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EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

Getting the most out of EQA

Annette Thomas

Expectations of EQA Provider has changed

Accreditation status – 17043	• If not accredited, labs should justify why
Clinically relevant Distribution frequency	• Variable across Schemes (EQALM study 2009) * • Where EQA used to assess IVDs, minimum of 6 distributions p.a. (BS EN 14136:2004) • For core tests - monthly
Clinically relevant material, range and number of samples	• Evidence of reproducibility • Cover clinically appropriate range • "Blinded" • Commutable materials • Challenging samples
Clinically relevant performance criteria	• Based on clinical outcomes • Based on biological variation

Scheme designed and overseen by appropriately competent professionals	• Clinical Scientist or medically qualified • Independent Scientific or Medical Advisory group.
Reporting to Professional body / Regulatory body.	• Mechanism for identification and reporting of Persistent Poor performance issues
Education	• Training • Helpline • Pre analytical • Post Analytical
Post-marketing surveillance	• Alerts manufacturers • Alerts competent authority • Alerts laboratories • Alerts professional bodies

* A Thomas, Accred Qual Assur (2009) 14: 439-444

Objectives of EQA

Provide a measure of the quality of a test

To supplement internal quality control procedures

Provide a measure of the “state of the art” of a test

To obtain consensus values when true values are unknown

To investigate factors in performance (methods, staff etc)

To act as an educational stimulus to improvement in performance

To provide a Post market vigilance service

To provide evidence and monitoring of harmonisation strategies

Provide an assessment of the whole testing process

Expectations of EQA Provider

Clinically relevant Distribution frequency

- Variable across Schemes (EQALM study 2009) *
- Where EQA used to assess IVDs, minimum of 6 distributions p.a. (BS EN 14136:2004)
- For core tests - monthly

Clinically relevant target, range, material and number of samples

- Assessment of reproducibility
- Assessment of trueness, traceability
- Clinically appropriate range
- Commutable materials
- Challenging samples

* A Thomas, Accred Qual Assur (2009) 14: 439-444

Clinically appropriate Target value

Improvements in the assessment of the analytical phase includes evaluation of trueness using target vales assigned with high order reference methods, utilising performance criteria that are appropriate for the clinical utility of the analyte and the use of clinically challenging samples.

Reference Measurement Service - Weqas EQA programmes

Weqas

Flame Atomic Absorption/ Emission Spectrometry

- Sodium, Potassium, Calcium
- Magnesium, Lithium

IFCC Enzymes

- AST, ALT, LDH, GGT

HPLC

- HbA1c **

** Provided by IFCC Ref lab, Netherlands

IDGC-MS & ID-LC-MS/MS

- 17ß-Oestradiol
- Progesterone
- Testosterone
- Cortisol
- Bile Acids
- Creatinine
- Cholesterol
- Glucose
- Urate
- Triglyceride
- HDL *

* Currently provided by CDC lab Rotterdam and WEQAS

Clinically Relevant Range and number of samples

- Sample numbers for each scheme assessed on an individual basis Appropriate sample matrices, endogenous, commutable, challenging, linear panels to assess method linearity, specificity and sensitivity (to assist with ISO15189).
- Covering pathological and analytical ranges. Careful selection of endogenous material to ensure range is covered, selected sources of patient material
- Cover critical “diagnostic cut points” e.g. high sensitivity Troponin, urine hCG, HbA1c, POCT CRP
- For Qualitative scheme, provide an appropriate number positive and negative pools, underpinned with known quantitative concentrations.

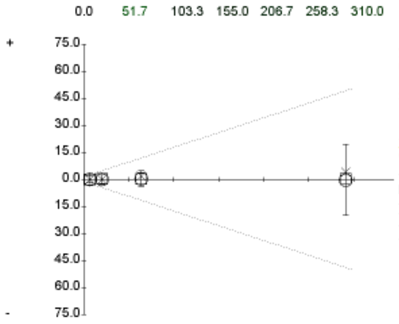
Clinically relevant samples

Weqas

Scheme: Cardiac Marker. Distribution Code: N207. Distribution Date: 24/10/17. Final. Report Issued: 23/11/17						
Troponin T (ng/L)		**1**	**2**	**3**	**4**	**Analyte SDI**
Reported Result		7.0	305.0	21.0	68.0	
Method Corrected Result		7.00	305.00	21.		
Roche High Sensitivity	Mean	7.31	300.39	21.		
	SD	0.97	9.86	1.		
	Number	54	57			
	Uncert.	0.166	1.632	0.1		
Cobas E Module	Mean	7.31	300.98	21.		
	SD	1.00	9.81	1.		
	Number	50	53			
	Uncert.	0.177	1.684	0.2		
Overall	Mean	7.32	300.96	21.		
	SD	0.99	10.34	1.		
	Number	56	59			
	Uncert.	0.165	1.682	0.2		
Reference Values						
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		1.29	24.78	2.4		
SDI		**-0.24**	**0.19**	**-0.**		

Please note: Linear regression uses CF corrected data.

This Distribution *N207*



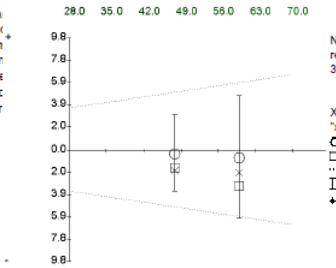
y = 1.01x
r = 1.0000
IS = 0
Sy.x = 0.7

Scheme: Glycated Haemoglobin. Distribution Code: H264. Distribution Date: 24/04/18. Final. Report Issued: 21/05/18					
HbA1c IFCC (mmol/mol)		**1**	**2**	**3**	**Analyte SDI**
Reported Result		58.0	46.0		
Method Corrected Result		58.00	46.00		
Affinity	Mean	59.35	47.51	38.92	
	SD	2.67	1.65	1.44	
	Number	17	17	10	
	Uncert.	0.811	0.501	0.570	
Afinion AS100	Mean	56.86	46.26	NNR	
	SD	1.02	1.01		
	Number	7	7		
	Uncert.	0.482	0.478		
Overall	Mean	59.99	47.80	38.82	
	SD	2.24	2.21	2.89	
	Number	147	145	123	
	Uncert.	0.231	0.229	0.326	
Reference Values IFCC		59.60	48.40		
Ref. Value Uncertainty		1.400	1.400		
Non-scoring Reference Values					
WeQas SD		2.92	2.50	2.18	
SDI		-0.46	-0.60		0.53

Sigma Metrics			
Critical Level 1: 50 mmol/mol			
Minimum Acceptable score	1.64	Critical Level 1 Sigma score	2.1
MAPS Allowable TE	7.7%		
MAPS Allowable bias %	3.6%	Lab |bias| %	3.4%
MAPS Allowable CV %	2.5%	Lab CV %	2.1%

Please note: Linear regression uses CF corrected data.

This Distribution *H264*



Scheme: PoCT CRP. Distribution Code: R7. Distribution Date: 17/04/18. Final. Report Issued: 4/05/18				
CRP (mg/L)		**1**	**2**	**Analyte SDI**
Reported Result		88.00	25.00	
Method Corrected Result		88.000	25.000	
QuikRead go	Mean	85.156	23.000	
	SD	8.054	2.875	
	Number	7	8	
	Uncert.	3.8053	1.2704	
QuikRead go	Mean	85.156	23.000	
	SD	8.054	2.875	
	Number	7	8	
	Uncert.	3.8053	1.2704	
Overall	Mean	78.617	22.000	
	SD	6.204	1.574	
	Number	35	36	
	Uncert.	1.3108	0.3279	
Reference Values				
Ref. Value Uncertainty				
Non-scoring Reference Values				
WeQas SD		5.703	1.740	
SDI		**0.50**	**1.15**	**0.82**

Please note: Linear regression uses CF corrected data.

SureScreen	SureScreen hCG GHCGC	Negative	Negative	Negative	Negative	3	1	1	0	1.67
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Negative	Negative	Negative	Negative	3	1	1	0	1.67
SureScreen	SureScreen hCG GHCGC	Negative	Positive	Positive	Negative	3	0	0	0	1.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen Midstream GHCGMS	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Veda.Lab	BabyCheck-1	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Veda.Lab	BabyCheck-1	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Veda.Lab	BabyCheck-1									
Veda.Lab	BabyCheck-1	Positive	Positive	Positive	Negative	0	0	0	0	0.00
VISITECT Pregnancy	VISITECT Pregnancy	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Interpretation		**Positive**	**Equivocal, further investigation**	**Equivocal, further investigation**	**Negative**					
Spiked Value		**Approximately 35 IU/L**	**Approximately 22 IU/L**	**Approximately 13 IU/L**	**Approximately 4 IU/L**					

Expectations of EQA Provider

Clinically relevant performance criteria

- Based on clinical outcomes
- Based on biological variation

Reporting to Professional body / Regulatory body.

- Mechanism for identification and reporting of Persistent Poor performance issues

* A Thomas, Accred Qual Assur (2009) 14: 439-444

DE GRUYTER Clin Chem Lab Med 2015; 53(6): 833–835

Consensus Statement

Sverre Sandberg*, Callum G. Fraser, Andrea Rita Horvath, Rob Jansen, Graham Jones, Wytze Oosterhuis, Per Hyltoft Petersen, Heinz Schimmel, Ken Sikaris and Mauro Panteghini

Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine

DOI 10.1515/cclm-2015-0067

The Organisers and the Scientific Programme Committee (SPC) of the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) on 'Defining analytical performance goals 15 years after the Stockholm Conference on Quality Specifications in Laboratory Medicine', held in Milan (IT) on November 24–25, 2014, are pleased to report on the success of the Conference.

The primary aim was to revisit the 'Consensus Agreement' from the Stockholm Conference investigating to what extent the advocated hierarchy is still valid or if it should be changed. A revision of the original hierarchy established by the Stockholm Conference was presented to the meeting with opportunity for discussion and feedback by conference participants. This revision further underwent modification and explanatory additions by the SPC in an attempt to simplify the hierarchy and improve its application by various stakeholders.

