“One of the guarantees of quality: External Quality Control”

Finlay MacKenzie

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Birmingham Quality

Mexico EMA 2017

Finlay MacKenzie

Director, Birmingham Quality

UK NEQAS Birmingham

The Narrative of EQA

- I am going to talk about:
  - Definitions and nomenclature
  - What is the EQA process?
  - Regulatory systems and structure of the NHS in the UK
  - What does EQA look like in practice?
  - Performance surveillance of Laboratories and post-market surveillance of kits/methods/products
  - Numbers, numbers and interpretation
  - Reference methods and commutability
  - Scoring systems and Scheme design
  - ***a rejection of the blind adherence to too many statistics on too few data points***

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Definitions of EQA

- External Quality Control
- Some call it ‘External Quality Assurance’
- I prefer External Quality Assessment
  - It is retrospective, and though part of a bigger system, it in itself cannot ‘assure’, neither can it ‘control’. It can assess, it can influence and it can point the way forward, it can drive improvement but it can’t ‘assure’ that everything will always be right all of the time.
- Total Quality Assurance is IQC + EQA + Training + Education + Accreditation + Audit etc etc

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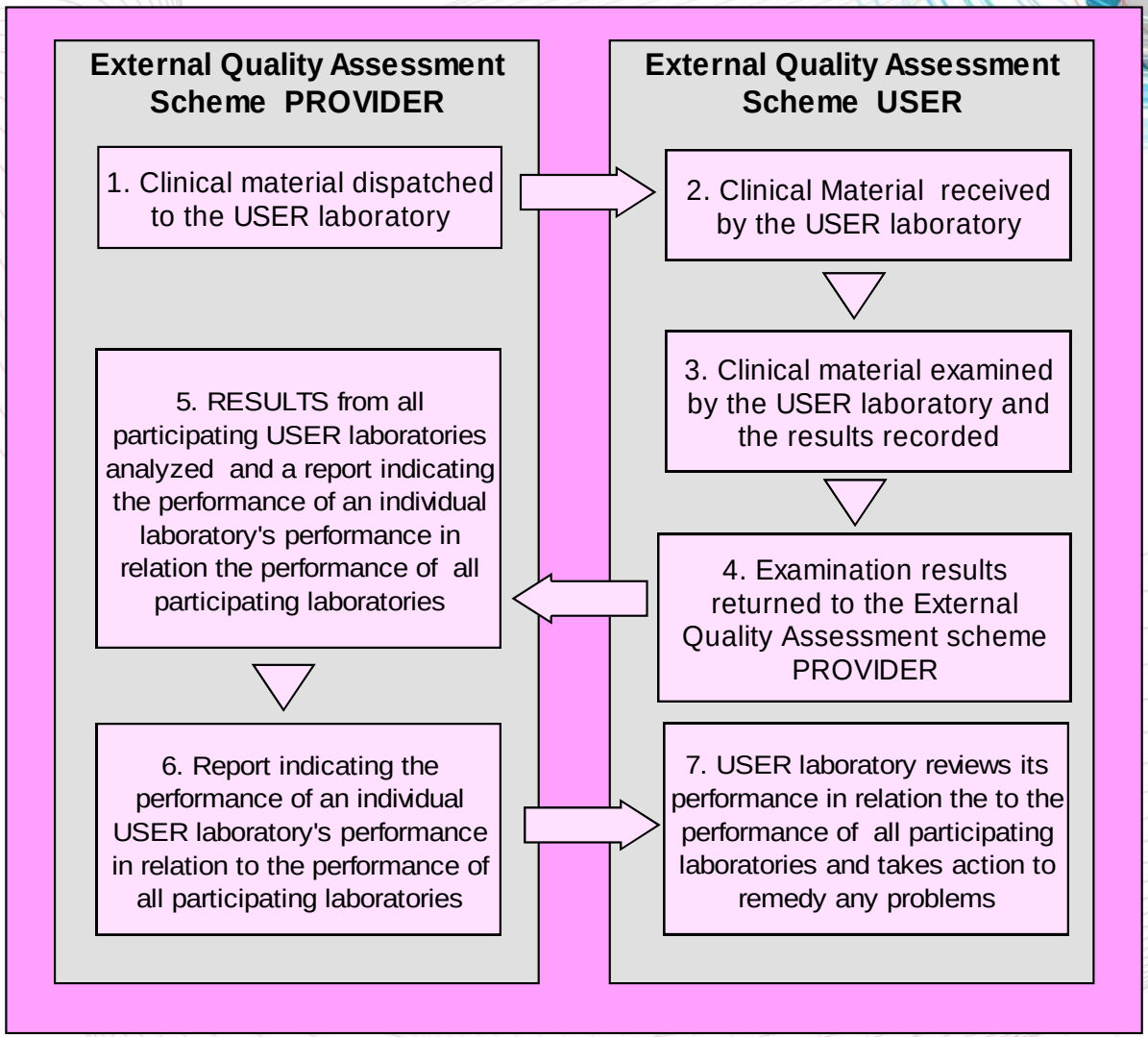
The EQA Process



