Questionnaire

Traceability in EQA

EQALM
European Organisation For External Quality Asssurance Providers in Laboratory Medicine

Clinical Chemistry 57:12
1670–1680 (2011)

Proficiency Testing/External Quality Assessment: Current Challenges and Future Directions

W. Greg Miller,[1*] Graham R.D. Jones,[2] Gary L. Horowitz,[3] and Cas Weykamp[4]

Table 3. Evaluation capabilities of PT/EQA related to scheme design.

	Sample characteristics			Evaluation capability: Accuracy: Individual laboratory: Absolute vs RMP or CRM	Relative to participant results: Overall	Relative to participant results: Peer group	Reproducibility: Individual laboratory intralab CV	Reproducibility: Measurement procedure interlab CV	Standardization or harmonization[b]: Measurement procedure calibration traceability: Absolute vs RMP or CRM	Standardization or harmonization[b]: Measurement procedure calibration traceability: Relative to participant results
Category	Commutable	Value assigned with RMP[a] or CRM	Replicate samples in survey							
1	Yes	Yes	Yes	X	X	X	X	X	X	X
2	Yes	Yes	No	X	X	X		X	X	X
3	Yes	No	Yes		X	X	X	X		X
4	Yes	No	No		X	X		X		X
5	No	No	Yes			X	X	X		
6	No	No	No			X		X		

[a] RMP, reference measurement procedure; CRM, certified reference material.

[b] Standardization when patient results are equivalent between measurement procedures and calibration is traceable to SI by use of a reference measurement procedure; harmonization when patient results are equivalent between measurement procedures and calibration is not traceable to a reference measurement procedure.

EQALM
European Organisation For External Quality Assurance Providers in Laboratory Medicine

QUESTIONNAIRE ON TRACEABILITY

QUESTIONNAIRE ON TRACEABILITY

GENERAL INFORMATION

Name EQA organisation	
Country	
Specify the total number of measurands in the schemes of your EQA organisation (includes all different disciplines like clinical chemistry, immunology, haematology etc).	
Specify the total number of measurands with target values traceable to primary standard	

SPECIFIC INFORMATION FOR MEASURANDS WITH REFERENCE METHOD TARGET VALUES

Please, complete the table below for each measurand with traceable target values

Measurand	Primary Standard	Reference Method	Value Assigment	No. of Reference Laboratories	Accreditation Reference Laboratories	No. of surveys with reference method target values per year	No. of participants	Do you have also for this measurand surveys without reference method target values	No. of surveys without reference method target values per year	Accreditation EQA programme for this measurand	Comments
			1=EQA organisation 2=Reference laboratory 3=both	If reference laboratories are used for value assigment, how many labs are used?	How many of the reference laboratories are accredited and which standard?			(Yes/No)		(Yes/No)	

Aim:

Investigation of the implementation of the use of value assignment with CRM or RMP's

European Organisation For External Quality Assurance Providers in Laboratory Medicine

QUESTIONNAIRE ON TRACEABILITY

No. of EQA organisations:	58	
No. of responders:	13	(= 22.5%)
No. of responders without CRM / RMP – VA:	5	
No. of responders with CRM / RMP – VA:	8	

