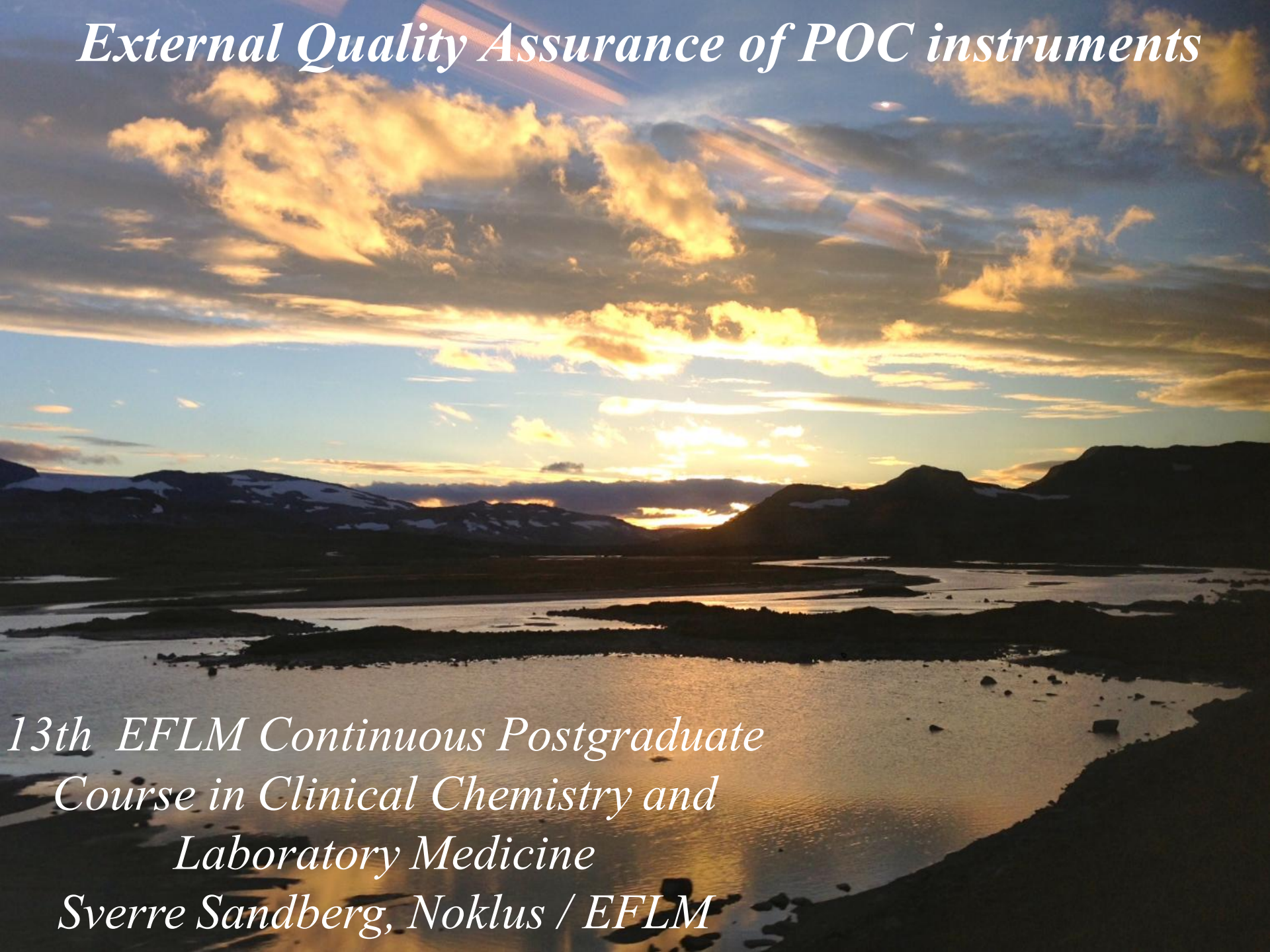
External Quality Assurance of POC instruments



13th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine

Sverre Sandberg, Noklus / EFLM

What I will talk about

- ✓What is special with EQA for POC
- ✓What is important with EQA
- ✓The total testing process
- ✓Examples of how it can be done