DE GRUYTER Clin Chem Lab Med 2017; 55(7): 949–955

Opinion Paper

Graham R.D. Jones*, Stephanie Albarede, Dagmar Kesseler, Finlay MacKenzie, Joy Mammen, Morten Pedersen, Anne Stavelin, Marc Thelen, Annette Thomas, Patrick J. Twomey, Emma Ventura and Mauro Panteghini, for the EFLM Task Finish Group – Analytical Performance Specifications for EQAS (TFG-APSEQA)

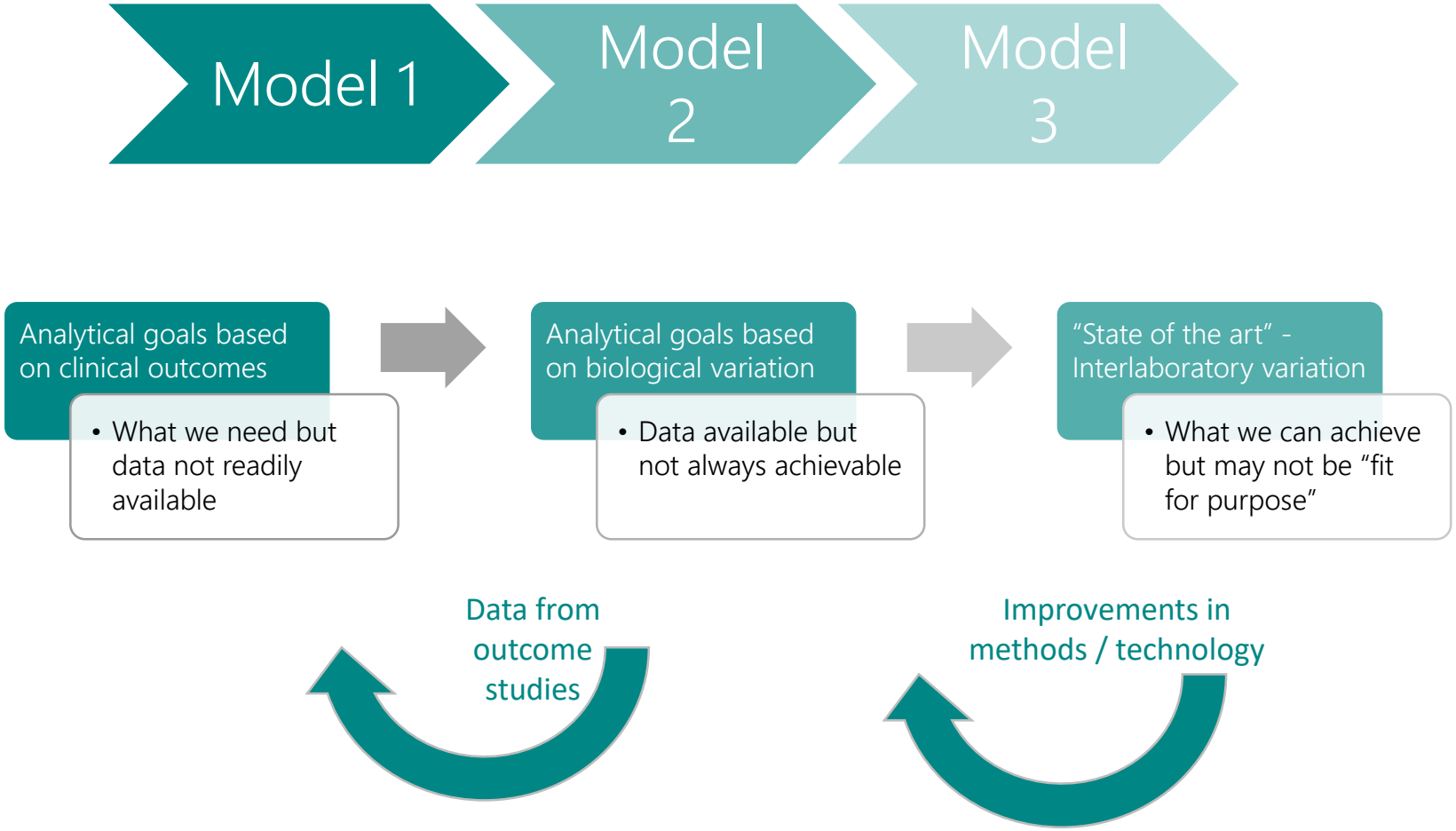
Analytical performance specifications for external quality assessment – definitions and descriptions

DOI 10.1515/cclm-2017-0151
Received February 21, 2017; accepted April 18, 2017; previously published online May 23, 2017

Abstract: External Quality Assurance (EQA) is vital to ensure acceptable analytical quality in medical laboratories. A key component of an EQA scheme is an analytical performance specification (APS) for each measurand that a laboratory can use to assess the extent of deviation of the obtained results from the target value. A consensus conference held in Milan in 2014 has proposed three models to set APS and these can be applied to setting APS for EQA. A goal arising from this conference is the harmonisation of EQA APS between different schemes to deliver consistent quality messages to laboratories irrespective

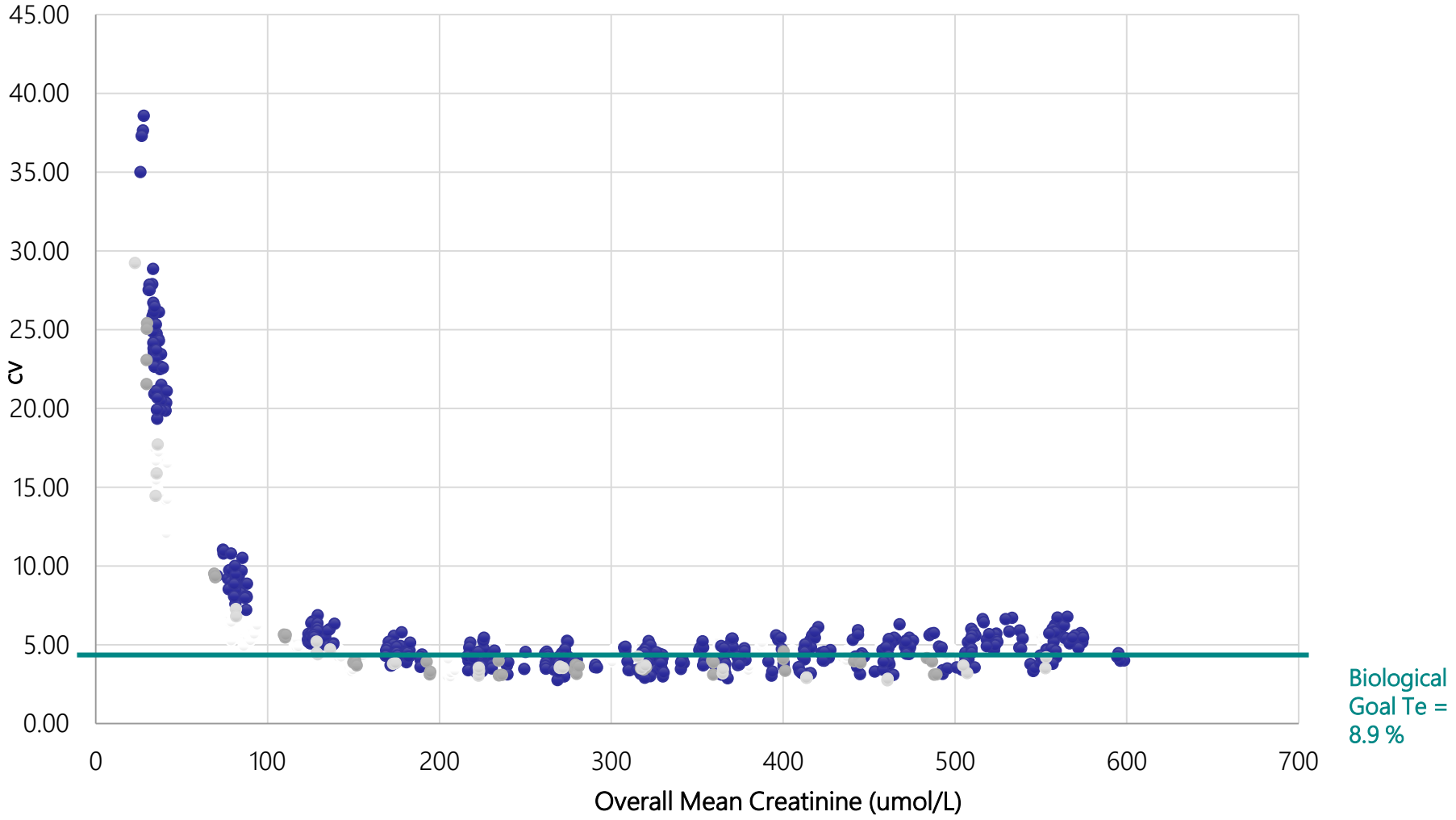
Laboratory Medicine (EFLM) Task and Finish Group on Performance Specifications for External Quality Assurance Schemes (TFG-APSEQA) and on clear terminology for EQA APS. The recommended terminology covers six elements required to understand APS: 1) a statement on the EQA material matrix and its commutability; 2) the method used to assign the target value; 3) the data set to which APS are applied; 4) the applicable analytical property being assessed (i.e. total error, bias, imprecision, uncertainty); 5) the rationale for the selection of the APS; and 6) the type of the Milan model(s) used to set the APS. The terminology is required for EQA participants and other interested parties to understand the meaning of meeting or not meeting APS.

