Benefits and disadvantages of POCT

EQALM Symposium
Bergen

2015-10-08

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What is POCT?

BOX 1

Laboratory investigations by POCT take place:*[1]

- Outside the laboratory
- In the immediate vicinity of the patient
- Without sample preparation and generally without pipetting steps. The test material is usually whole blood.
- With measuring instruments intended or used for single samples
- With "ready-to-use" reagents
- Without the necessity of in-depth medical technical qualification for operating the instrument
- With rapid availability of the results
- With the immediate deduction of therapeutic consequences from the results

From Junker, et al 2010

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Erytrocyte sedimentation rate (ESR)

The classical POCT test, although the results are not very rapid.

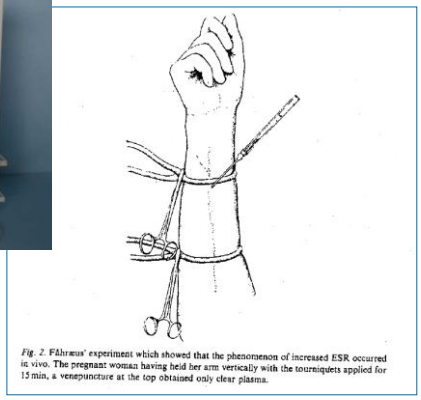

Fig. 2. Fåhræus' experiment which showed that the phenomenon of increased ESR occurred in vivo. The pregnant woman having held her arm vertically with the tourniquets applied for 15 min, a venepuncture at the top obtained only clear plasma.

L. H. Breimer, and P. Sourander, 'Robin Fahraeus 1888-1968', *Int J Microcirc Clin Exp, 8 (1989), 121-6.*

Traditional POCT in Sweden

Tabell 2.

Analys	Medelvärde	Totalt	Total number of tests (milj) 1993
B-Hemoglobin	3 887	97 175	ca 3,5
B-SR	2 792	69 800	ca 2,5
B-Glukos	1 901	45 525	ca 1,2
U-Testremsa	5 570	139 250	ca 5,0
Summa kliniskt kemiska analyser	23 662	591 550	ca 21,4 milj

Constant use

Total number of tests 2012

B-Hb	ca 4,0 milj
B-SR	ca 2,0 milj
P-Glucose	ca 6,5 milj
Urine teststrip	ca 6,5 milj
P-CRP	ca 2.4 milj

A new test compared to 1993!

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POCT will develop and increase in the future

Technical development – increased possibility to measure on small volumes of blood.

The POCT market increases more rapidly than the hospital lab market

If you need 20 µl blood to do the measurement, you don't need 1 000 µl sample. The capillary sampling procedures will improve.

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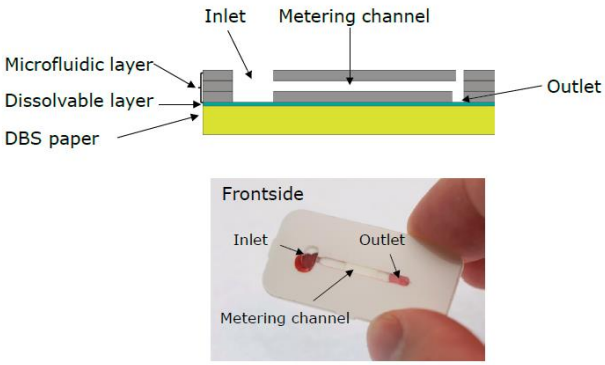
Microfluidics on top of DBS paper



Roxhed et al, KTH, Stockholm

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Molecular biology POCT tests will come

Alere™ i Influenza A & B
Molecular. In Minutes.™
The First CLIA-Waived
Molecular Rapid Flu Test

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POCT flow cytometry for CD4 count