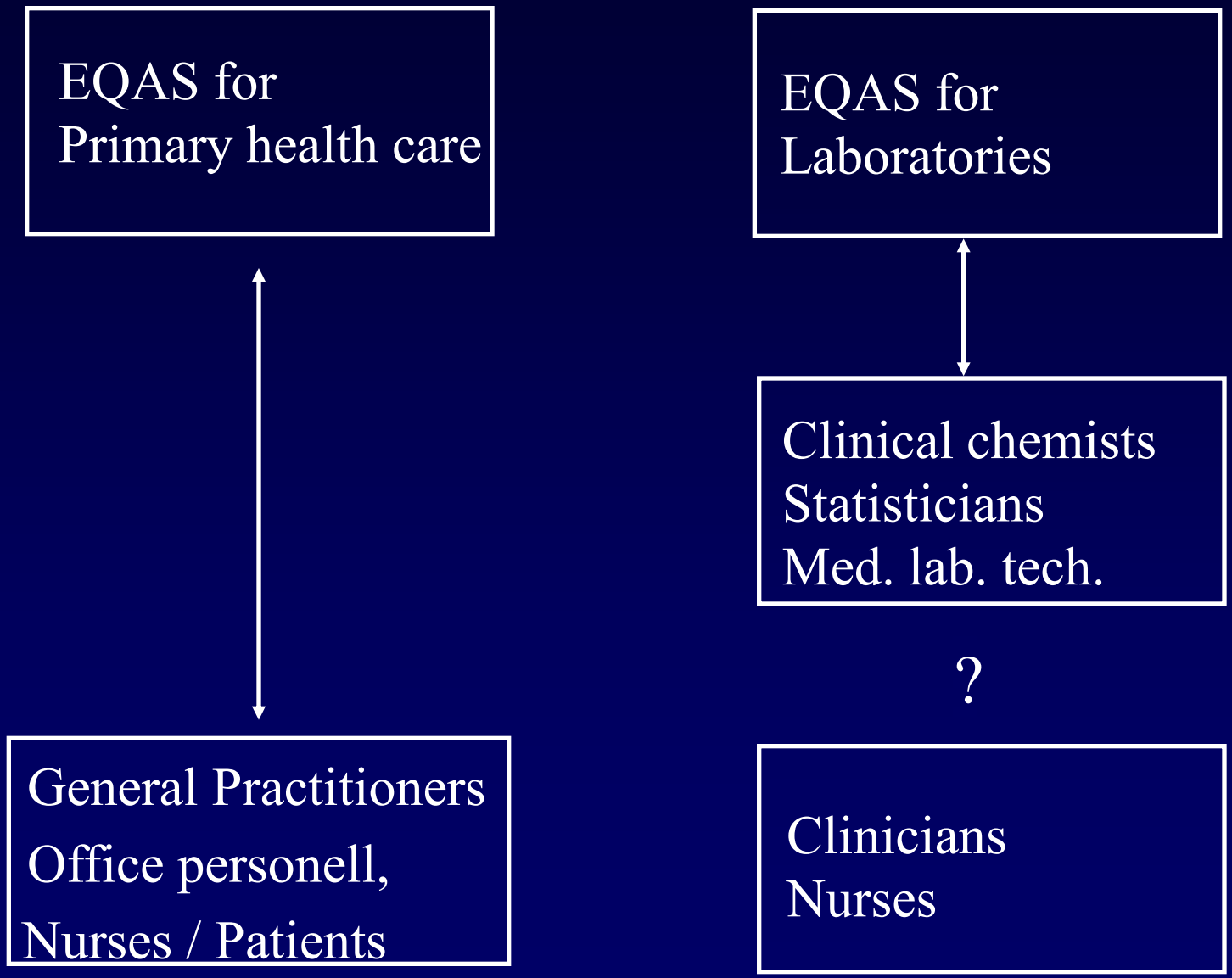
Analytical quality assurance POC

- Everything is different
- Should we use internal quality control, for which analytes, what rules 2_{3s}, ?? / split sample?
- Can we show that this is of importance?
- What do we do with the alarms?
- How to perform EQAS, how often?
- How to perform quality assurance of self-measurement?

Analytical quality assurance of POCT -challenges

- Challenges
  - Easy to use
  - “Everybody can do it”
  - “No mistakes can be done”
  - “The instrument will give an error message if something is wrong”
  - Often used by people with little or no lab experience
  - Expensive to perform controls

Differences in EQAS for POC testing and hospital laboratories



EQA and POC - what is the difference from usual EQA?

- Often many participants / user
- Situated in remote areas
- Users with little knowledge about the laboratory
- Direct communication with patients, nurses, clinicians, GP-offices

EQA categories

EQA category	Commutable material	Reference target value	Replicate measurements
1	Yes	Yes	Yes
2	Yes	Yes	No
3	Yes	No	Yes
4	Yes	No	No
5	No	No	Yes
6	No	No	No

Quality specifications should be given

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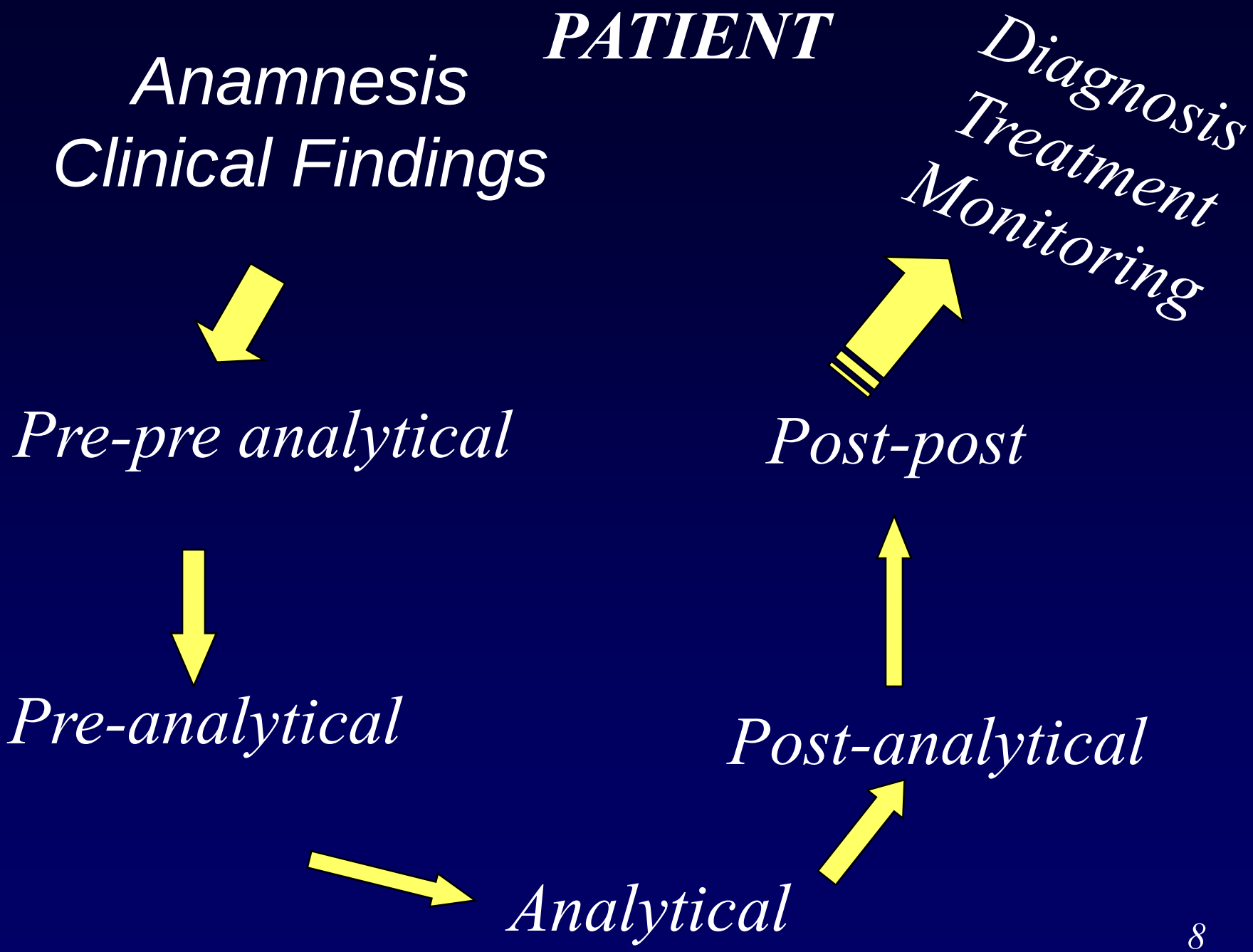

PATIENT
Anamnesis
Clinical Findings
Diagnosis
Treatment
Monitoring
Pre-pre analytical
Post-post
Pre-analytical
Post-analytical
Analytical

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2003):

5.6.4.