Clinically Relevant Performance Specification



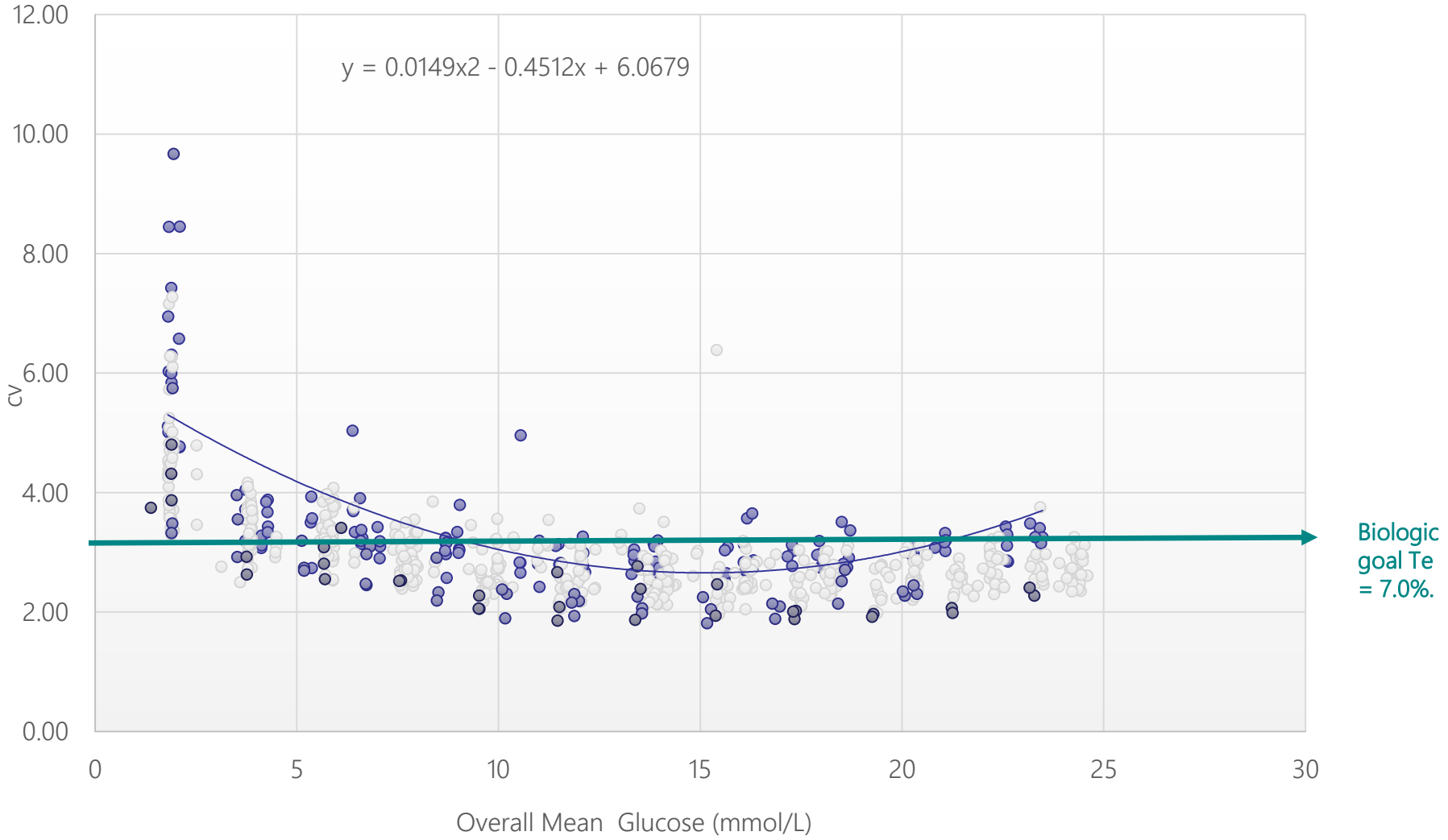
“State of the art” v Biology

Creatinine Precision Profile (CV %)



Biological goal is only achievable down to 150umol/l Creatinine

Glucose Precision Profile (CV%)



Biological goal is only achievable down to 4 mmol/l Glucose

Table 1: Examples of current variation in models used to assign analytical performance specifications (APS) to External Quality Assurance (EQA) schemes.

EQA Program	Models
CSCQ Switzerland	Governmental regulations (combination of BV and state of the art) and Combination of limits given by scientific societies and Z-score
CTCB France	Z-score/state of the art/limits given by scientific societies or other/limits based on clinical impact
DEKS Denmark	Combination of BV, state of the art and expert opinion
NOKLUS Norway	Fixed percentage limits and based on a combination of BV, state of the art and expert opinion
RCPAQAP Australia	Combination of BV and state of the art
SEHH Spain	Statistical/state of the art/BV
SEQC Spain	Combination of BV and statistical results
SKML The Netherlands	Combination of BV and state of the art
WEQAS UK	Combination of BV and state of the art
CMCEQAS	Combination of state of the art and statistical considerations

Expectations of EQA Provider

Education

- Training
- Helpline
- Pre analytical
- Post Analytical

Post-marketing surveillance

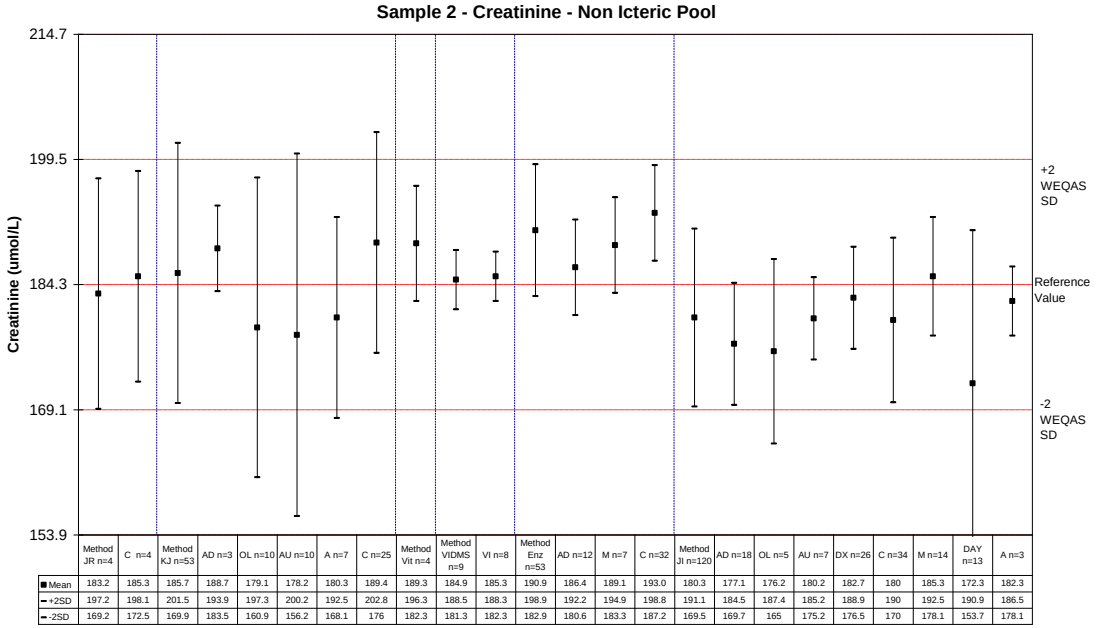
- Alerts manufacturers
- Alerts competent authority
- Alerts laboratories
- Alerts professional bodies

* A Thomas, Accred Qual Assur (2009) 14: 439-444

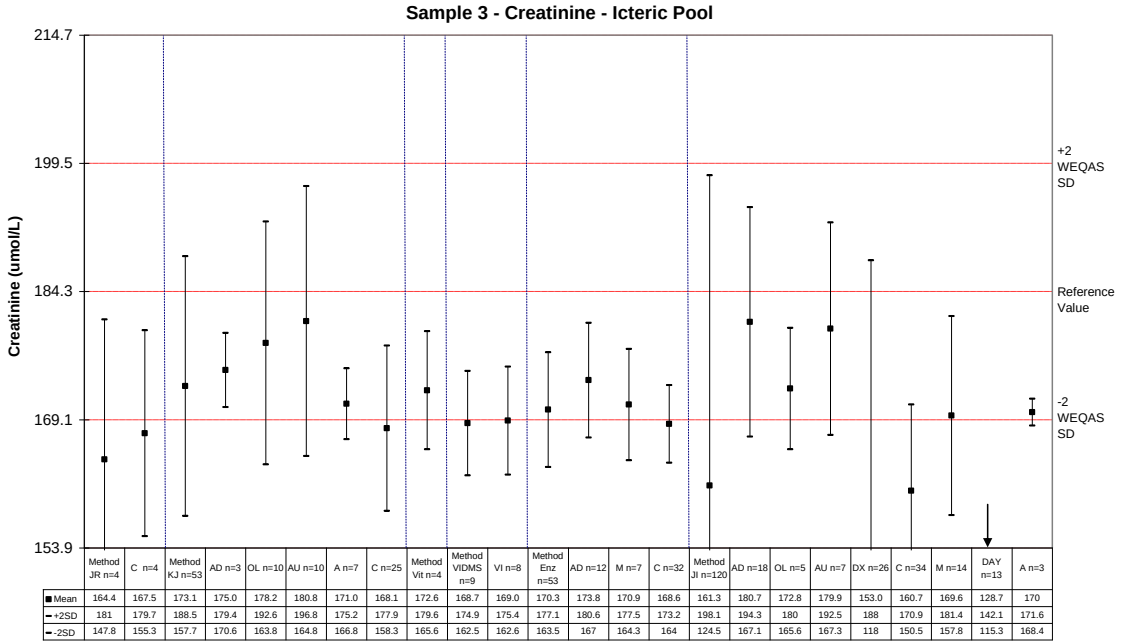
Weqas Pre / Post Analytical / Interpretive Programmes

- Serum Indices Programme, report semi-quantitative and qualitative results
- Questionnaires sent out as part of Programme repertoire to assess current practice and use of National guidelines e.g. pre analytical sample handling, Adjusted Calcium equations, Porphyrin Standards
- Interference Studies e.g. HIL samples various programmes, Bilirubin effect on Salicylate & Paracetamol
- Post analytical cases provided with Programmes e.g. Porphyrin interpretation cases, Macroprolactin samples
- EQA for calculated parameters.
- Foetal Fibronectin, Pre-eclampsia, D-dimer, – participants can report quantitative, qualitative (post-analytical interpretation)

Interference Reports – bilirubin effect on creatinine



	Method JR n=4	C n=4	Method KJ n=53	AD n=3	OL n=10	AU n=10	A n=7	C n=25	Method Vit n=4	Method VIDMS n=9	VI n=8	Method Enz n=53	AD n=12	M n=7	C n=32	Method JI n=120	AD n=18	OL n=5	AU n=7	DX n=26	C n=34	M n=14	DAY n=13	A n=3
Mean	183.2	185.3	185.7	188.7	179.1	178.2	180.3	189.4	189.3	184.9	185.3	190.9	186.4	189.1	193.0	180.3	177.1	176.2	180.2	182.7	180	185.3	172.3	182.3
+2SD	197.2	198.1	201.5	193.9	197.3	200.2	192.5	202.8	196.3	188.5	188.3	198.9	192.2	194.9	198.8	191.1	184.5	187.4	185.2	188.9	190	192.5	190.9	186.5
-2SD	169.2	172.5	169.9	183.5	160.9	156.2	168.1	176	182.3	181.3	182.3	182.9	180.6	183.3	187.2	169.5	169.7	165	175.2	176.5	170	178.1	153.7	178.1