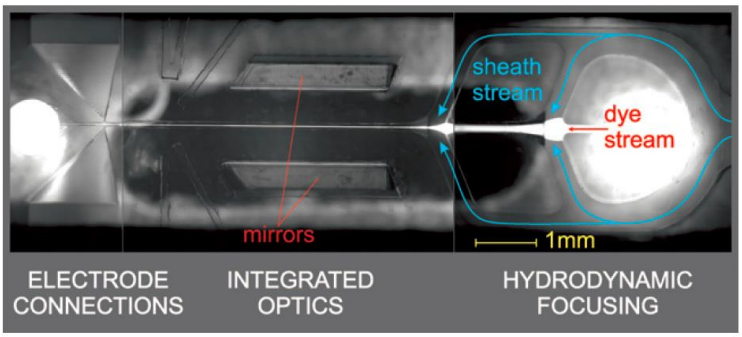

Fig. 2 Combined bright field image and fluorescence image of a micro-fluidic device (*cf.* Fig. 1) to demonstrate hydrodynamic focussing.

Kummrow Aet al. Microfluidic structures for flow cytometric analysis of hydrodynamically focussed blood cells fabricated by ultraprecision micromachining. Lab Chip. 2009 Apr 7;9(7):972-8

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One benefit with POCT

- All test results should be evaluated with respect to the clinical condition
- The ”law of prevalence”:
  - unexpected laboratory results must be repeated or further investigated.
  - easier to evaluate a result that is presented during the consultation.

"Either this is the wrong chart or—let's just hope this is the wrong chart."

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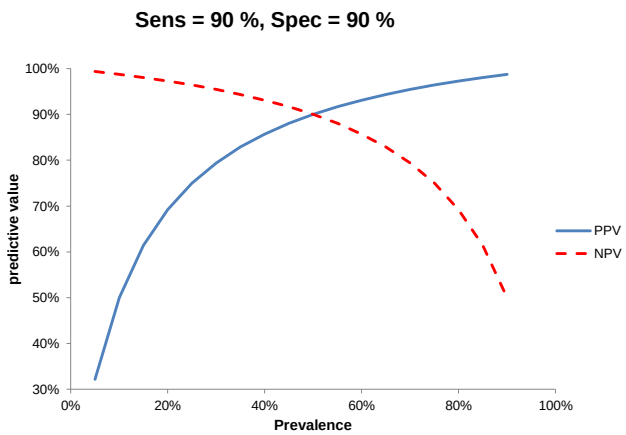
Quality requirements for POCT



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POCT tests in PHC in Sweden today, in ranked order by "how often do we perform a test"

POCT	Rank
Urine test strip	1
P—Glucose	2
P—CRP	3
Strep A	4
B—Hemoglobin	5
B—Sedimentation reaction	6
F-Hb (FOB)	7
B—HbA1c	8
B—Leukocytes	9
B—Trombocyter	10
P—PK [INR]	11
U—Albumin/creatinine ratio	12
U—Albumin, low level (µAlb)	13
U—hCG	14
P—Mononucleosis test	15
P—Creatinine	16
P—Potassium	17
P—Cholesterol	18
P—Triglycerides	19
P—HDL-cholesterol	20

POCT	Rank
P—ALAT	21
P—LDL-cholesterol	22
P—Sodium	23
P—ALP	24
Lkc—Differential count (3-part)	25
P—ASAT	26
P—GT	27
Pt—OGTT	28
P—hydroxybuturate (ketones)	29
P—Urate	30
P—Allergen spec IgE (allergy test, nc	31
P—BNP	32
P—D-Dimer	33
P—Troponine (T and I)	34
Pt—Alchohol breath test	35
Lkc—Differential count (5-part)	36
P—Pancreas amylase	37
F—Calprotectine	38
U—Drug test (screen)	39
P—Urea	40