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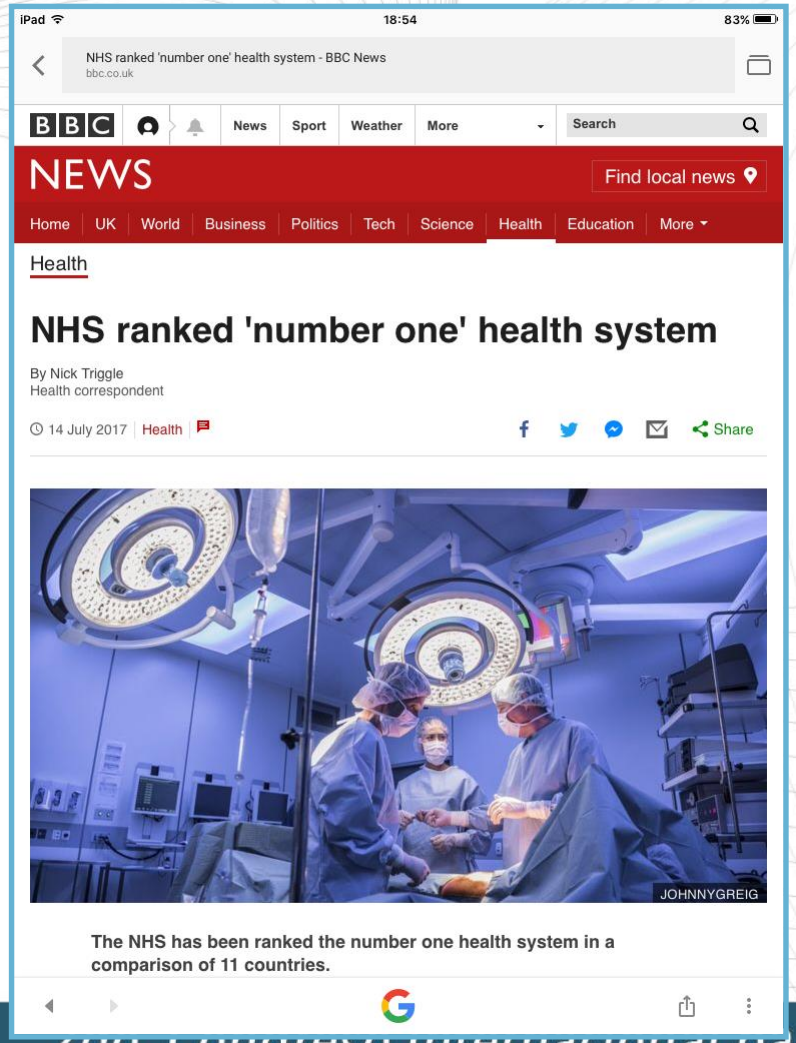
The UK is either the best in the world or is struggling for funding *(fake news?)* It is true that **treatment is free** at the point of contact



The NHS

NHS organisations and boards

NHS Trust Development Authority

Following the scrapping of strategic health authorities, this body is responsible for overseeing the performance management and governance of NHS trusts that have not yet achieved foundation status. This includes clinical quality and managing trusts' progress towards foundation trust status. Ministers want all trusts to achieve foundation status.

Find out more about foundation trusts

Monitor

Monitor is the sector regulator for healthcare, responsible for licensing healthcare providers, regulating prices for NHS services and addressing restrictions on competition that act against patients' interests.

Find out more about Monitor

NHS England

NHS England (formerly The NHS Commissioning Board) is charged with improving the health outcomes for people in England, in line with the NHS mandate set by the government. It oversees the work of clinical commissioning groups (CCGs) and holds them to account, allocates resources, and commissions certain services such as primary care and highly specialised services that can be organised better and more efficiently at a regional or national level. It is accountable to the health secretary.

Find out more about NHS England

Health Education England

Health Education England (HEE) leads education, training and workforce development nationally. It promotes high-quality education and training that is responsive to the changing needs of patients and local communities. Professional regulators are still responsible for setting and upholding standards. HEE has six professional boards. Its medical board is responsible for ensuring that training posts are filled by high-quality candidates, that curriculum-based training is delivered, that academic medicine's needs are recognised, and that there is enough capacity in the health service to deliver high-quality training.

Find out more about Health Education England

Local authorities

Local government has a new set of duties to protect and improve public health. These include commissioning and providing public health services. The BMA has lobbied to ensure councils have adequate funding and that the independence of directors of public health, and public health doctors, in speaking out is protected. The BMA has also been working to ensure a smooth transition for public health doctors from primary care trusts, and ensured that Public Health England's code of conduct did not restrict their ability to raise issues of concern.

Local education and training boards

Feedback

Local education and training boards

Local education and training boards (LETBs) are now responsible for workforce planning, education and training at a local level. They bring together all healthcare and public health providers of NHS-funded services, education providers, professional bodies and local government and universities or research centres. They are accountable to Health Education England and will host postgraduate deaneries and their functions.

Find out more about LETBs

Public Health England

Public Health England is responsible for leading and managing an integrated public health delivery service. It has taken over the roles of organisations including the Health Protection Agency, National Treatment Agency, public health observatories and cancer registries. It has 15 centres across England, each of which provides leadership and support across all three domains of public health - health protection, health improvement and healthcare public health.

This includes:

- supporting local government in its leadership of the local public health system
- supporting directors of public health
- working with the NHS England on commissioning key specialist services and national public health programmes
- providing leadership in responding to emergencies.

Healthwatch

New patient and public bodies, known as local Healthwatch have been established. Local Healthwatch acts as a point of contact for individuals, community groups and voluntary organisations when dealing with health and social care and has a representative seat on the health and wellbeing board.

See more about Healthwatch

Health and wellbeing boards

Health and wellbeing boards have been established in each upper tier local authority to promote integrated working across health and social care. With representatives from local authorities, health and social care, public health and patient groups, health and wellbeing boards produce the Joint Strategic Needs Assessment (JSNA) and Joint Health and Wellbeing Strategy (JHWS) identifying local priorities for commissioners.

Find out more about health and wellbeing boards

Clinical commissioning groups

England's 211 clinical commissioning groups (CCGs) are taking over from primary care trusts and are responsible for £65bn of the £95bn NHS commissioning budget. They now plan and commission hospital care and community and mental health services. All GP practices have to be members of a CCG, and every CCG board must include at least one hospital doctor, nurse and member of the public.