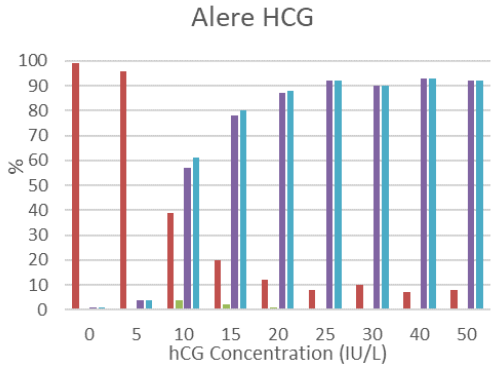


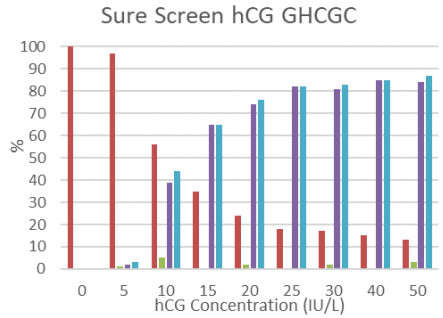
	Method JR n=4	C n=4	Method KJ n=53	AD n=3	OL n=10	AU n=10	A n=7	C n=25	Method Vit n=4	Method VIDMS n=9	VI n=8	Method Enz n=53	AD n=12	M n=7	C n=32	Method JI n=120	AD n=18	OL n=5	AU n=7	DX n=26	C n=34	M n=14	DAY n=13	A n=3
Mean	164.4	167.5	173.1	175.0	178.2	180.8	171.0	168.1	172.6	168.7	169.0	170.3	173.8	170.9	168.6	161.3	180.7	172.8	179.9	153.0	160.7	169.6	128.7	170
+2SD	181	179.7	188.5	179.4	192.6	196.8	175.2	177.9	179.6	174.9	175.4	177.1	180.6	177.5	173.2	198.1	194.3	180	192.5	188	170.9	181.4	142.1	171.6
-2SD	147.8	155.3	157.7	170.6	163.8	164.8	166.8	158.3	165.6	162.5	162.6	163.5	167	164.3	164	124.5	167.1	165.6	167.3	118	150.5	157.8	115.3	168.4

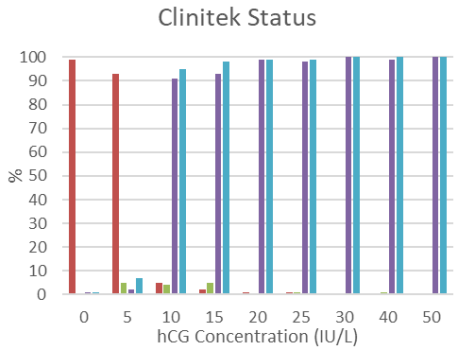
The reference value (ID-GCMS) was 184.3 µmol/L for sample 2 and 184.4 µmol/L for sample 3

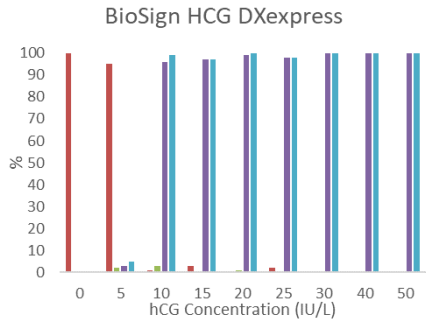
Specificity and Sensitivity Studies

Assessment of analytical sensitivity of Pregnancy testing kits.









Percentage of negative results (red), equivocal results (green), positive results (purple) and positive plus equivocal (light blue) for each pregnancy testing kit / device at each conc.

Assessment of analytical specificity of total Bile Acid methods

Four pools of human serum were prepared, and spiked with approximately 100µmol/L of each of the major bile acids and target value assigned using an ID-GCMS method

	CHOLIC ACID ID-GCMS Target				DEOXYCHOLIC ID-GCMS Target			
	103.2 µmol/L				108.8 µmol/L			
Returned results	mean	SD	n	% recovery	mean	SD	n	% recovery
overall	101.18	7.54	111	98.06	137.80	15.87	110	126.68
Enz-Thio-NADH	99.89	6.59	95	96.81	141.27	15.64	94	129.87
Enz-Formazan	89.5	1.50	5	86.74	137.00	15.00	2	125.94
Enz-Formazan (Sentinel)	112.41	4.90	15	108.95	119.42	5.08	15	109.78
POOL ID	URSODEOXYCHOLIC Gavimetric target				CHENODEOXYCHOLIC ID-GCMS Target			
	100 µmol/L				77.1 µmol/L			
Returned results	mean	SD	n	% recovery	mean	SD	n	% recovery
overall	57.81	8.44	107	57.81	56.05	7.30	107	72.66
Enz-Thio-NADH	56.00	4.44	98	56.00	54.25	4.61	95	70.32
Enz-Formazan	51.50	0.5	2	51.50	51.00	2.00	2	66.11
Enz-Formazan (Sentinel)	90.47	3.33	15	90.47	77.05	2.88	12	99.88

The study highlights the importance of using reference methods to assign target values rather than consensus mean and presents strong evidence on the variability in specificities of the methods for the different bile.

Weqas Post Analytical / Interpretive Programmes – Porphyrin Programme

			PBG Case 1						
Lab Code	Result (umol/l)	Result (umol/mmol creatinine)	Comment	Elevated PBG	Acute Porphyria / Acute attack	Result telephoned	Advise discuss with NAPS	Samples for further investigation / ID	Total Out of 5
AXP	644.3	52.6	Increased Urine Porphobilinogen, consistent with a diagnosis of acute porphyria. Contact metabolic medicine or the National Acute Porphyria Service for advice on management	1	1		1		3
BZ	789	62.6	Result suggest acute porphyria. Please send 5-10 ml EDTA blood and a small portion (5-10g wet weight) of fresh faeces in a universal container. All samples should be protected from light.		1			1	2
EN	627	51.5	Significantly raised urine PBG, consistent with active acute porphyria. Advise collect further urine, blood and stool sample for further characterisation. Seek advice from national acute porphyria service regarding patient management.	1	1		1	1	4
FB	664	58.2	Significantly raised PBG + PBG/Creatinine ratio consistent with acute porphyria attack. Result telephoned to ITU + discussed with medical staff. Advise discuss with NAPS for appropriate haem arginate treatment, current medication to determine any porphyrinogenic drugs + appropriate management of hyponatraemia (NAPS emergency protocol), follow up to determine specific form of acute porphyria to include monitoring PBG/Creatinine, urine porphyrin HPLC, plasma porphyrin scan, faecal porphyrin HPLC, plasma porphyrin scan, faecal porphyrin HPLC (ensure samples light protected). Genetic analysis offered following identifying type of acute porphyria. Family studies/family history of porphyria and appropriate cascade screening. patient hospital records + emergency protocol (acute porphyria) alert added. When well consult patient regarding medi-alert card/other.	1	1	1	1	1	5

Educational role (quality improvement)

Pre-analytical effects

Performance of methods – state of the art

- accuracy
- precision
- limits of detection
- linearity

Susceptibility of methods to interference

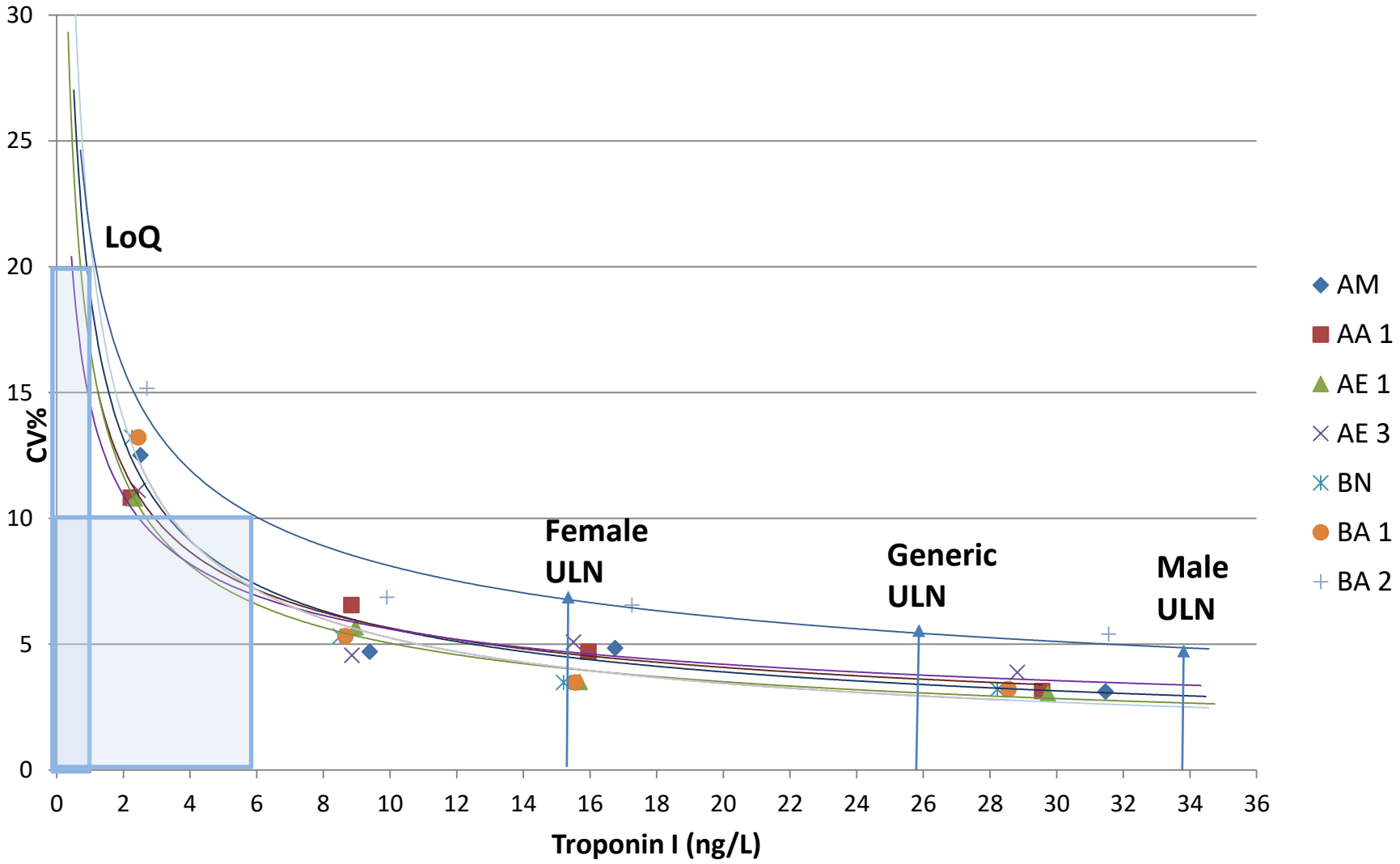
- including other analytes and matrix

Interpretation of results – standard units, global cut off

Undertaking audit of clinical services – identify good practice

Understanding how to use Quality tools – IQC, EQA, audit

Method performance – hs TnI



ISO 15180 tools from EQA reports

Weqas

Scheme: Serum Chemistry. Distribution Code: RH.
Distribution Date: 2/01/18. Final. Report Issued: 24/01/18