External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- ad post-examination procedures

Analytical quality specificaitons

Similar or different compared to hospital laboratories?

Dependent on the use of the test.

Guidelines Recommendation to participate in EQA schemes

- ISO 22870 2005. Point-of-care testing (POCT) - Requirements for quality and competence.

- CLSI POCT 07-A 2010. Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline.

- NCCLS H49-A 2004. Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline.

Example POCT INR

Stavelin A, Clinical Chemistry and Laboratory Medicine. 2011 50:81–8.

European countries that do not provide EQA for POC INR testing (n=19): Belgium, Bulgaria, Croatia, France, Germany, Iceland, Ireland, Italy, Latvia, Luxemburg, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Turkey.

European country	External Quality Assessment organizer	
Austria	ÖQUASTA	Austrian Society of Quality Assurance and Standardization
Czech Republic	SEKK	External quality assessment system for clinical laboratories
Denmark	DEKS	Danish Institute for External Quality Assurance for Laboratories in Health Care
Finland	Labquality	Labquality
Hungary	QualiCont	In Vitro Diagnostic Quality Control Nonprofit Public Utility Ltd.
Netherlands	ECAT	External quality Control of diagnostic Assays and Tests
	FNT	Federation of Netherlands Thrombosis services
Norway	NOKLUS	The Norwegian Quality Improvement of Primary Care Laboratories
Switzerland	CSCQ	The Quality Control Center Switzerland
	MQ	Association of Medical Quality Control
United Kingdom	UKNEQAS	United Kingdom National External Quality Assessment Scheme
	WEQAS	Welsh External Quality Assessment Schemes

In Norway:
Government and the Norwegian Medical Association established an organization to take care of improving laboratory quality of POC instruments

NOKLUS

NOKLUS - 2012

2879 participants in NOKLUS

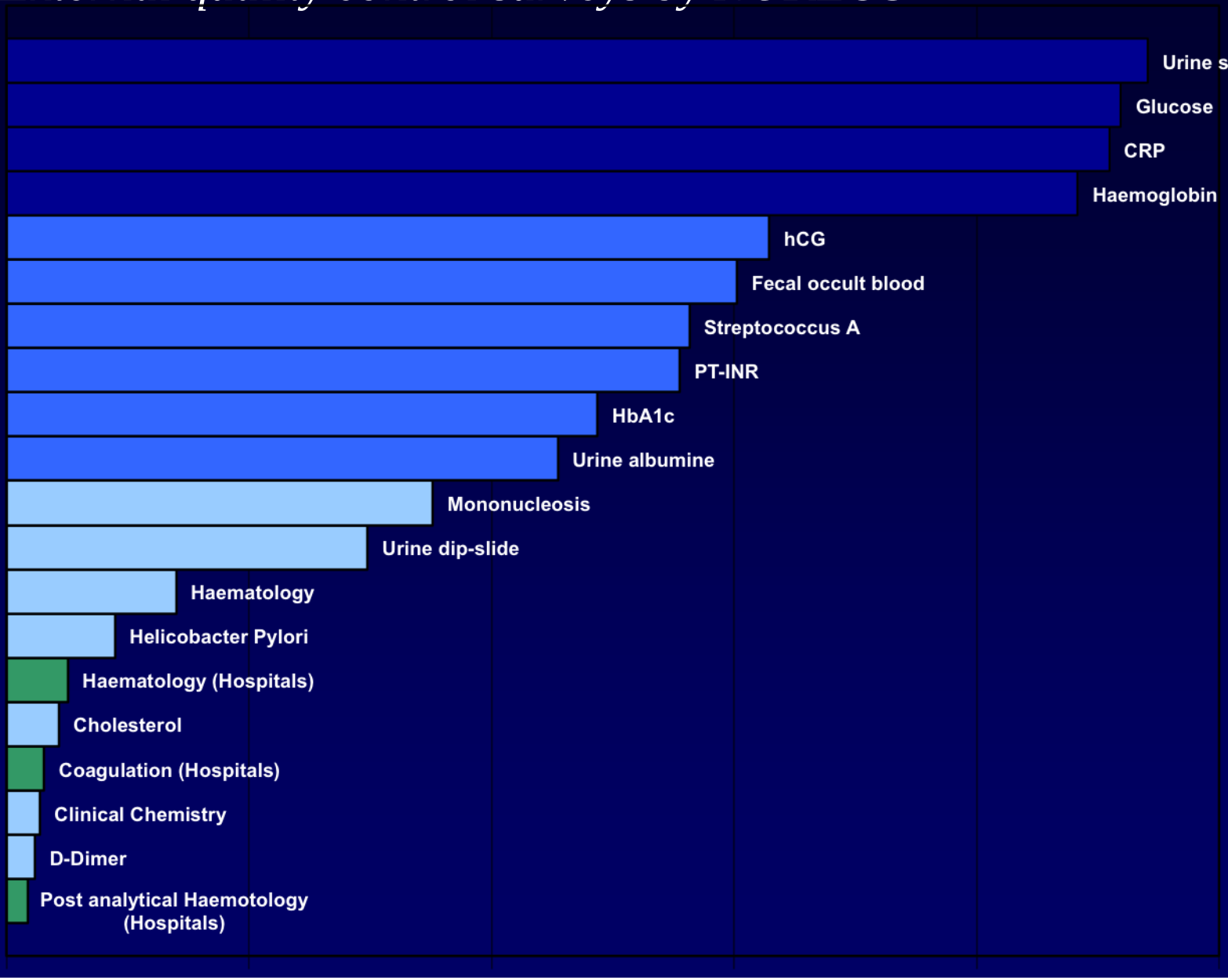
- 1755 GPs offices (99,8%)
- 928 (92 %) nursing homes
- Others, oil platforms, military, police etc

Laboratory consultants visit the participants

518 courses with 7192 participants

36 schemes for EQAS

External quality control surveys by NOKLUS



How to do it

- Traditional EQA by circulating samples
  - Often non-commutable samples
- Split sample with GP office / hospital
  - Will include also preanalyticl factors + additional factors/errors related to “master” instrument(s)
  - Native samples

New EQA model for POCT

Clinical Chemistry 59:2
363–371 (2013)

Laboratory Management

External Quality Assessment of Point-of-Care Methods: Model For Combined Assessment of Method Bias and Single-Participant Performance by the Use of Native Patient Samples and Noncommutable Control Materials

Anne Stavelin,[1,2] Per Hyltoft Petersen,[1] Una Ø. Sølvik,[2] and Sverre Sandberg[2,3]

NOKLUS

- ✓ Method bias is established by split sample analyses of patients samples e.g. 100 samples for each method.