QUESTIONNAIRE ON TRACEABILITY

No. of responders with CRM / RMP – VA: 8

Total no. of measurands: 47 – 1500

No. of measurands with CRM / RMP – VA: 2 – 43

Percentage measurands with CRM / RMP – VA: 1% - 11%

QUESTIONNAIRE ON TRACEABILITY

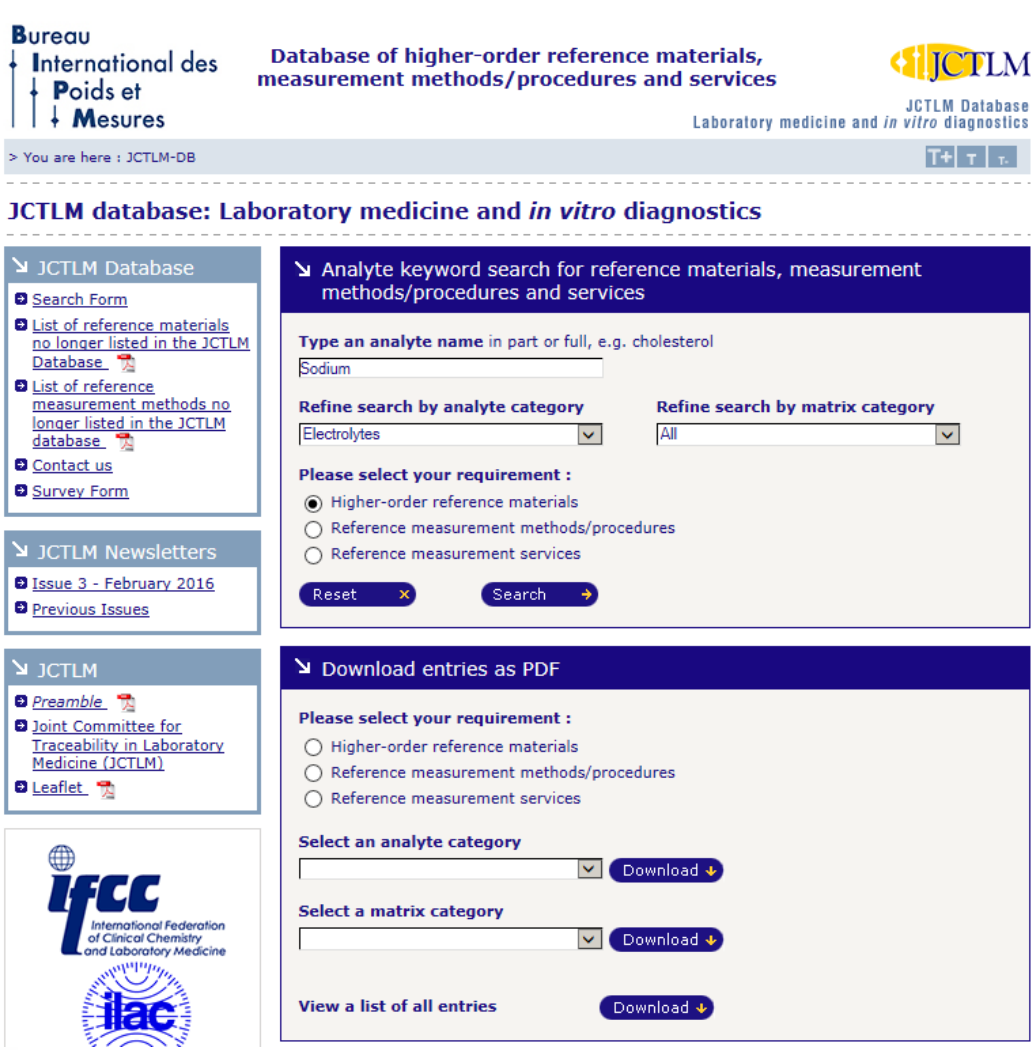
Measurands
Serum - 17-OH-progesterone
Serum - Aldosterone
Serum - ALP
Serum - ALT
Serum - Amylase
Serum - AST
Serum - Bilirubin total
Serum - Bile acids total
Serum - Calcium
Serum - Chloride
Serum - Cholesterol
Serum - CK
Serum - Cortisol
Serum - Creatinine
Serum - CRP
Serum - Digoxin
Serum - Digitoxin
Serum - Estradiol
Serum - Estriol
Serum - GGT
Serum - Glucose
Serum - Glycerides total
Serum - HDL Cholesterol

