital, Helsinki, Finland
[d] Department of Pathology, University of Utah Health Sciences Center, Salt Lake City, UT, United States

- In pregnancy, hCG immunoreactivity due to many variants:
  - hCG (intact hCG)
  - hCG-h (hyperglycosylated hCG)
  - hCGn (nicked hCG)
  - hCGβ (free β subunit)

  } Urine & serum

  -hCGβcf (the core fragment of hCGβ } Urine only

Point of care (POC) and Over The Counter (OTC)

POC hCG devices differentially recognize the many hCG variants

	Qualitative CG device						
	Sure-Vue	Clinitest	QuickVue+	Osom	hCG Combo	ICON II	Elecsys[a], IU/L, pmol/L[b]
	Anti-α (u) Anti-CG dimer (u)	Anti -CG dimer (m) Anti-β (m)	Proprietary (p) Anti-β (m)	Anti-α (m) Anti-β (m)	Anti-α (m) Anti-β (m)	Anti-α (m) Anti-β (m)	Anti-β (m) Anti-β (m)
hCG	10/10	10/10	10/10	5/5	10/10	10/10	1220 NA[d]
hCGn	10/10	10/10	10/10	10/10	10/10	10/10	2263 7800
hCGβ	10/10	10/10	10/10	0/10	10/10	10/10	2336 8800
hCGβn	10/10	10/10	10/10	0/10	10/10	10/10	630 3300
hCGβcf	0/10	10/10	6/10	0/10	10/10	0/10	815 10 200
hCGα	0/10	0/10	0/10	0/5	0/10	0/10	<2.0 8400

Sigel & Grenache Clin Chem 2007;53:989-90

What else ?

Accreditation needs / ISO 22870

POCT coordinator / Quality manager

Laboratory management shall appoint an individual with defined responsibility for ensuring that the POCT quality management system is implemented and maintained.

Document control

Manuals and instructions for use of POCT shall be subject to document control and readily available to users.

The laboratory director or designee shall appoint a multidisciplinary POCT management group

Staff training and education

a) the context and clinical utility of POCT
b) the theoretical aspects of the measuring system
c) sample collection and handling
d) reagent storage
e) quality control
f) infection control
g) limitations of the measuring systems
h) response to results outside predefined limits
i) documentation and reporting of results

User identification – using others barcodes

Patient identification

Laboratory management shall conduct an annual review of POCT.

Competence assessments

Do we have the man power to comply?

Medical staff and competence!!!

POCT QC programs and external QC

Campbell et al.