Find out more about clinical commissioning groups

Feedback

Commissioning support units

GPs and other clinicians involved in clinical commissioning groups (CCGs) need support to commission effectively. Commissioning support encompasses a range of functions, from transactional services such as payroll and IT services, to equipping CCGs with the complex population level data required to inform commissioning decisions.

Primary care trust (PCT) clusters are currently developing commissioning support organisations, to be hosted by the NHS England until 2016. CCGs may choose to host their own, internal support services, or contract from the PCT-cluster developed bodies, private or third sector organisations.

Find out more about commissioning support units

Clinical networks

The networks are hosted and funded by NHS England, and advise on specific conditions or patient groups where improvements can be made through an integrated, whole-system approach. The networks advise local commissioners, help reduce variation in services, and encourage innovation.

Find out more about clinical networks

Clinical senates

These are led by clinicians to provide multidisciplinary input to strategic clinical decision-making. The groups, 12 of which are due to be established, should help ensure that clinical commissioning groups, local authorities and the NHS England (formerly the NHS Commissioning Board) have access to a broad range of clinical input to inform their decisions. Senates include medical, nursing and allied healthcare professional representation as well as patients, volunteers and other groups.

Find out more about clinical senates

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England

Created: 12 May 2012

Patients and the changing NHS

There is a lot going on in the NHS, especially in England.

We want to make sure you have the full story and know how to have your say.

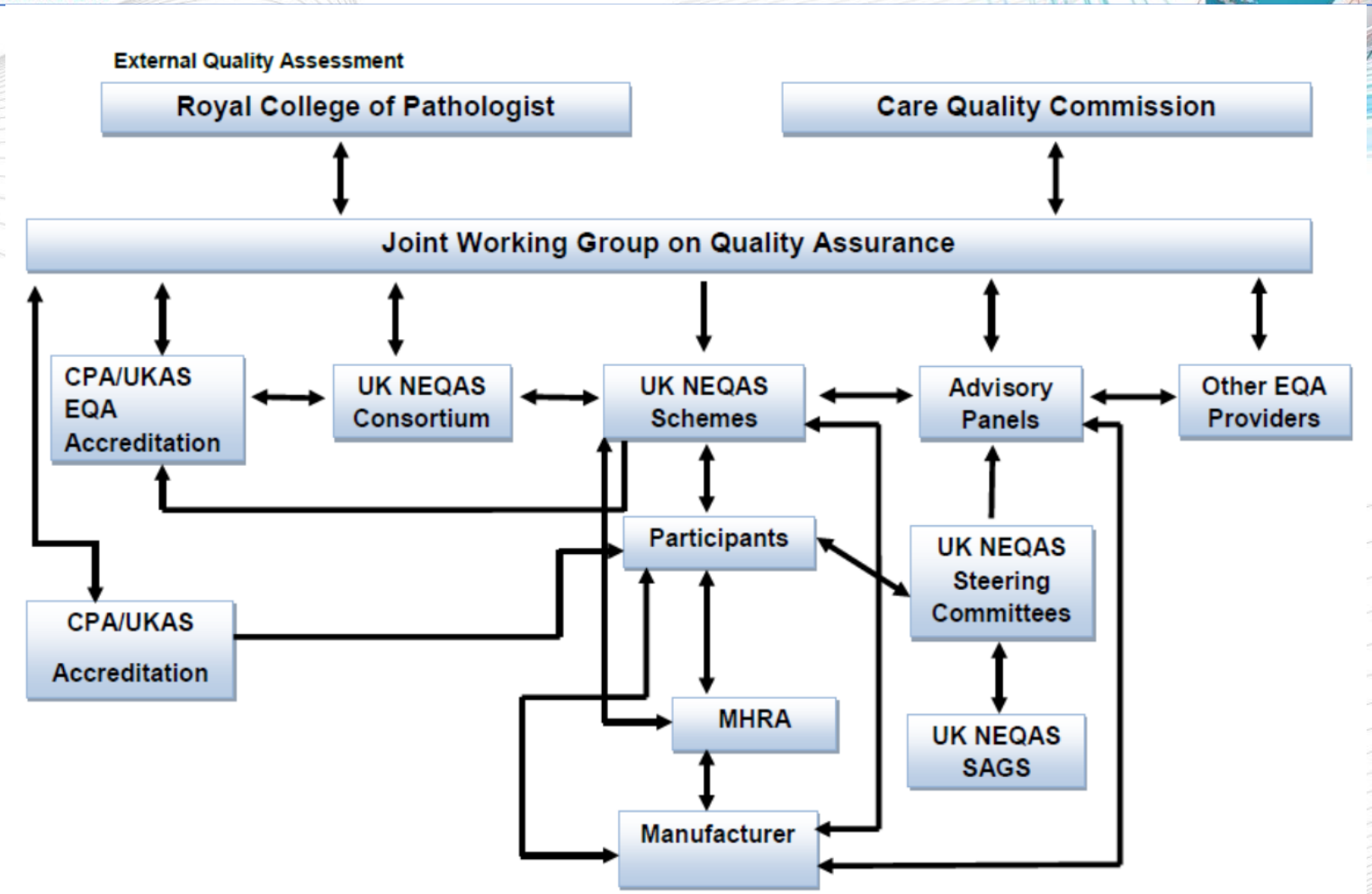
Read more about what is happening in the NHS