Glucose (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		11.4	8.1	20.7	1.8	
Method Corrected Result		11.40	8.10	20.70	1.80	
Hexokinase	Mean	11.42	8.21	21.11	1.85	
	SD	0.20	0.15	0.41	0.05	
	Number	170	172	169	168	
	Uncert.	0.015	0.012	0.032	0.004	
Cobas C Module	Mean	11.45	8.26	21.13	1.88	
	SD	0.17	0.13	0.31	0.04	
	Number	91	95	92	91	
	Uncert.	0.018	0.013	0.033	0.004	
Overall	Mean	11.39	8.21	21.05	1.86	
	SD	0.22	0.15	0.46	0.06	
	Number	191	188	188	186	
	Uncert.	0.016	0.011	0.033	0.004	
Reference Values ID-GCMS		11.40	8.15	20.95	1.76	
Ref. Value Uncertainty		0.100	0.070	0.190	0.020	
Non-scoring Reference Values						
WeQas SD		0.34	0.25	0.65	0.12	
SDI		**0.00**	**-0.20**	**-0.38**	**0.34**	**0.23**

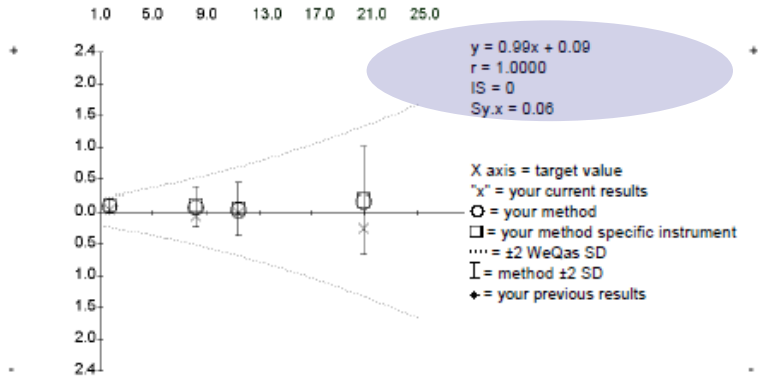
Sigma Metrics

Critical Level 1: 7 mmol/l

Minimum Acceptable score	1.62	Critical Level 1 Sigma score	7.4
MAPS Allowable TE	6.9%		
MAPS Allowable bias %	2.20%	Lab |bias| %	0.2%
MAPS Allowable CV %	2.90%	Lab CV %	0.9%

Please note: Linear regression uses CF corrected data.

This Distribution *RH* **Prev**



traceability to higher order method

Linearity assessment

Troubleshooting Support & post market vigilance

Now part of the EQA providers role

To provide help with

- Participant Performance queries
- report interpretation
- Provide additional material for problem solving

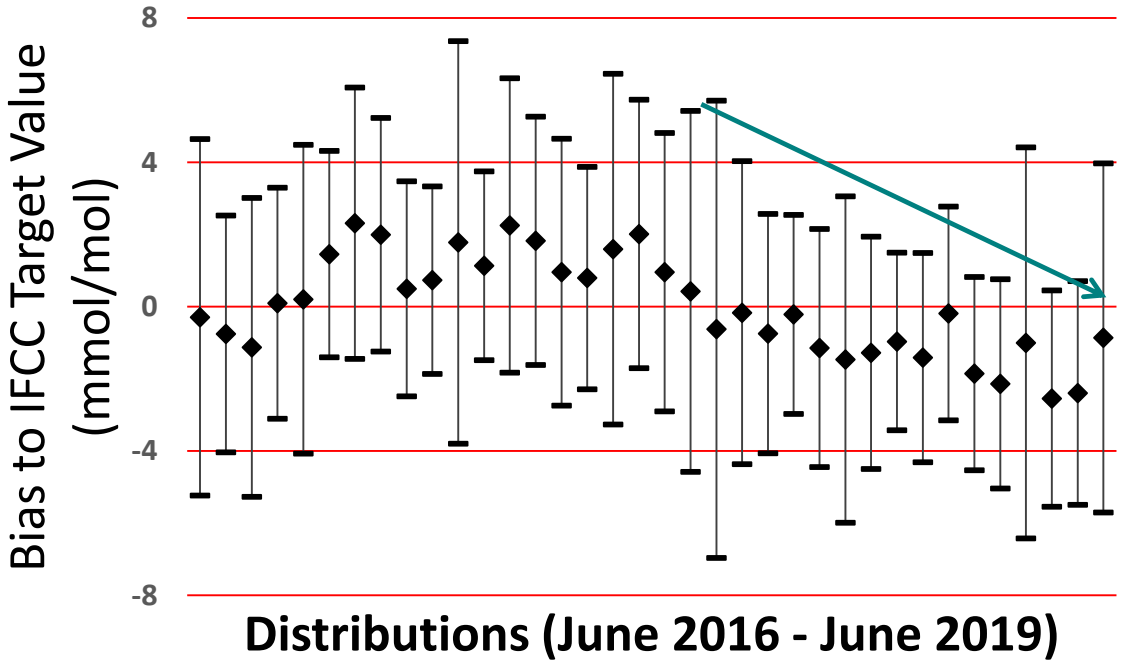
To alert manufacturers of potential issue

- To assist in issue resolution

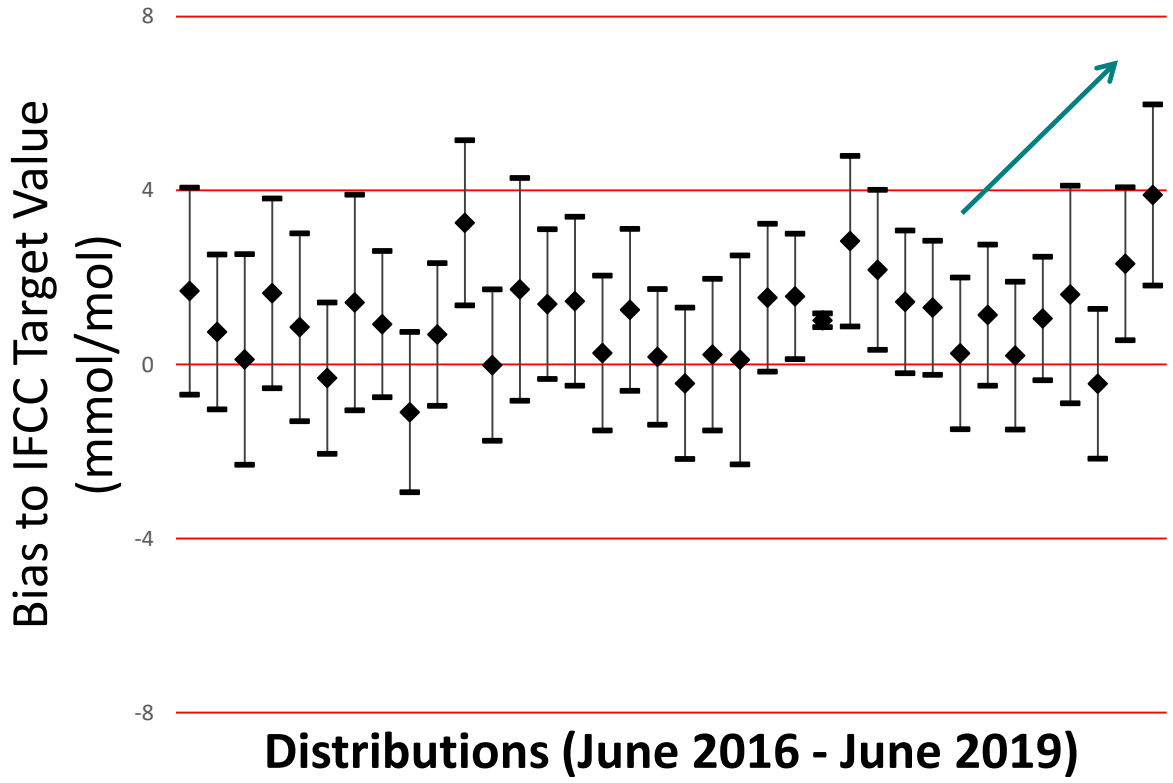
To alert regulatory authority

Weqas

DCA 2000/ Vantage HbA1c Bias Plot

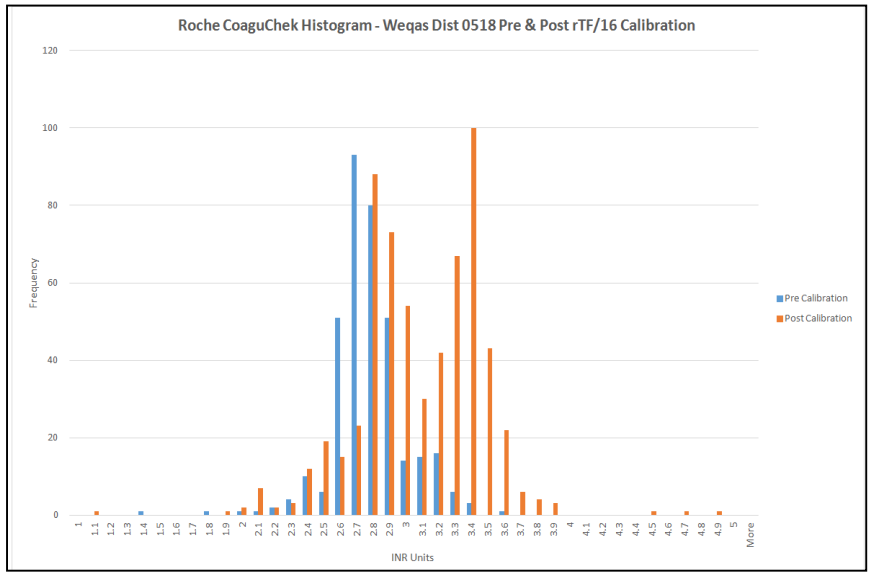


G8 HbA1c Bias Plot

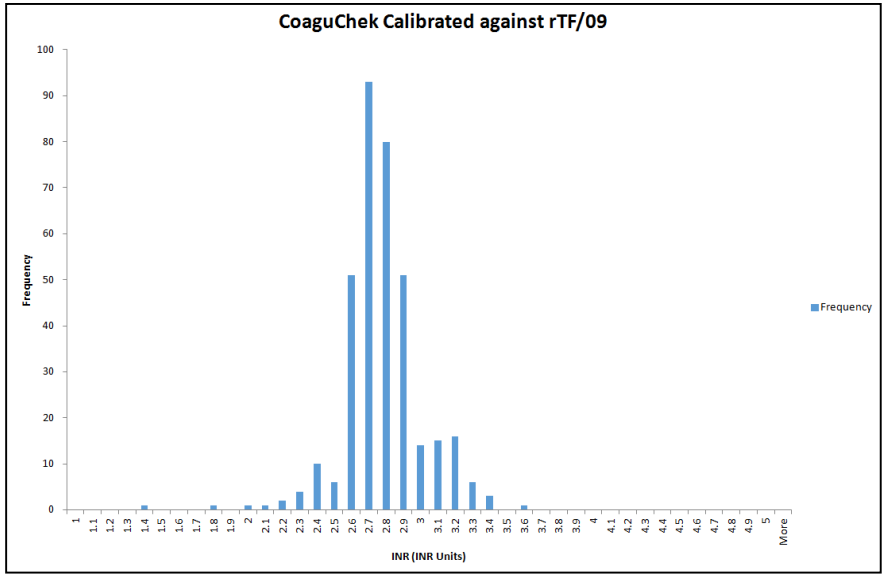


Post Market vigilance – INR thromboplastin

INR results classified into pre and post recalibration.



participants using strips calibrated to WHO reference thromboplastin rTF/09



The pre calibration strips compared well with the results from Distribution 0517 (Median 2.8) however much higher results and a wider distribution of results was observed for the post calibration strips. Weqas immediately contacted the manufacturer and sent them the data.

