



C entre Suisse de Contrôle de Qualité
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C entro Svizzero di Controllo della Qualità
Q uality Control Center Switzerland



EQA provider experience with POCT

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2015-10-08

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POCT in Switzerland

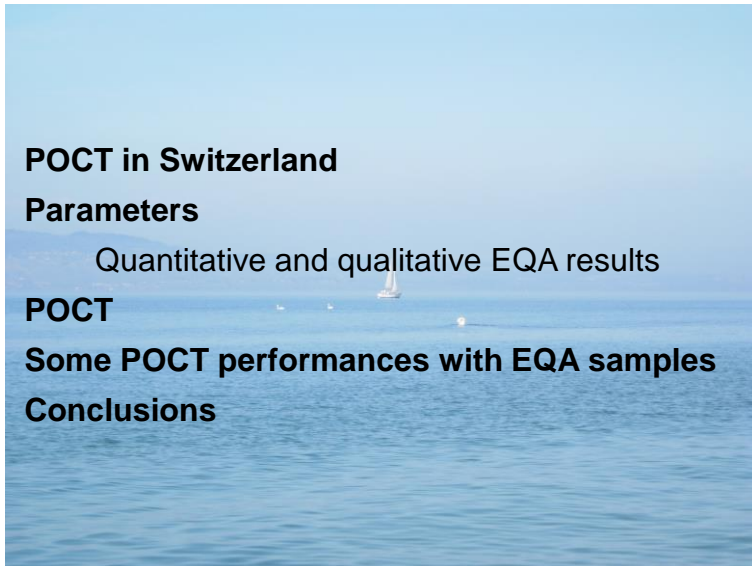
Parameters

Quantitative and qualitative EQA results

POCT

Some POCT performances with EQA samples

Conclusions



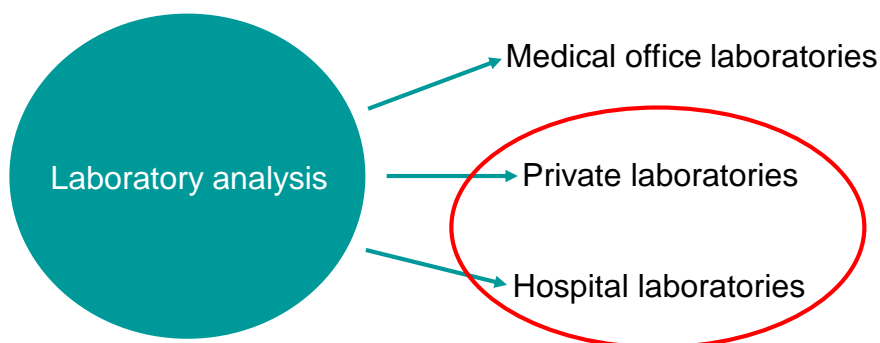
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Switzerland



The participation in an EQA programme is mandatory for the list of parameters established by the QUALAB¹.

The frequency is the same for all types of laboratories and devices, POCT and non-POCT (min. 4 surveys/year).

The tolerance (in %, with the consensus target) is the same for all types of devices, POCT and non-POCT.

The criteria for the yearly performance (certificate) are identical for results obtained by POCT and non-POCT.

¹ www.qualab.ch

POCT are very common in hospital and private laboratories:

- Clinical chemistry
- Urinary analyses
- Haematology
- Haemostasis
- Blood gas analyses
- Cardiac markers
- Toxicology
- Infectious markers
- ...

EQA results

Quantitative parameters

P-D-Dimer
 S-Glucose
 B-Haemoglobin

Qualitative parameters

Strep A Ag
 S-HIV Ab(Ag)
 U-βhCG

2 levels
 3 surveys
 (per level, similar concentrations,
 results from 2011 to now)

Positive and negative
 samples
 (results from 2010 to now)

Interlaboratory CV%
 (3 surveys)

% false pos and
 false neg results
 (all the surveys)

Mandatory



Percentages of POCT EQA results obtained by private and hospital laboratories

Parameter	%
D-Dimer	35
Glucose	26
Haemoglobin	19
Strep A	15
HIV-Ab(Ag)	70
βhCG	62