Feedback

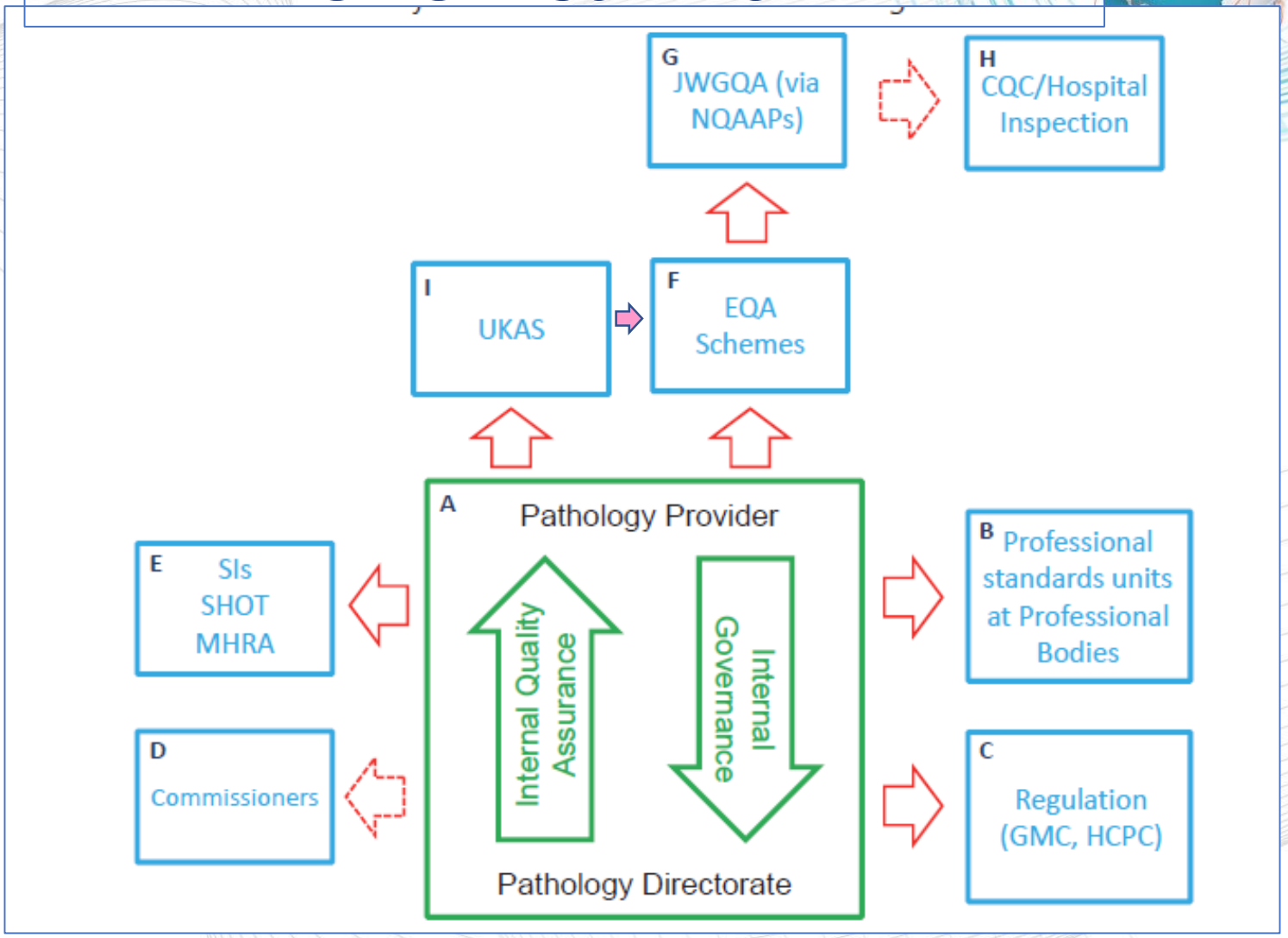
complicated structure across *England*

Now having SSTs of 1 to 2 million people where Labs and hospitals and local government don't always cover same geographical locale!

The Regulatory Environment



Pathology Quality Assurance Review Jan 2014



ISO 15189:2012

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ROLE OF EXTERNAL QUALITY ASSESSMENT

EQA provides assessment of:

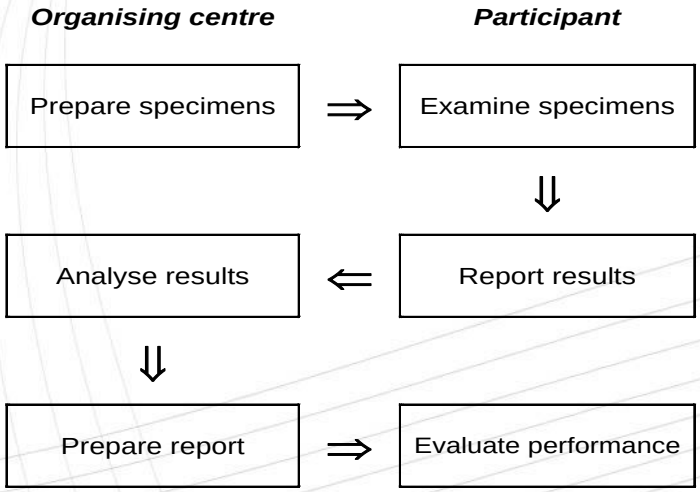
- **the overall performance (state of the art)**
- **the influence of analytical procedures (method, reagent, instrument, calibration)**
- **individual laboratory performance**
- **the specimens distributed**

EQA PROVIDES AN EDUCATIONAL STIMULUS TO IMPROVEMENT

EFFECTIVE EQA

To be effective, EQA must be accepted and seen as useful, requiring:

- **full, regular participation**
- **specimens treated as routine**
- **confidence in scheme design**
- **remedial action taken**