- ✓ Participant performance is estimated by deviation from method specific target value using non-commutable control material.

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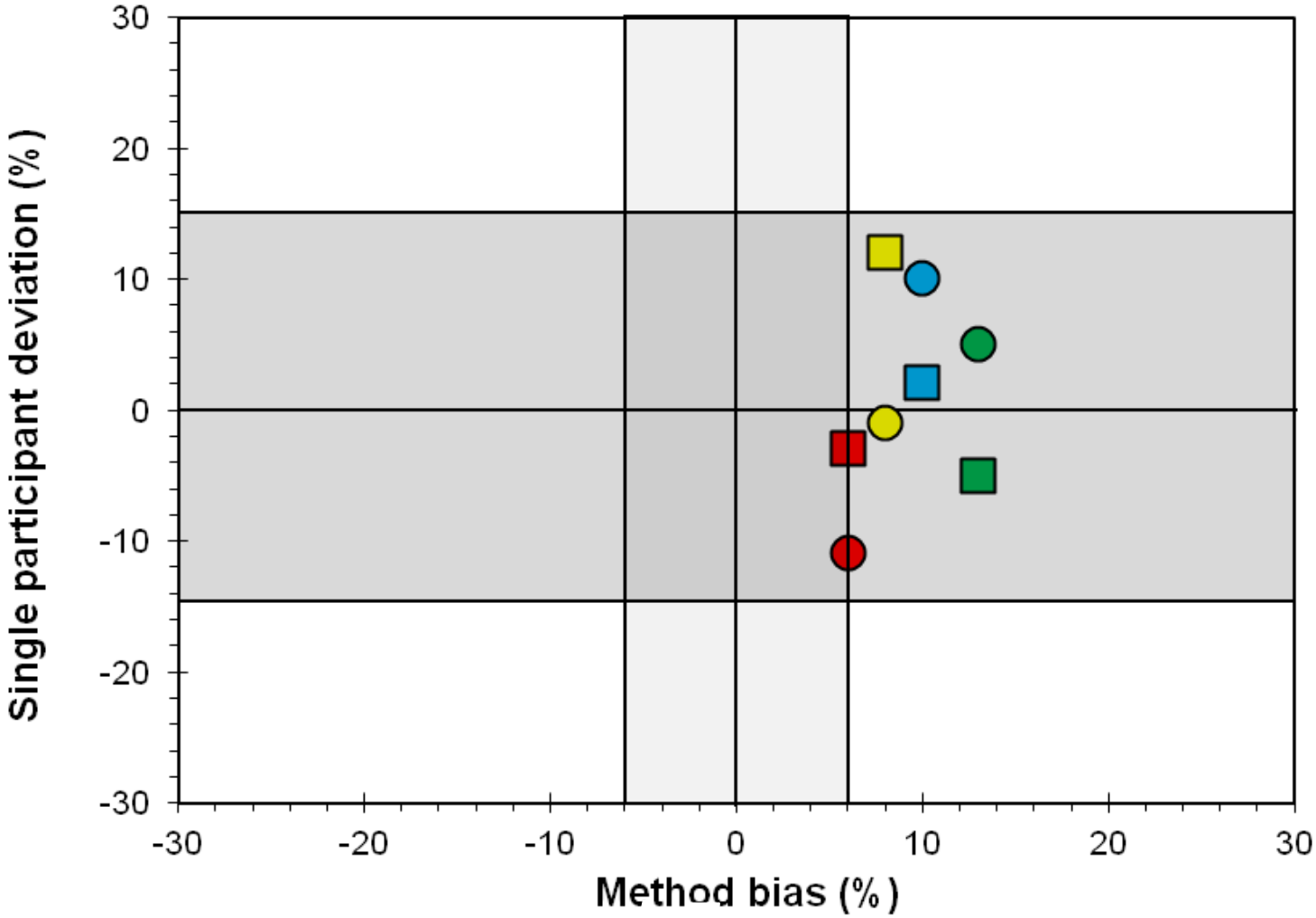
Example 1



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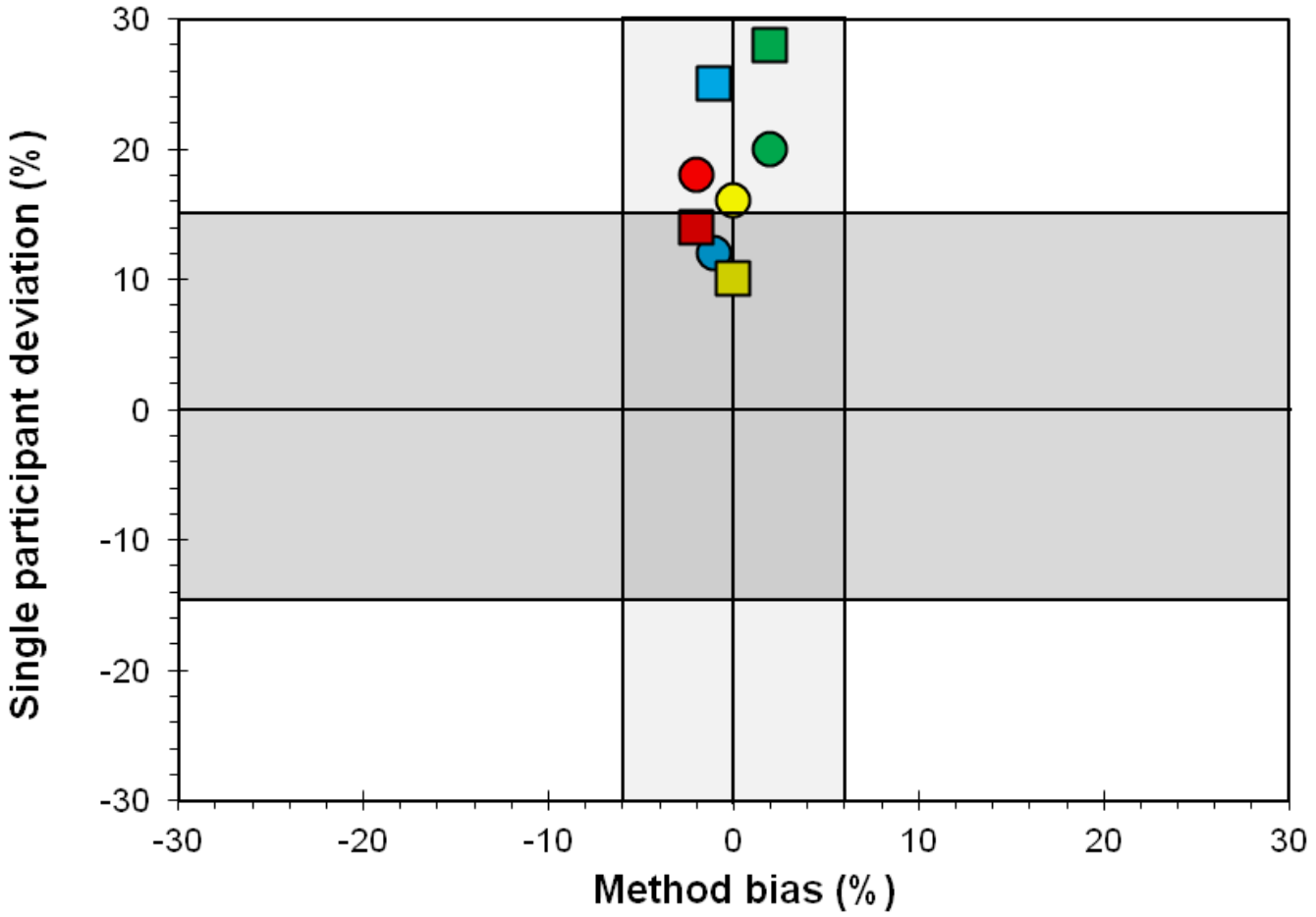
Example 2