Aug 2018 – Urgent field safety notice issued to inform users that the manufacturer was reverting back to previous WHO reference standard.

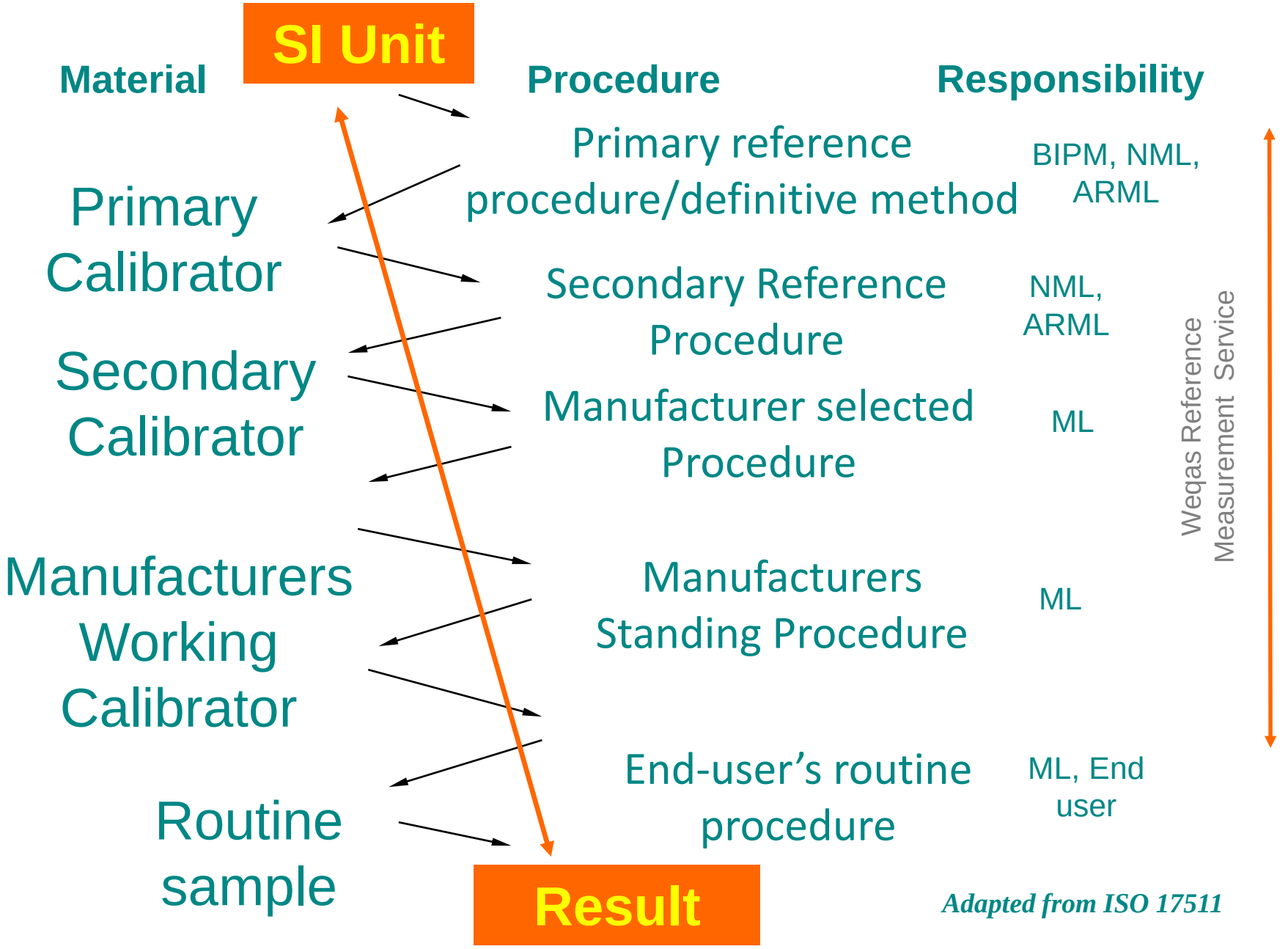
Web portals

A wealth of additional information can be provided to participants with direct links to the Weqas databases providing useful troubleshooting tools.

Can also provide tools for laboratories to achieve ISO 15189 accreditation

ISO 15189 clause 5.3.1.4 - Traceability

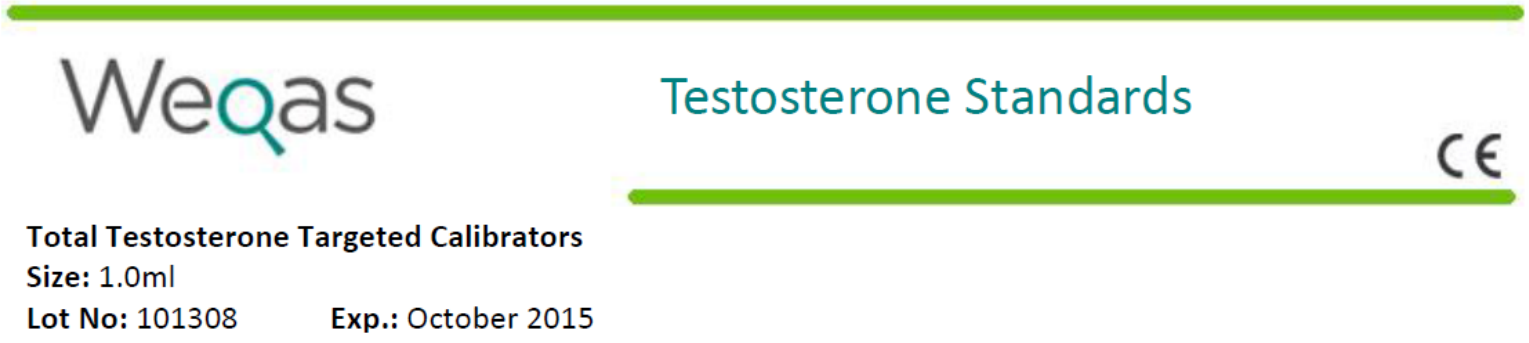
- **Equipment calibration and metrological traceability**
- The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:
- b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;
- c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals.
- Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.
- *NOTE Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.*
- Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:
- — use of certified reference materials;……



Adapted from ISO 17511

Traceability – Weqas QC-RM

- Testosterone and Cortisol Tandem MS standards are assayed quality control material for verification of "in house" prepared calibrators
- Standards prepared and value assigned using the Weqas Reference Measurement Laboratory using traceable material of the highest metrological order.
- Assists with ISO 15189:2012 compliance.



Testosterone Targeted Calibrators

Sample ID	Target Value (nmol/L)	SD	%CV	Expanded Uncertainty
Level 0	0	-	-	-
Level 1*	0.50	-	-	-
Level 2	1.04	0.02	2.00	0.03
Level 3	2.88	0.05	1.85	0.09
Level 4	7.63	0.16	2.09	0.24
Level 5	15.1	0.31	2.06	0.48
Level 6	23.48	0.29	1.24	0.74
Level 7	38.32	0.84	2.20	1.21

Scheme: Serum Chemistry. Distribution Code: RH.
Distribution Date: 2/01/18. Final. Report Issued: 24/01/18

Glucose (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		11.4	8.1	20.7	1.8	
Method Corrected Result		11.40	8.10	20.70	1.80	
Hexokinase	Mean	11.42	8.21	21.11	1.85	
	SD	0.20	0.15	0.41	0.05	
	Number	170	172	169	168	
	Uncert.	0.015	0.012	0.032	0.004	
Cobas C Module	Mean	11.45	8.26	21.13	1.88	
	SD	0.17	0.13	0.31	0.04	
	Number	91	95	92	91	
	Uncert.	0.018	0.013	0.033	0.004	
Overall	Mean	11.39	8.21	21.05	1.86	
	SD	0.22	0.15	0.46	0.06	
	Number	191	188	188	186	
	Uncert.	0.016	0.011	0.033	0.004	
Reference Values ID-GCMS		11.40	8.15	20.95	1.76	
Ref. Value Uncertainty		0.100	0.070	0.130	0.020	
Non-scoring Reference Values						
WeQas SD		0.34	0.25	0.65	0.12	
SDI		**0.00**	**-0.20**	**-0.38**	**0.34**	**0.23**

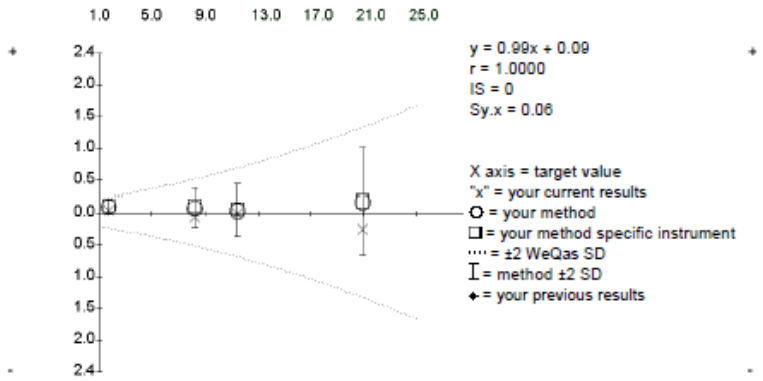
Sigma Metrics

Critical Level 1: 7 mmol/l

Minimum Acceptable score	1.62	Critical Level 1 Sigma score	7.4
MAPS Allowable TE	6.9%		
MAPS Allowable bias %	2.20%	Lab |bias| %	0.2%
MAPS Allowable CV %	2.90%	Lab CV %	0.9%

Please note: Linear regression uses CF corrected data.