Scheme Design

For EQA success, participants must have confidence in the scientific validity as well as the reliability of its operation, or they will not take action on information from the scheme

- **sufficient recent data, achieved through:**
  - **frequent distributions**
    - **at least 4 per year**
    - **monthly ideal**
    - **multi-specimen distributions**
  - **rapid feedback of performance information**
    - **before the next distribution**
    - **few days ideal**
    - **faster using our web service!**
- **an appropriate basis for assessment**
  - **stable, homogeneous specimens**
    - **behave like clinical specimens**
  - **reliable and valid target values**
- **effective communication of performance data**
  - **a rolling time window scoring system**
  - **structured, informative and intelligible reports**

SCORING

- **Purpose of scoring:**
  - **comparison of performance over:**

	Time	Place
Individual lab	yes	yes
All participants	yes	yes

- **Requirements of scoring:**
  - **robust**
  - **independent of other participants' performance**
    - **a 'z score' *(SDD, SDI)* based on observed SD is <u>not</u> satisfactory in my opinion despite it being widely used across the world**

yes	Participation (return rate)
yes	Non-analytical errors ('blunders')
?	Accuracy (total error) – single survey
yes	Accuracy – running
No	Imprecision – <u>NO</u> ! must assess from IQC . . .
yes	Bias – running
yes	Consistency of bias - running

'THE ABC OF EQA' ~ Basic Scheme Statistics and Nomenclature

- There are:
- Specimen level statistics
- Rolling time window level statistics

- Laboratory-specific
- Method-specific
- Overall *[all laboratories, all methods]*

- A set of three complementary scores:
  - A is for Accuracy (total error)
  - B is for Bias
  - C is for Consistency of bias

- Percentage bias:
  - bias = (result - target) / target * 100 %
- transformed bias:
  - = bias * 'degree of difficulty factor' *[normalised]*

- The role of EQA within the overall QA setting

  Our scores are unashamedly robust, trend [data] scores. This is their strength
- If you want to know if your run, batch or day's work is fit to be released then you must operate a good, robust IQC programme as part of your total QA policy
- EQA data is by its very nature retrospective. It is not intended to allow you to pass or fail each assay run. It does, however, give an incredible amount of valuable information that is impossible to glean from IQC data alone

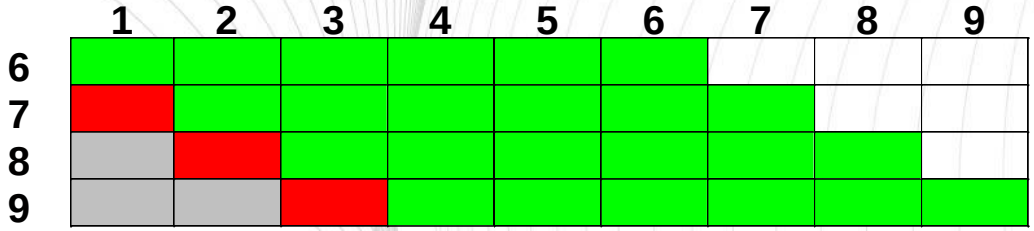
The basics of EQA

- **EQA gives information on *relative* bias**
- **If the specimens are commutable and reference methods are available, EQA can give information on *absolute* bias**
- **The frequency of testing, the scheme design and concentration levels addressed are crucial in assessing whether the data from EQA is relevant and truly meaningful**

The Basics of the ABC Scoring system

- **Each of these 3 scores is calculated over a rolling time window**

- **Each 'running score' comprises data (results) from many specimens**
  - ***they are therefore always being updated with fresh current data, and at the same time historical data drops out of the 'time window':***