Co-operation between Stakeholders Essential to Pushing POCT Implementation

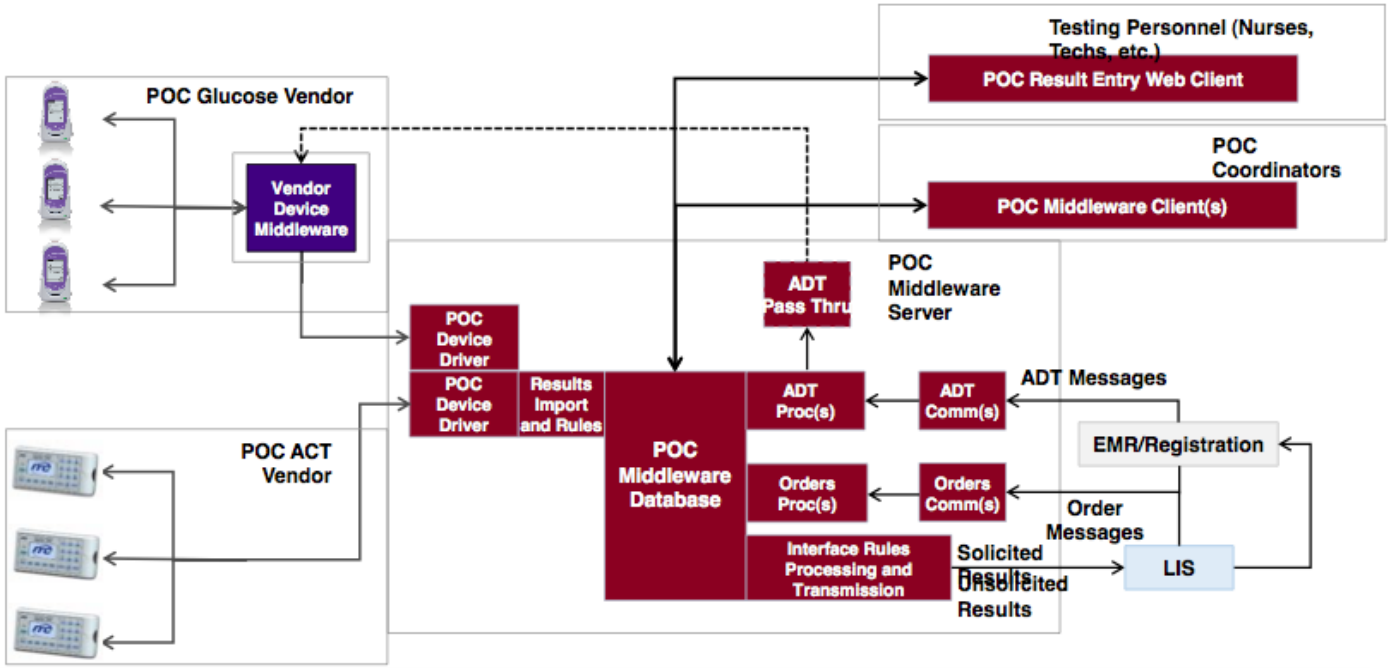
Connectivity / IT

Traceability of measurement and operations

Can the device be connected to a local database for electronic transfer of results?
Can software updates be performed electronically?

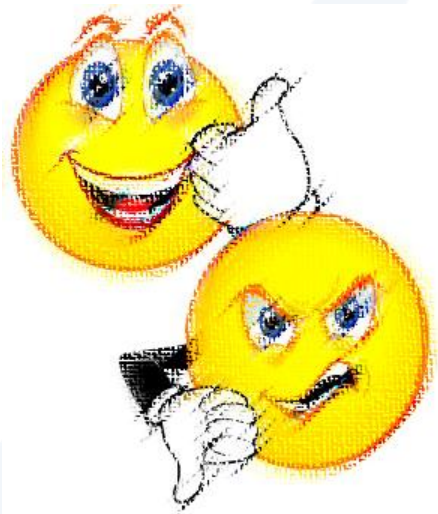
Prevent pre- and post analytics errors

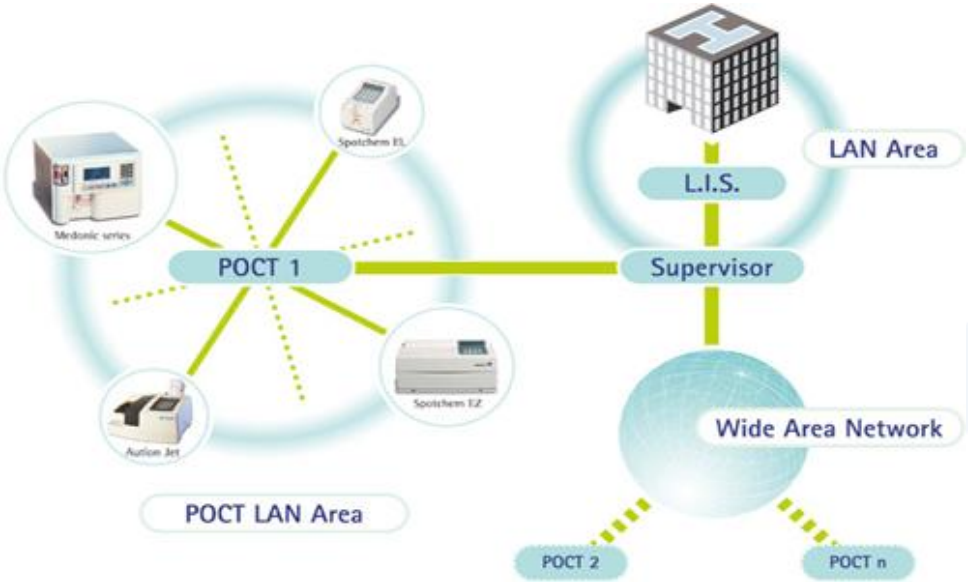
1. Quality control ranges
2. Critical reference ranges
3. Reagents / strip / control lot numbers
4. Expiration dates
5. Valid operator lists
6. Patient identifiers (e.g. medical record number, account number, date of birth, location)
7. Clearing data from device memory



I.T / Communication / continuing education

- IT – middleware
- Written: information bulletin, collection procedures, competences…
- Staffs training, Multidisciplinary team meeting, Brainstroming with prescribers
- e-learning
- Intra- / internet





Budgetary impact of POCT

Costs for POCT

FTE for testing coordinators

Higher reagent cost

Capital costs
-Analyzers
-Information system

Lower accuracy

Need for repeats

Potential savings from POCT

Laboratory FTE (about 1 FTE / 25000 specimens)

Blood conservation (replacement cost 0.50$/mL)

Capital costs
- Avoid setup of satellite lab
- Avoid puchase of analyzers

Faster results
- Faster therapeutic action
- Increased nursing efficiency
- Improved patient outcomes

Hortin et al.

Challenges for POCT

- Location
- Cost
- Medical necessity
- Test utilization
- Analytical quality / understanding limitations
- Test performance by non-lab personnel
- Regulatory concerns
- Accreditation
- Impact of POCT on hospital and central lab operations
- Gvt regulation

Thank you very much….

…for your attention !

damien.gruson@uclouvain.be