This Distribution *RH* **Prev**



Traceability From Weqas Reports

- Reference measurement values shown on report (and reference value uncertainty)
- Full traceability chain to SI units available.
- Lab results compared directly to reference values
- SDI scores, Sigma scores and bias plot based on reference values

Scheme: Serum Chemistry. Distribution Code: RH. Distribution Date: 2/01/18. Final. Report Issued: 24/01/18						
Glucose (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		11.4	8.1	20.7	1.8	
Method Corrected Result		11.40	8.10	20.70	1.80	
Hexokinase	Mean	11.42	8.21	21.11	1.85	
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Ref. Value Uncertainty		0.100	0.070	0.190	0.020	
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WeQas SD		0.34	0.25	0.65	0.12	
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Sigma Metrics			
Critical Level 1: 7 mmol/l			
Minimum Acceptable score	1.62	Critical Level 1 Sigma score	7.4
MAPS Allowable TE	6.9%		
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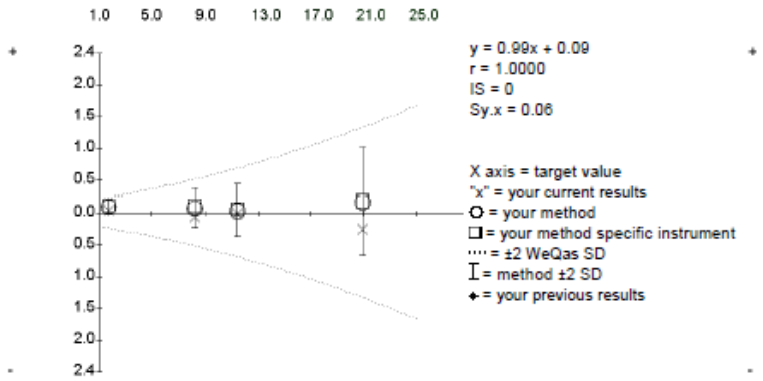
Please note: Linear regression uses CF corrected data.

This Distribution *RH* **Prev**



Uncertainty

Laboratory within run Imprecision:

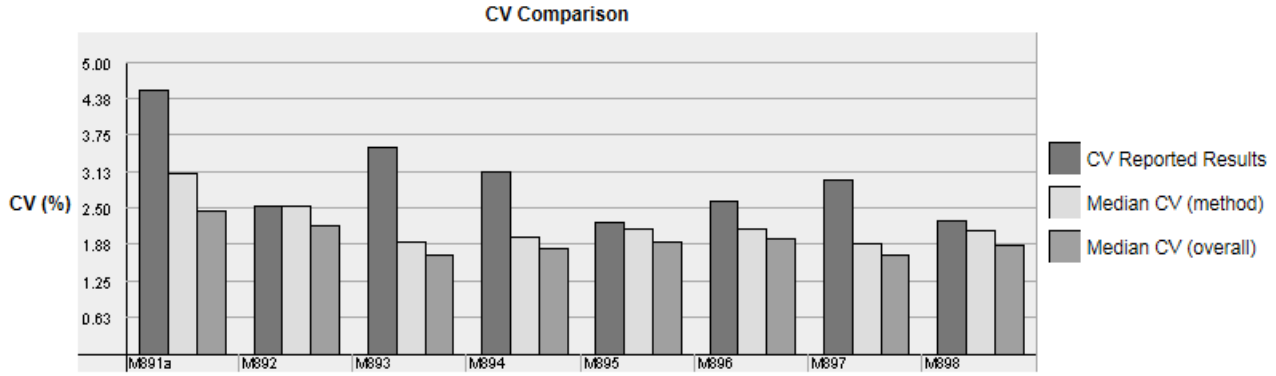
Sy.x = 0.06 mmol/L

CV% = (Sy.x/ x)*100 = 0.06/7*100 = 0.86%

Method Uncertainty From Weqas End of Batch Reports

Analyte: Creatinine (µmol/L)

Method: **Jaffe - IDMS**	**M891a**	**M892**	**M893**	**M894**	**M895**	**M896**	**M897**	**M898**
Section Stats								
Mean reported results	64.5	133.6	206.8	276.7	346.9	420.1	490.6	558.4
SD reported results	2.9	3.4	7.3	8.6	7.8	11.0	14.7	12.7
CV(%) reported results	4.51	2.52	3.52	3.10	2.25	2.61	2.99	2.27
Number of results	5	5	4	3	5	5	5	6
Method Result Stats								
Mean method mean	67.7	139.3	213.3	286.6	357.4	428.9	498.4	570.0
Median CV	3.08	2.52	1.91	2.00	2.14	2.14	1.88	2.11
Overall Result Stats								
Median CV	2.44	2.19	1.69	1.81	1.92	1.97	1.70	1.85



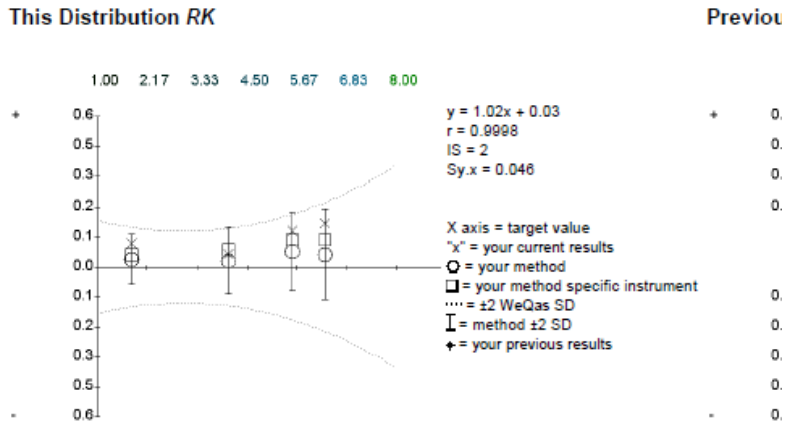
Between batch CV% provided on End of Batch reports (6-12 month review)

Pool M891a - CV% of reported results: 4.51%

Method Linearity from Weqas

Scheme: Serum Chemistry. Distribution Code: RK. Distribution Date: 3/04/18. Final. Report Issued: 8/05/18						
Potassium (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		6.50	4.10	5.70	1.90	
Method Corrected Result		6.500	4.100	5.700	1.900	
Indirect ISE	Mean	6.379	4.073	5.618	1.841	
	SD	0.088	0.065	0.077	0.048	
	Number	179	176	174	177	
	Uncert.	0.0066	0.0049	0.0058	0.0036	
Cobas C Module	Mean	6.437	4.119	5.666	1.857	
	SD	0.049	0.036	0.048	0.046	
	Number	97	95	99	99	
	Uncert.	0.0050	0.0037	0.0049	0.0047	
Overall	Mean	6.380	4.075	5.618	1.837	
	SD	0.088	0.065	0.078	0.052	
	Number	184	183	181	183	
	Uncert.	0.0065	0.0048	0.0058	0.0038	
Reference Values FAAS / FAES		6.330	4.050	5.560	1.810	
Ref. Value Uncertainty		0.0440	0.0280	0.0390	0.0130	
Non-scoring Reference Values						
WeQas SD		0.127	0.076	0.104	0.077	
SDI		1.34	0.66	1.34	1.17	

Please note: Linear regression uses CF corrected data.



Linear series of 8 pools distributed for most routine chemistry programmes

Linear series cover wide analytical and pathological range

Chemistry QCRM linearity panel available as a range of up to 8 samples and are suitable for ISO 15189 method verification

Weqas

Serum Chemistry QCRM

CE

Serum Chemistry Quality Control Reference Material
Size: 3.5mL
Lot No: 080118/93 **Exp.: Jan-2020**

Creatinine

Pool	ID-GCMS Target Value (µmol/L)	Expanded Uncertainty
932	110.98	1.38
934	262.15	3.25
936	414.37	5.14
938	559.71	6.94

Weqas Regional EQA Reports

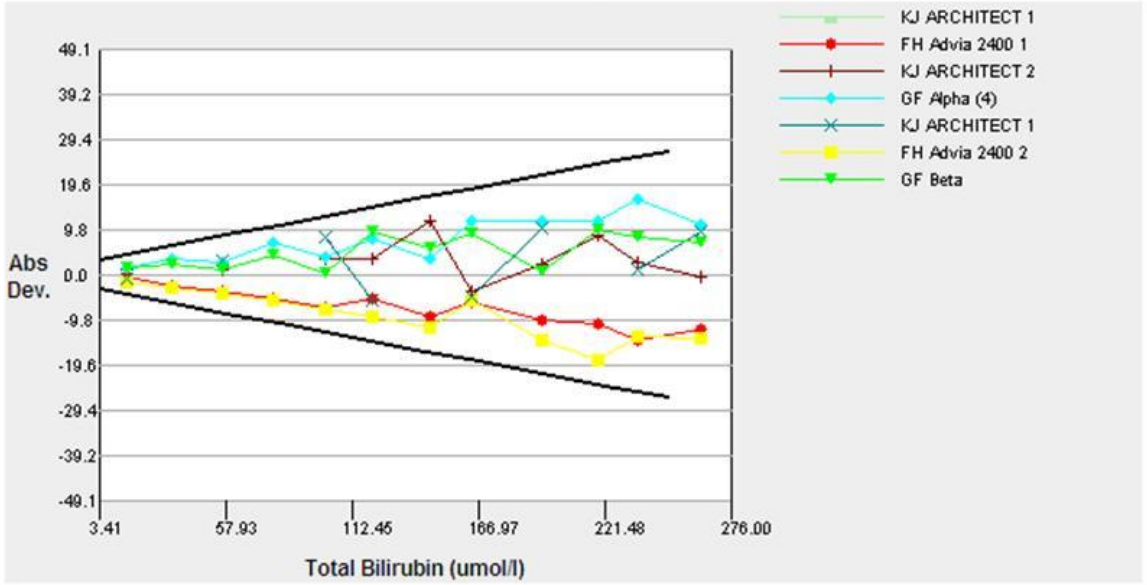
5. EOB Absolute Deviation Report

For the labs in the region, for the selected batch, deviation reports give mean reported results and look at absolute and % deviation from the regional mean on a per analyte basis.

Absolute Deviation from Regional Means

		B291	B297	B300	B296	B301	B292	B293	B294	B295	B298	B299	B302
FH	Advia 2400 1	-0.59	-9.31	-10.89	-5.39	-14.48	-2.56	-3.67	-5.22	-7.38	-6.15	-10.04	-11.82
FH	Advia 2400 2	-1.92	-11.48	-18.52	-9.36	-13.35	-2.92	-4.20	-5.86	-7.84	-5.65	-14.51	-14.05
GF	Beta	1.21	5.82	9.58	9.14	8.08	2.24	1.13	4.21	0.06	8.95	0.72	6.72
GF	Alpha (4)	1.21	3.49	11.58	7.81	16.42	3.24	2.47	6.88	3.72	11.62	11.72	10.72
KJ	ARCHITECT 2	0.88	11.49	8.25	3.48	2.42	1.91 *	1.13	4.21 *	3.39	-3.88	2.06	-0.62
KJ	ARCHITECT 1	-0.79	6.49 *	1.25 *	-5.69	0.92	0.91 *	3.13	1.21 *	8.06	-4.88	10.06	9.05
KJ	ARCHITECT 1	3.21 *	16.49 *	9.25 *	16.81 *	-	-	-	-	-	-	-	-
	Weqas SD	2.31	8.61	12.09	7.39	12.90	3.24	4.27	5.34	6.41	9.47	10.93	14.24

* - not included in group mean



EQA Challenges – the patient test workflow

How do we assess the full patient testing pathway ?
How can we mimic the laboratory and POCT test workflow with greater use of automation?
How can we assess the integrity of the data?