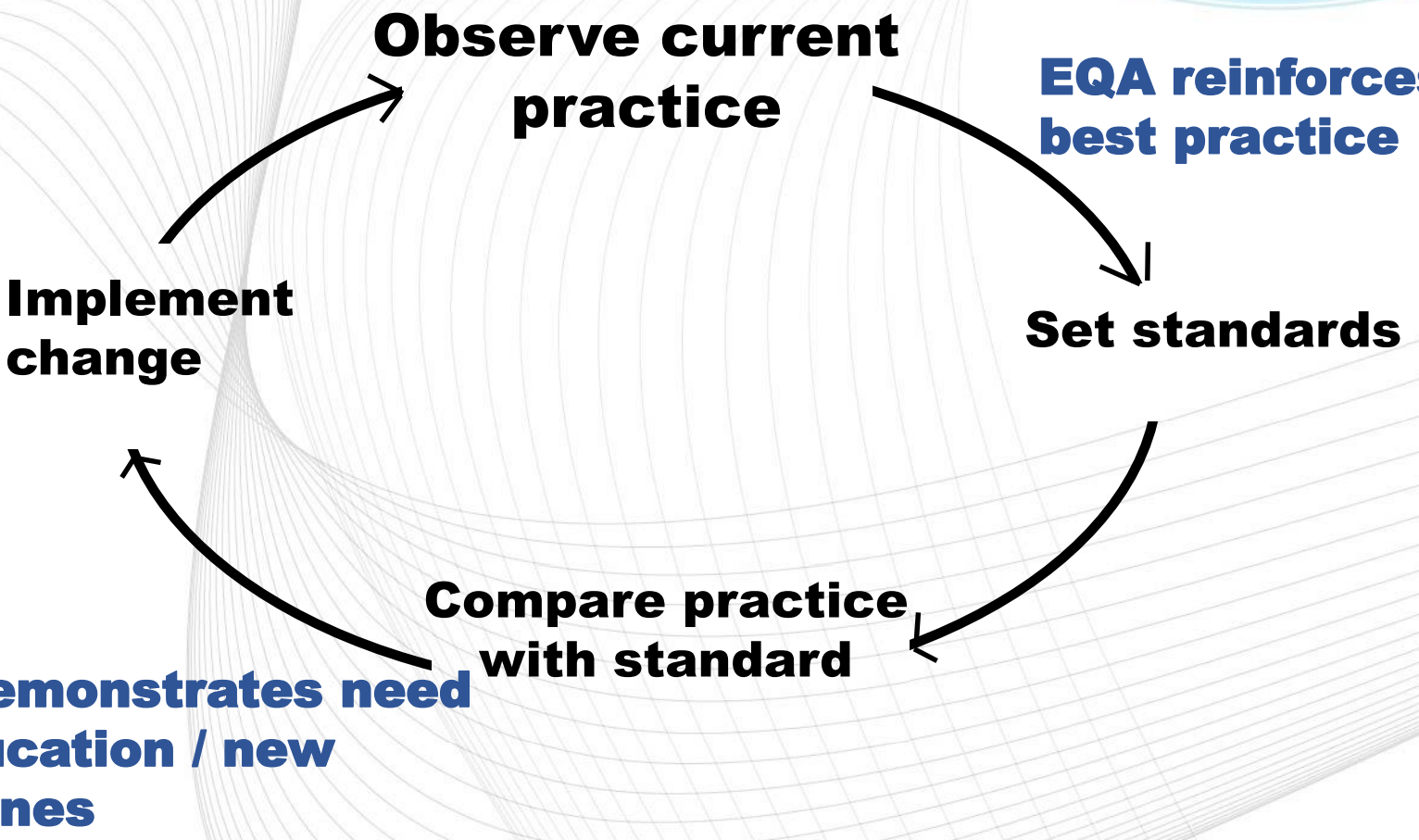


- **The time window we have employed has been set at 6 distributions (equivalent to 6 months) for 'standard schemes' (3 specimens monthly)**

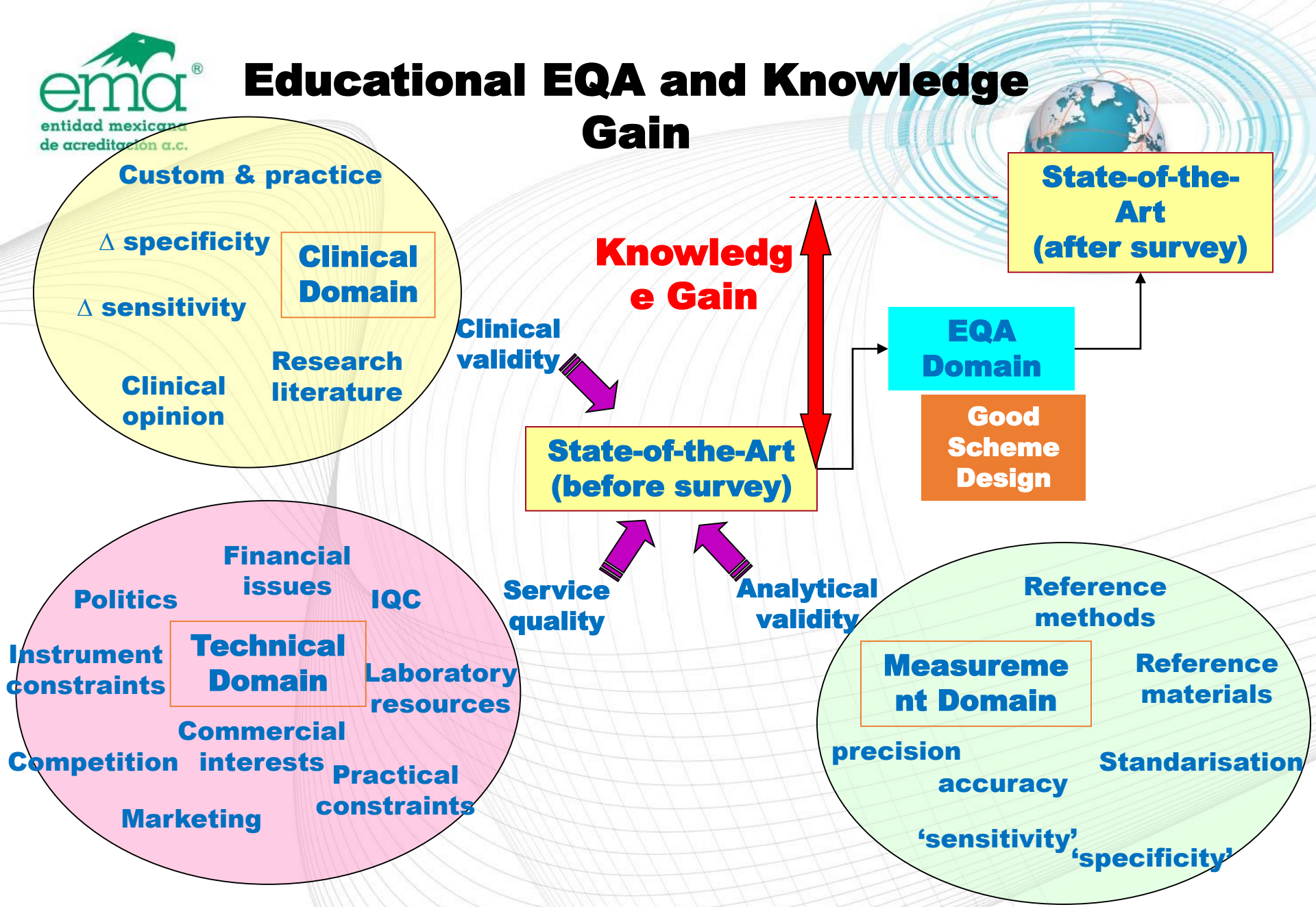
- **In order to obtain sufficient data from less frequently assessed assays, a period of 12 months may be required**