POCT devices:

- Handheld, portable, and transportable¹
- Handheld and small bench-top²
- Bedside and near-bedside³

Two groups:

- 1) bedside = handheld
- 2) near-bedside = portable, transportable, small bench-top

¹ Louie RF et al. Lab Med. 2000

² Briggs A et al. Br J Haematol. 2012

³ Larsson A et al. Ups J Med Sci. 2015



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POCT

Quantitative EQA parameters

POCT: bedside



DD

Cobas h232
(Roche)

Hb



Hemocue
(Radiometer)



Accu-Chek
(Roche)



Ascensia
(Bayer)

Glu

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POCT

Quantitative EQA parameters

POCT: near-bedside

DD



Cardiac reader
(Roche)



Triage meter
(Alere)

Glu



Drichem
(Fuji)



Reflotron
(Roche)

Hb



ABX Micros
(Horiba)



ACTdiff
(Beckman Coulter)



KX21
(Sysmex)



pocH-100i
(Sysmex)



XS
(Sysmex)

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		Level 1	Level 2
POCT devices	Bedside	[1.1] ; n=110	[2.2] ; n=75
	Near-bedside	[1.7] ; n=58	[2.4] ; n=85
Big analysers		[1.9] ; n=327	[2.3] ; n=85

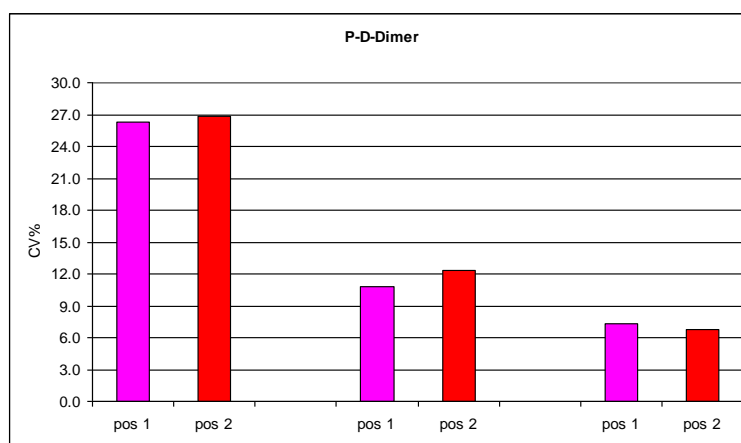
3 surveys ; [] : concentration in mg DD/L ; n : number of results

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Level 1
Level 2



POCT: bedside & near-bedside Big analysers

CV in agreement with other studies¹

¹ Spannagl M. et al. 2005. Blood Coagul Fibrinolysis

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		Level 1	Level 2
POCT devices	Bedside	[11.6] ; n=1345	[4.5] ; n=1399
	Near-bedside	[11.2] ; n=125	[4.8] ; n=120
Big analysers		[11.0] ; n=480	[4.5] ; n=497

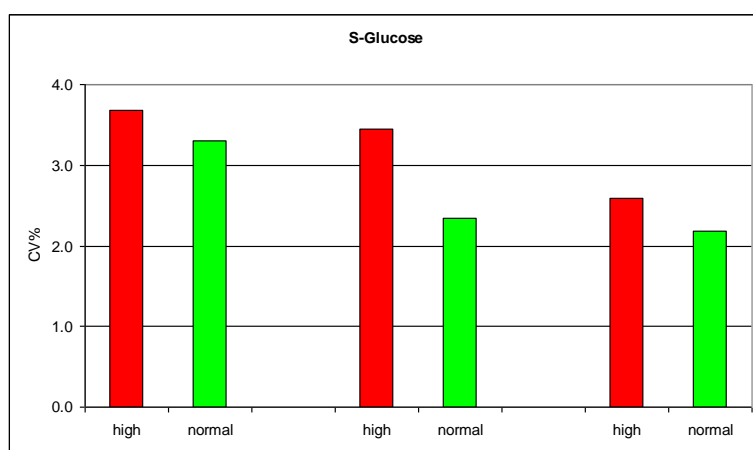
3 surveys ; [] : concentration in mmol/L ; n : number of results

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Level 1
 Level 2



POCT: bedside & near-bedside Big analysers

CV in agreement with other studies¹

¹ Kuo CY et al. 2011. Diabetes Technol Ther.