Measurands
Serum - LDH
Serum - Lithium
Serum - Magnesium
Serum - Phoshate inorganic
Serum - Potassium
Serum - Progesterone
Serum - 17-OH-progesterone
Serum - Protein total
Serum - Sodium
Serum - Testosterone
Serum - Theophylin
Serum - Triglycerides
Serum - tT3
Serum - tT4
Serum - Urea
Serum - Uric acid
Urine - Creatinine
Blood - Hemoglobin A1c
Blood - Hemoglobin total
Blood - Erythrocytes
Blood - Leucocytes

Electrolytes

Measurand	Number	CRM	RMP
Sodium	4	SRM 919b, NIST	ICP-OES ICP-MS Flame atomic emmision
Potassium	4	SRM 918b, NIST	ICP-OES ICP-IDMS Flame atomic emmision
Calcium	4	SRM 915, NIST	ICP-OES ICP-IDMS Flame atomic emmision
Lithium	4	SRM 924a, NIST	ICP-OES ICP-IDMS Flame atomic emmision
Magnesium	4	SRM 929, NIST	ICP-OES ICP-IDMS Flame atomic emmision
Chloride	3	SRM 919b, NIST	Coulormetric titration ICP-IDMS

http://www.bipm.org/jctlm/home.do



EQALM
European Organisation For External Quality Assurance Providers in Laboratory Medicine

http://www.bipm.org/jctlm/home.do

Categories:

- Blood counting
- Blood gases
- Blood grouping
- Coagulation Factors
- Drugs
- Electrolytes
- Enzymes
- Metabolites and substrates
- Micribial serology
- Non-electrolyte metals
- Non-peptide hormones
- Nucleic acids
- Proteins
- Vitamines and micronutrients
- Other

http://www.bipm.org/jctlm/home.do

JCTLM

Analyte	Matrix/Material	Name of the reference material	Producer	Quantity	Range of certified values in reference material	Range of expanded uncertainties for certified value	Listed in
potassium	potassium chloride; pure, crystalline compound	SRM 918b, Potassium Chloride (Clinical Standard)	NIST (National Institute of Standards and Technology), United States Phone : +1 301 975 6776 Fax : +1 301 948 3730 srminfo@nist.gov	Mass fraction	52.4121 %	0.0086 % relative Level of confidence 95 %	List I
potassium	2 % nitric acid solution	DMR-57, Potassium spectrometric solution	CENAM (Centro Nacional de Metrología), Mexico Phone : +52 (442) 211 05 00 Fax : +52 (442) 211 05 69 gsainz@cenam.mx	Mass concentration	996 mg/L	1.2 % Level of confidence 95 %	List I
potassium	frozen human serum	HRM-2002A, Potassium, Calcium and Sodium in Frozen Human Serum	HSA (Health Sciences Authority), Singapore Phone : +65 6775 1605 ext 104 Fax : +65 6775 1398 HSA_CML@hsa.gov.sg	Amount-of-substance concentration	4.03 mmol/l to 4.89 mmol/l	0.08 mmol/l to 0.13 mmol/l Level of confidence 95 %	List I
potassium	human serum	SRM 956c, Electrolytes in frozen human serum	NIST (National Institute of Standards and Technology), United States Phone : +1 301 975 6776 Fax : +1 301 948 3730 srminfo@nist.gov	Amount-of-substance concentration	1.982 mmol/L to 5.976 mmol/L	0.017 mmol/L to 0.051 mmol/L Level of confidence 95 %	List I

Conclusions from questionnaire

1) Not all EQA organisers use samples with CRM/RMP assigned target values.

- No CRM/RMP available?
- Costs?
- Organisational limitations?

2) A maximum of 10% of the measurands included in an EQA programme is covered by the use of samples with CRM/RMP assigened target values.

- Does the smaller portion reflects to largest portion of clinical test?
- Are we limited by the fact no CRM/RMP for the neasurand is available?

QUESTIONS TO BE DISCUSSED

1) Can we only assess the “truth” using EQA sample with target value traceable to a CRM?

2) Can we only use sample directly traceable to a CRM/RMP or can we also use indirect traceability for samples used in EQA surveys?

3) Should all samples used in EQA surveys be traceable to a CRM/RMP?