[Though the details are dependent on individual schemes, the principle holds true for any UK NEQAS Birmingham scheme]

EQA as audit - a quality improvement cycle



Educational EQA and Knowledge Gain



Government

funding

DH / NHS | NICE

policy, national standards

Professions

training, best practice, audit

Clinicians | Scientists

Patients

CPA / UKAS | Laboratories | MHRA

standards | comparability | safety

EQA | Industry

trueness, traceability

JCTLM, NMIs

QUALITY IN LABORATORY MEDICINE
"FIT FOR PURPOSE"

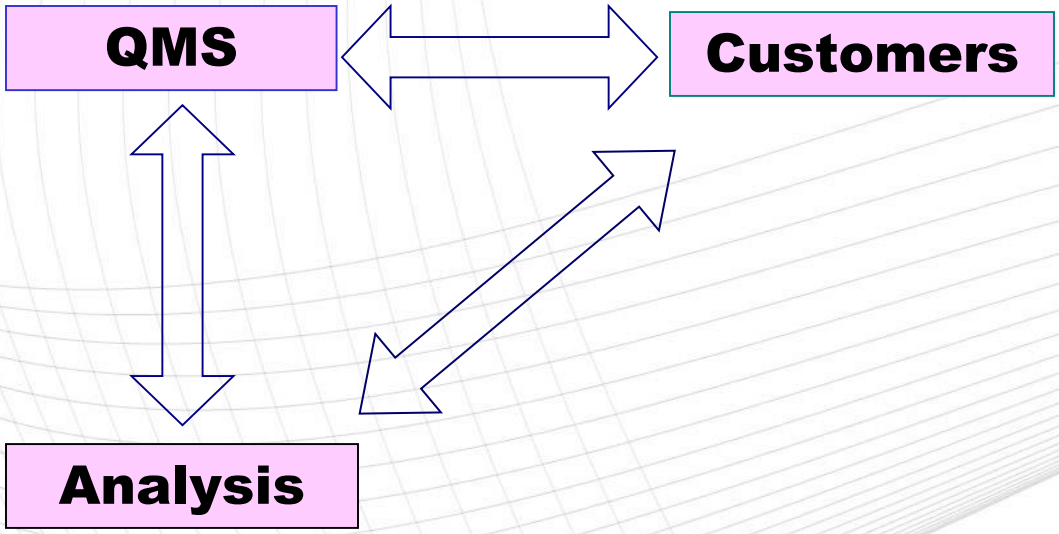
- **Right result**
- **Right test**
- **Right time**
- **Right specimen**
- **Right patient**
- **Right reference data**
- **Right cost**

Elements of a Quality System

- **Quality assurance**
  - **all measures taken to (try to) assure quality**
- **Internal quality control**
  - **analytical precision (reproducibility)**
- **External quality assessment (EQA)**
  - **analytical trueness (lack of bias)**
- **Audit**
  - **local appraisal of adherence to (local) guidelines & standards**
- **Accreditation**
  - **external appraisal of adherence to objective professional standards**

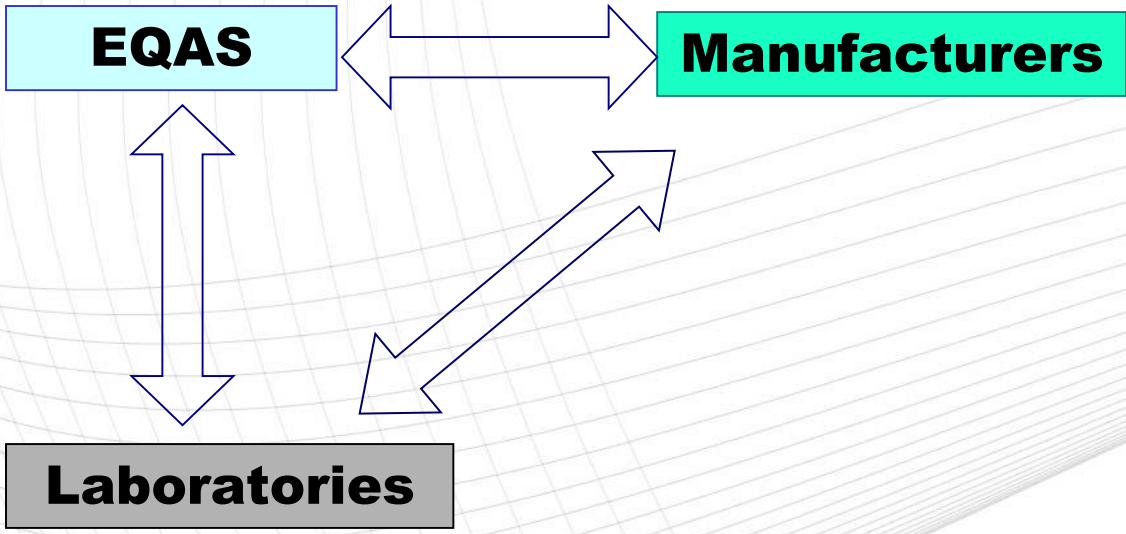
- Do I have a Quality System and do I audit it?
- Do I have a Quality Manager?
- Do I have quality specifications for each investigation?
- Do I have appropriate IQC?
- Are IQC data reviewed regularly and acted upon in real time?
- Do I have appropriate internal audit with documented preventative and corrective action?
- Are adverse incidents appropriately identified, recorded & acted upon?
- Are all staff appropriately trained?
- Do I have a complaints log?
- Do I assess and review customer satisfaction?