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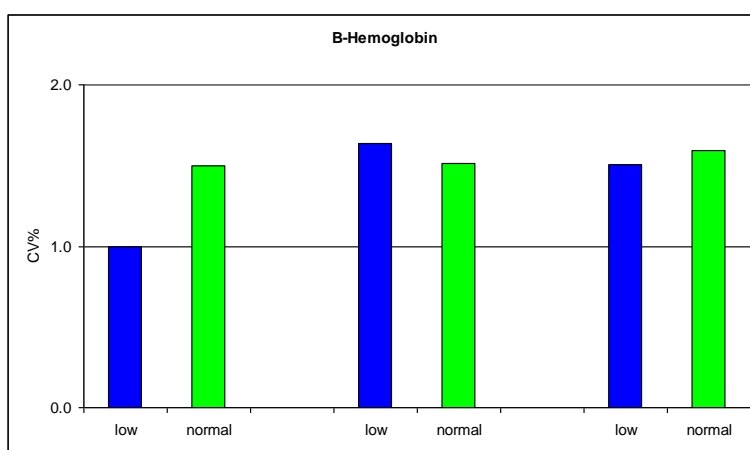


		Level 1	Level 2
POCT devices	Bedside	[72] ; n=30	[145] ; n=28
	Near-bedside	[71] ; n=469	[147] ; n=479
Big analysers		[72] ; n=341	[148] ; n=348

3 surveys ; [] : concentration in g/L ; n : number of results



■ Level 1
■ Level 2



POCT: bedside & near-bedside Big analysers

Qualitative EQA parameters

POCT

POCT: bedside (quick test)

HIV Ab(Ag)



Alere
bioLytical

Strep A Ag



β hCG



Alere
BioNexia
Clearview
Quidel
VedaLab
...



Binax
BioNexia
Inverness
Princeton
Quidel
Ultimed
VedaLab
...

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POCT

	β hCG	HIV Ab(Ag)	Strep A Ag
POS			
n	373	680	1329
% false neg (n)	0.5 (2)	1.5 (10)	1.0 (13)
NEG			
n	231	226	389
% false pos (n)	1.3 (3)	0.4 (1)	0.5 (2)

Acceptable?

- All the surveys (from 2010 to now).
- The number of errors is randomly distributed among laboratories and type of quick tests, and does not depend on the concentration.

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Can we rely on POCT results?

Quantitative parameters

With EQA samples, some devices obtain high interlaboratory CV, while others have low interlaboratory CV.

In our experience, the performances of POCT devices also rely on the technicians' skills, especially for POCT with high CV.

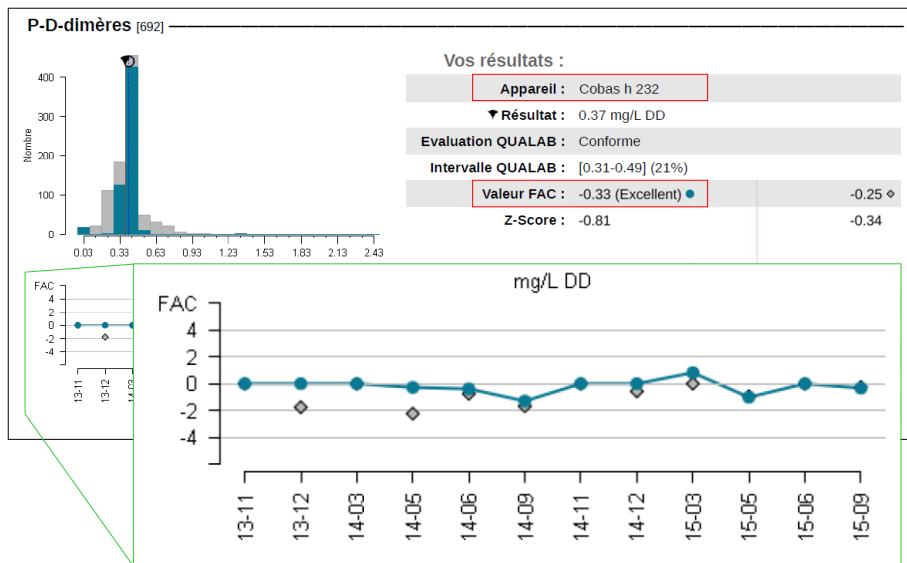
However, a well trained technician can obtain satisfactory results with a less "robust" device (high CV).