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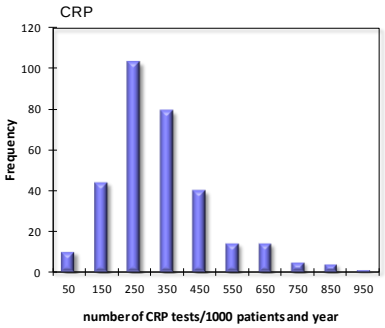
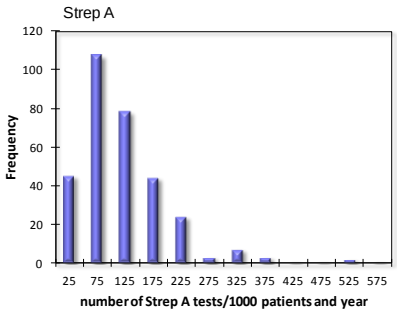
Great variability of POCT use in 300 Primary Health Care centers in Sweden





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Possible explanations for the variation

	Frequency of Strep A tests	Frequency of CRP tests
Private vs publicly owned PHC	-ns-	-ns-
Short vs long distance to hospital	-ns-	-ns-
Participation in EQA vs non participation	-ns-	-ns-
Accreditated vs non-accreditated laboratory	-ns-	-ns-
Biotechnologist vs non-biotechnologists as performer of POCT	-ns-	-ns-
Small PHC versus large PHC	-ns-	-ns-
Regional differences n.o.s	yes	yes

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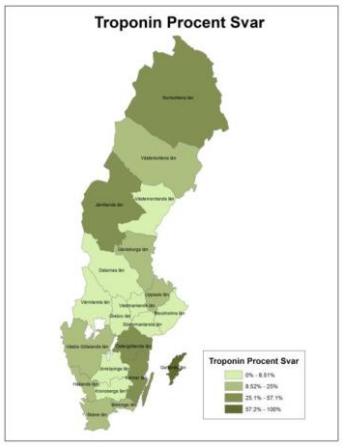
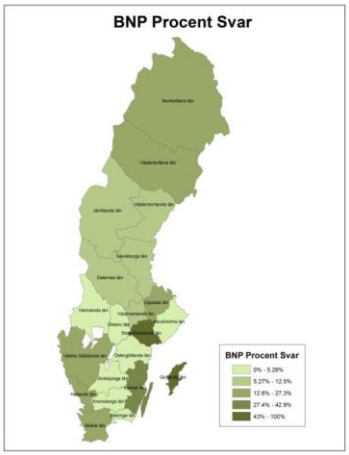
The co-variation of test profiles is platform dependent





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Regional variations in use of POCT

Due to:

- Different ”case-mix” among the patients ?
- Impact from ”local enthusiast” users ?
- Impact from enthusiastic IVD producers and dealers ?
- Different reimbursement systems ?

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The main reasons for using POCT

1. Simplify logistics and might reduce risk for preanalytical errors
2. Reduce prescription of antibiotics
3. Results are easier to evaluate for the requester.
4. Improve patient confidence
5. Improve decision making and shorten turn around times

[Back up procedure in case of emergencies]
[Convincing distributers of POCT devices]

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The main reasons not to use POCT

Table 2. Categorization of articles assessed within the literature review process.

Barrier Category	References	Total	% of assessed articles
Economic issues	16,23–53	32	65
Quality assurance and regulatory issues	16,23–30,33,35–47,49,50,54–60	32	65
Device performance and data management issues	16,24–26,28,29,34–38,41,45,47,49,53,56,57,61–67	25	51
Staff and operational issues	24,26–28,31–33,36–38,41,50–53,55,59	17	35
No specific barriers identified	68–70	3	6

Quinn et al, Barriers to hospital-based clinical adoption of point-of-care testing (POCT): A systematic narrative review. Critical reviews in clinical laboratory sciences. 2015 Aug 18:1-12 2015

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Summary

In several areas are the quality of POCT good enough today
- the quality will continue to improve
- the range of tests will increase

The cost is, and will remain, high (x 5-10?)

Education necessary for staff using POCT, routines should be documented, a quality system in place

Specific EQA services need to be developed

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