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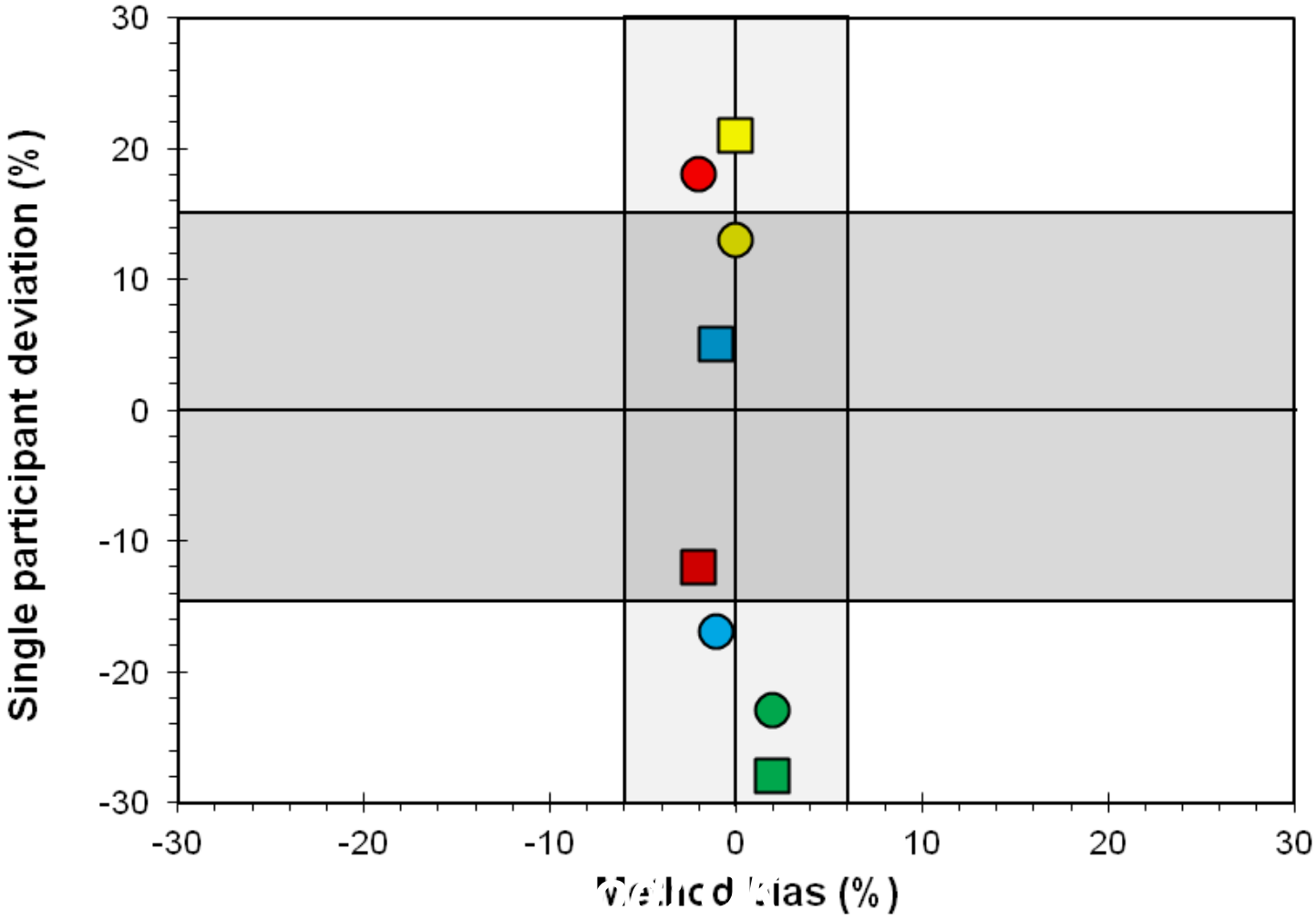
Example 3


Single participant deviation (%)
30
20
10
0
-10
-20
-30
-30
-20
-10
0
10
20
30
Method bias (%)

Problem with control material

Clinical Chemistry 51:9
1632–1636 (2005)