The results obtained by a "robust" device (low CV) are less influenced by the technicians' skills.

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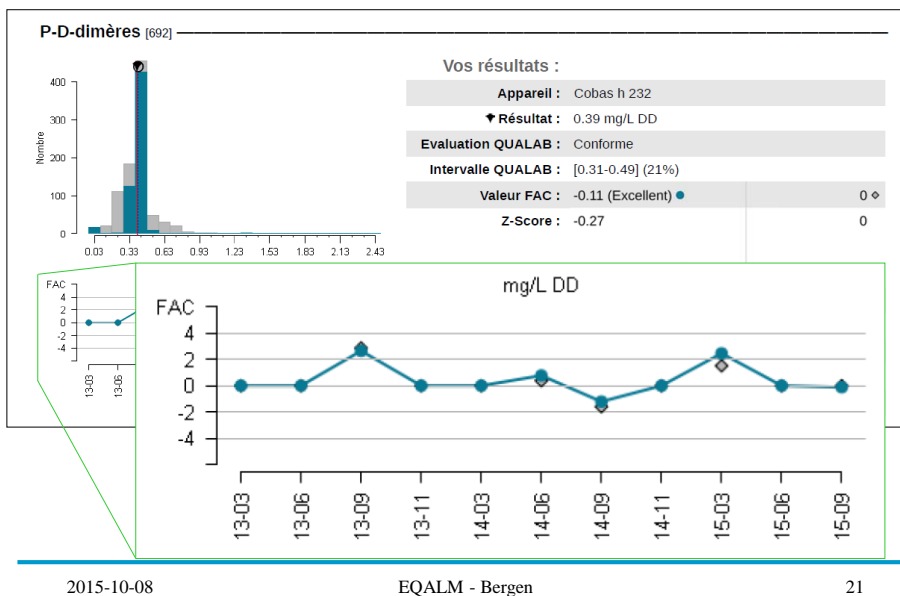
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Conclusions 2

Can we rely on POCT results?

Qualitative parameters

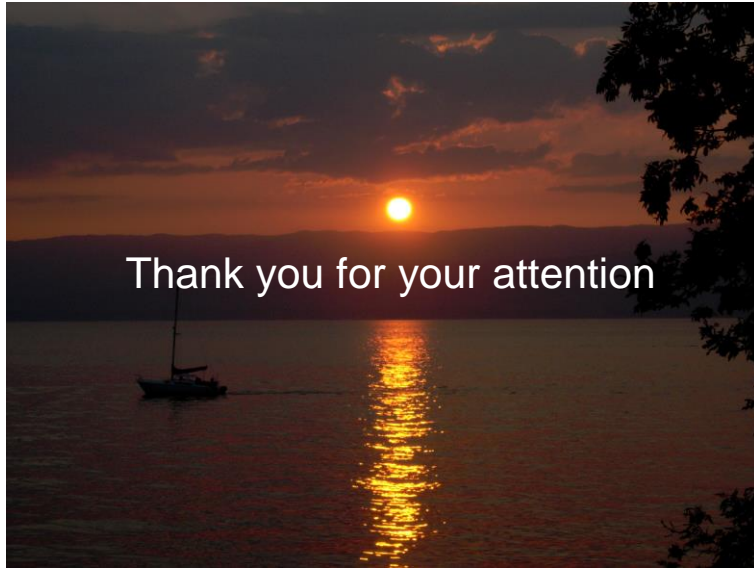
Our EQA results indicate that the performances of POCT devices (quick tests), which are very easy to use, are also dependant on the skills of the technicians using them.

We observe some errors, but not on a frequent basis, randomly distributed between users.

Since these devices only have two possible answers (pos/neg), an error could potentially have serious consequences.



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