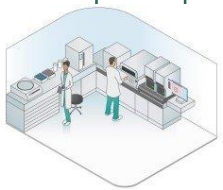
Laboratory test workflow

- e-test request by clinician
- Patient demographics/ order/ clinical details sent to lab LIMS
- Patient demographic barcode label printed
- Sample taken
- Sample barcoded and transported to laboratory

Pre-analytical
Outside lab

Pre-analytical
Inside lab

- Sample scanned / matched in LIMS
- Sample prepared – robotics module
- Intelligent workflow sends to 1 of n analytical modules



- Indices check
- Sample Analysed on 1 of n modules
- Quality control checks

Analytical

Post analytical

- Authorisation / Interpretation
- e-Reporting

EQA workflow

- EQA Sample labelled with instructions and shipped to laboratory

Pre-analytical
Outside lab – EQA provider

Pre-analytical
Inside lab

- EQA Sample information manually entered in LIMS
- Bar code generated
- Sample scanned
- Analyser selected

- Indices check
- Sample Analysed on selected or all modules
- Quality Control checks

Analytical

Post analytical

- Results released (may include Interpretation)
- Results transcribed onto EQA return form and/or
- Entered into EQA portal

POCT test workflow

- Test requested by clinician
- User bar code scanned – details checked in POCT middleware
- Patient ID scanned - details checked in POCT middleware
- Sample taken (cap/ven)

Pre-analytical
Outside lab

Analytical

- Sample Analysed
- Quality control checks

- Results available immediately
- Auto Validation
- Connectivity to LIMS
- e-Reporting

Post analytical

EQA workflow

- EQA Sample labelled (may not have unique bar code)
- Sample and instructions shipped to laboratory

Pre-analytical
Outside lab – EQA provider

Pre-analytical
Inside lab

EQA details manually entered in POCT middleware
EQA barcode generated
EQA Sample and instructions transported to POCT site

- User bar code scanned
- EQA sample ID scanned

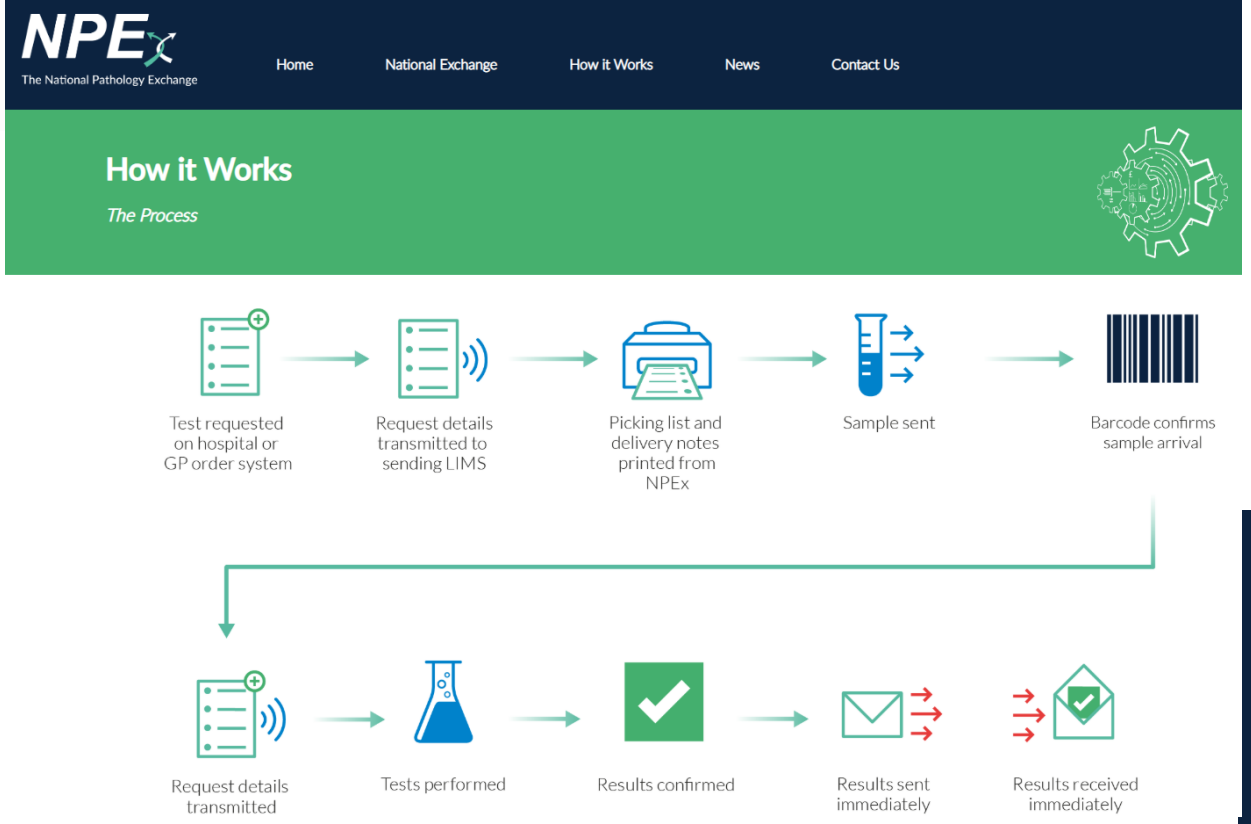
Pre-analytical
Outside lab

Analytical

- Sample Analysed
- Quality Control checks

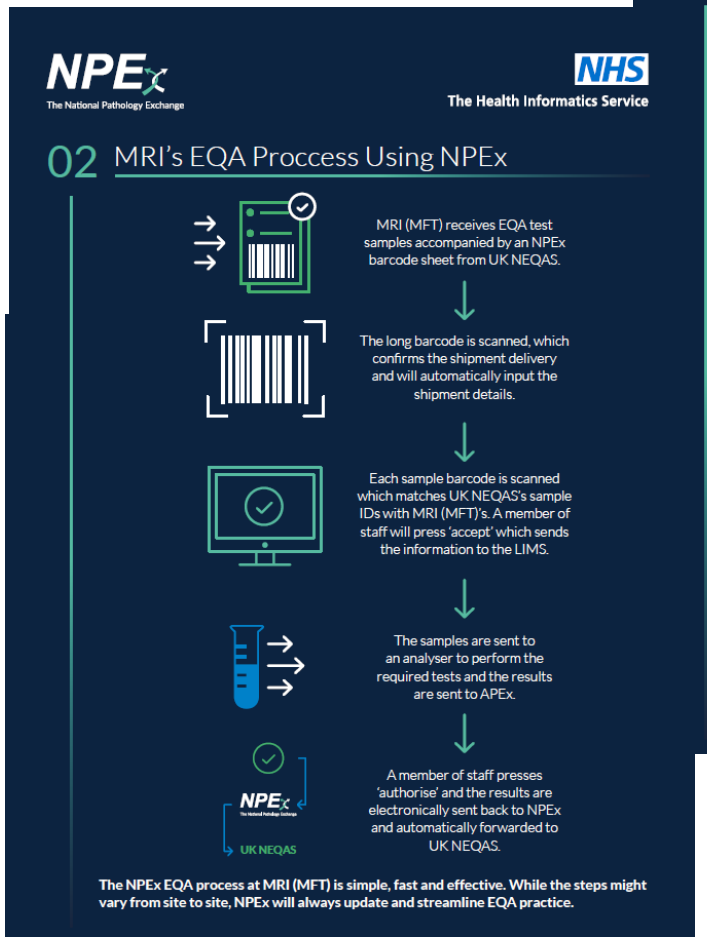
- Results released (may include Interpretation)
- Results transcribed onto EQA return form and/or
- Entered into EQA portal

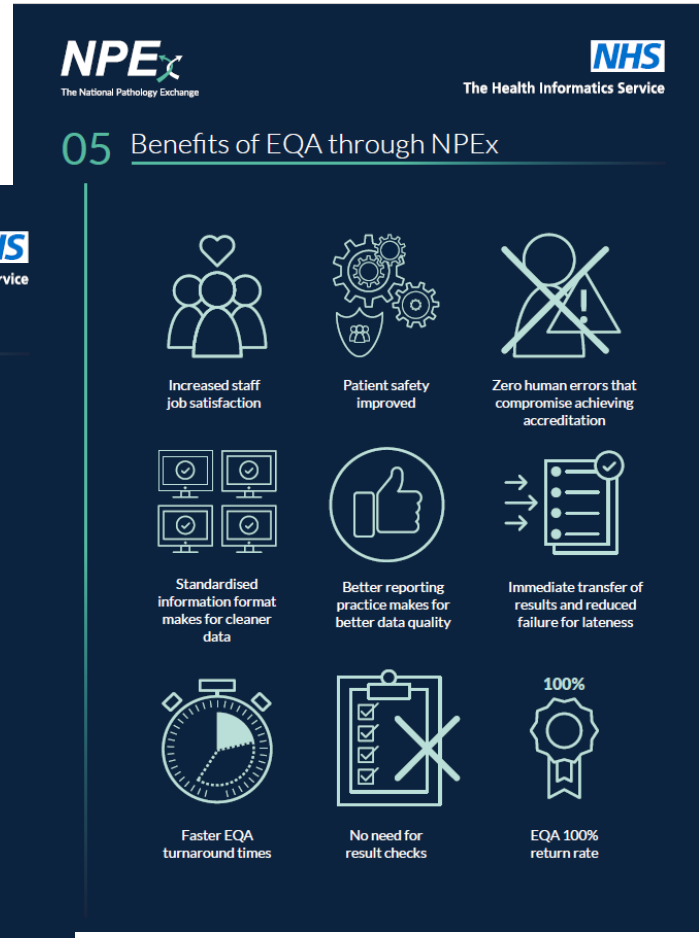
Post analytical



NPEx is working with Weqas to enable the transfer of EQA requests and referrals through the solution.

Will accommodate both laboratory and POCT workflows.





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Fax: 02920 314760
Email: contact@weqas.com

EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

Thank you

Any Questions?