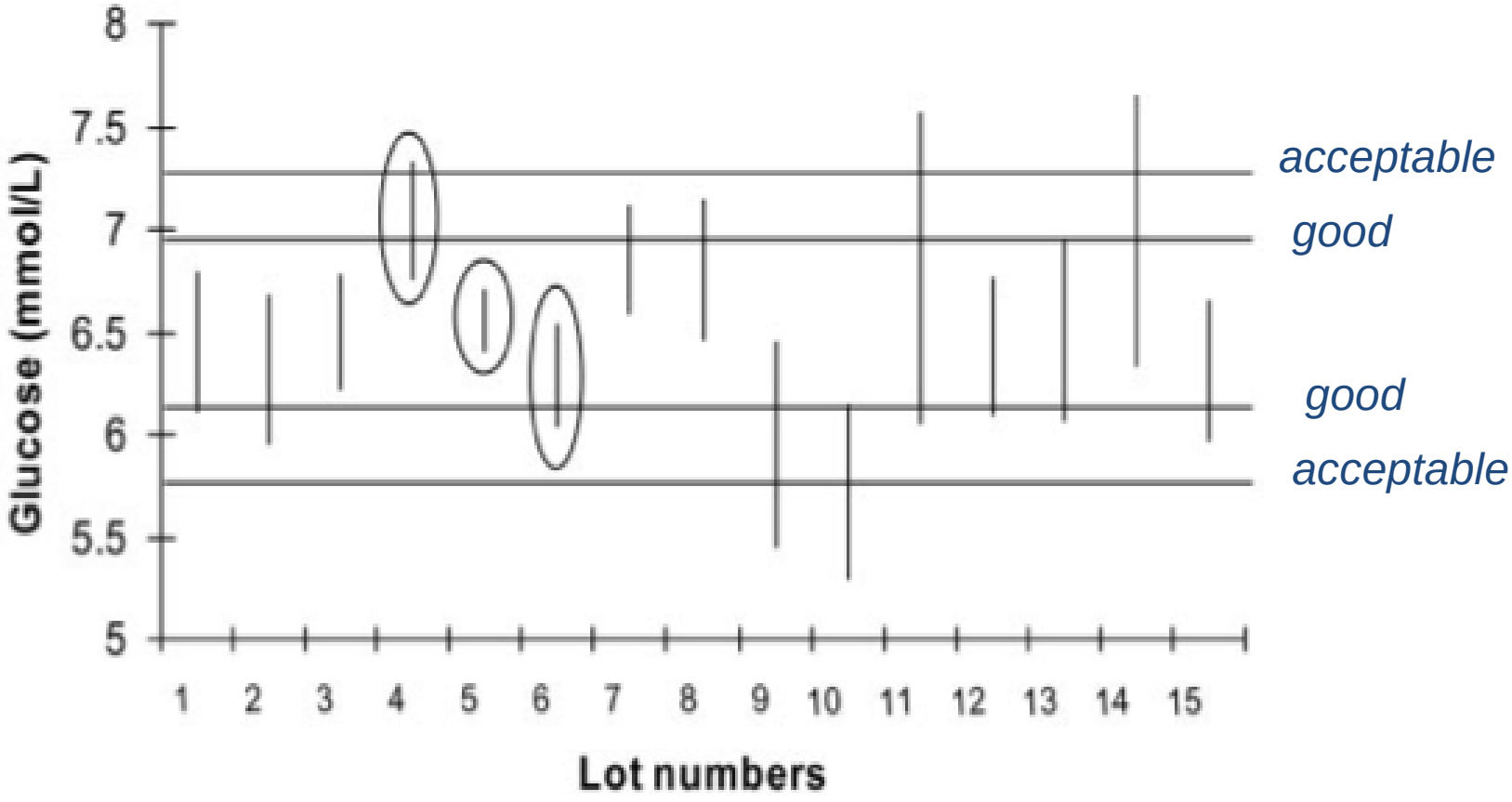
Evidence-Based
Laboratory Medicine
and Test Utilization

Between-Lot Variation in External Quality Assessment of Glucose: Clinical Importance and Effect on Participant Performance Evaluation

GUNN B.B. KRISTENSEN,* NINA GADE CHRISTENSEN, GEIR THUE, and SVERRE SANDBERG

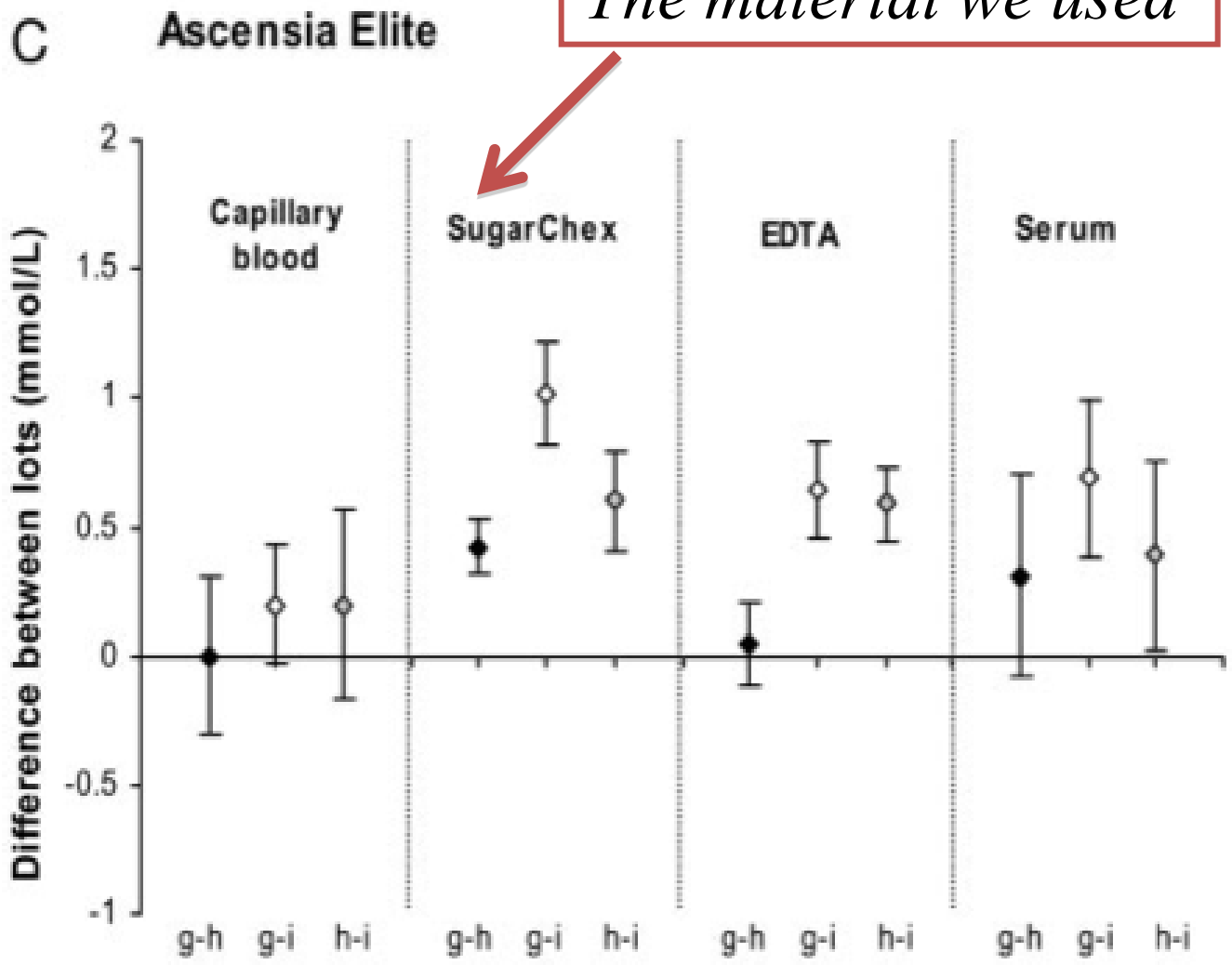
NOKLUS

Selection of lot numbers for the study from the routine EQAS,shown for the Ascensia Elite glucometer (n= 262 instruments).



Different lots and different control materials

The material we used



Should there be quality specifications depending on the source of the target values?

- Commutable material with target value
  - Method variation
  - Lot variation
  - Participants performance
- Method median
  - Lot variation
  - Participants performance
- Lot median
  - Participants performance

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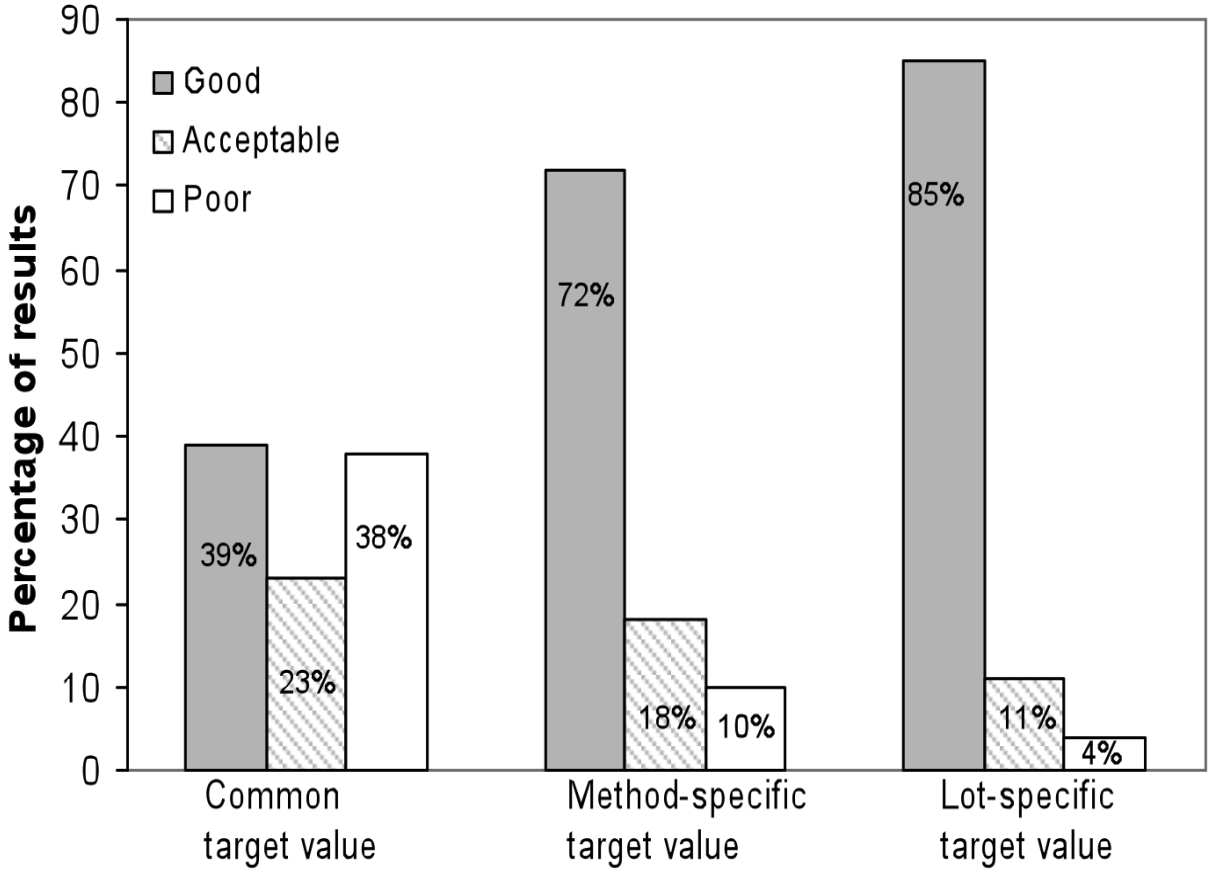
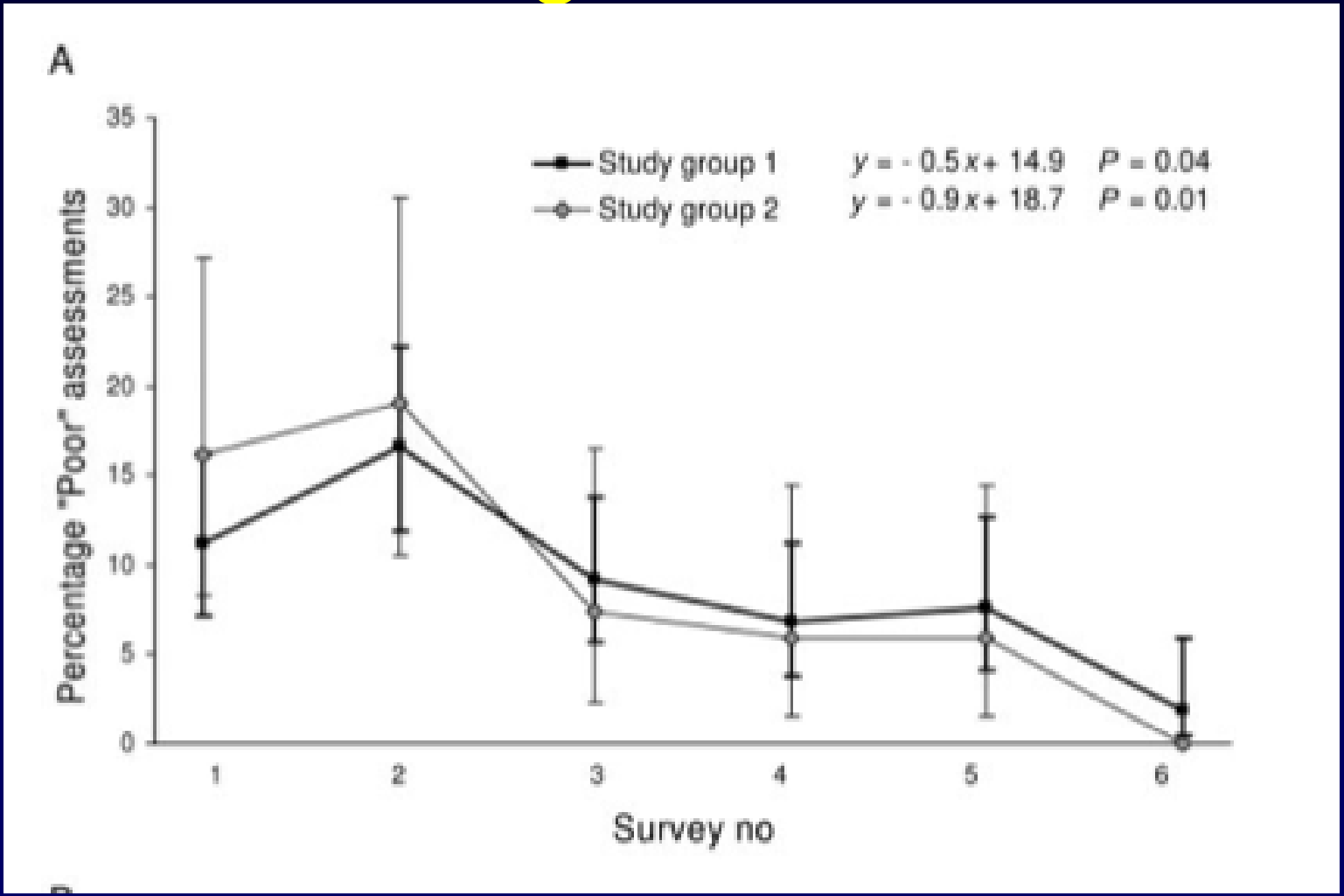
Should target limits be set depending on a common target value, method specific target value or lot specific target value



EQAS for self-monitoring. glucose



Kristensen GBB et al. Clin Chem. 2006: 52:1311–7.

Post-analytical quality assurance

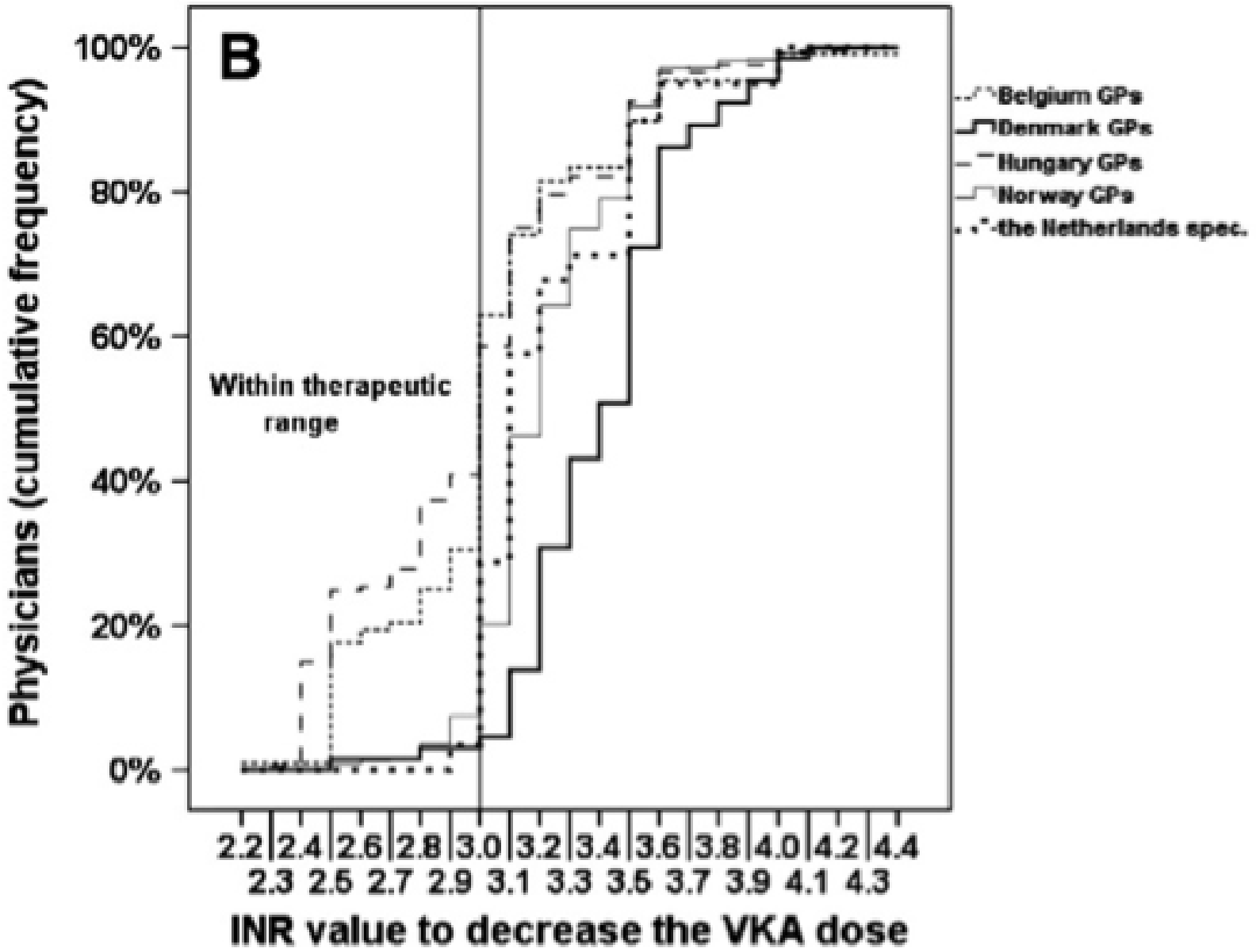
- How to report the result?
- How does the co-worker or patient interpret the result?
- How do the physicians interpret the result?
- What are the actions?

Interpretation and action

Patient A is a 76-year-old man with permanent atrial fibrillation and hypertension who is treated with warfarin and antihypertensives. The therapeutic interval for this patient is INR 2,0-3,0 (target INR 2,5). He is otherwise healthy and is feeling well at the moment. His INR results have been stable, and have varied between 2,0 and 2,8 during the last months.

His INR today is 2,3, and you decide not to change the warfarin dose.

If you were to decrease his warfarin dose, how high must this next INR value be? ___.



Kristoffersen A-H et al. Thromb Res. 2012;130:309–15.

Create a process for EQA of POC devices

1. Control material, target values, replicates.
2. Frequency
3. Follow up
4. Pre- and post-analytical aspects.


EuroLabFocus
The Patient & Laboratory Medicine
EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE
UEMS
Liverpool, UK
The Association for Clinical Biochemistry & Laboratory Medicine
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7-10 October 2014


Thank you