Triangle 1 - quality specification and customer satisfaction



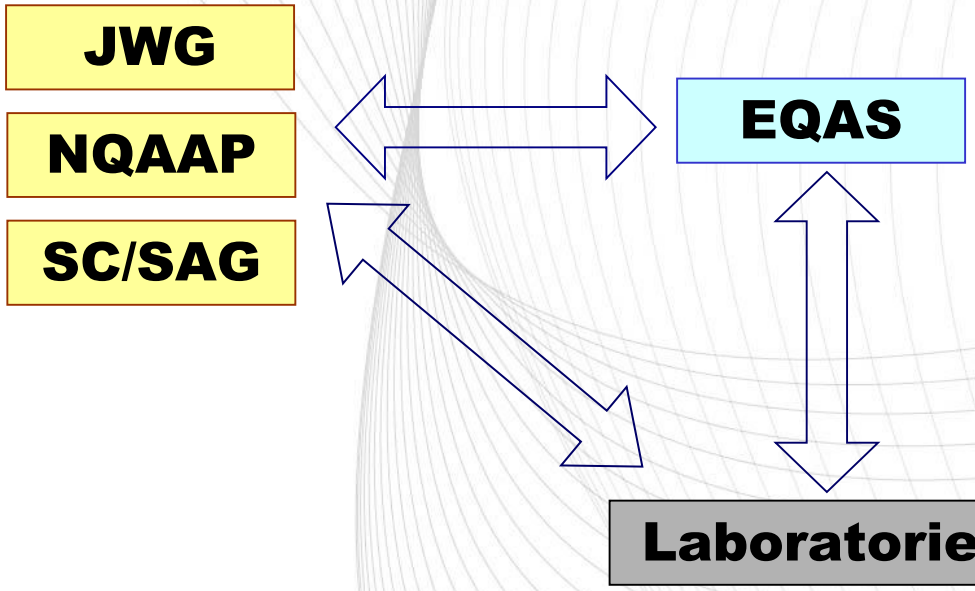
Triangle 2 - method selection, evaluation and IQC/EQA

- Am I using the right method?
- Do I understand its characteristics and limitations?
- Are my IQC materials appropriate?
- Are my calibrators and reagents in date?
- Do I know who to speak to at the company?
- Do I have the latest method information?
- Does the company respond adequately to enquiries?
- Is my IQC OK in respect of clinical applications and requirements?
- Is my method correctly classified in the EQA scheme?
- Does my EQAS performance reflect that of the method group?



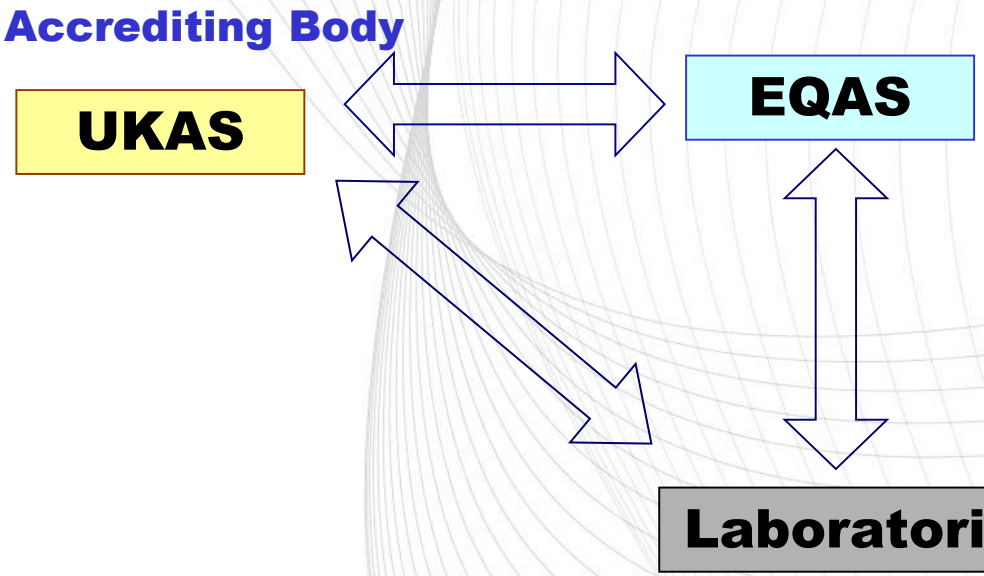
Triangle 3 - EQA performance surveillance

Oversight Bodies



- Do I understand the role of Steering Committees and Specialist Advisory Groups?
- Do I understand the role of the NQAAPs and JWG?
- Is my EQA provider accredited to ISO17043
- Are my EQA participation details correct?
- Is my method classification correct?
- Do I understand scheme design?
- Do I get the most out of participation?
- Am I a poor performer?
- Do I respond quickly to poor performance correspondence?

Triangle 4 - Accreditation



- **Is my organisation accredited to the appropriate Standard ?**
  - **ISO 15189 for labs**
  - **ISO 17043 for EQA schemes**

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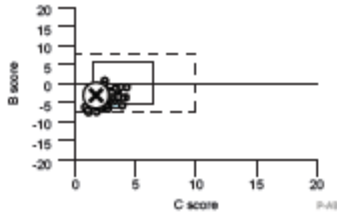
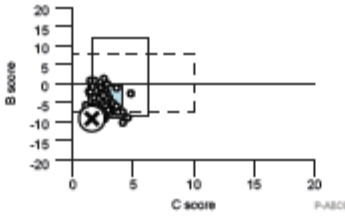
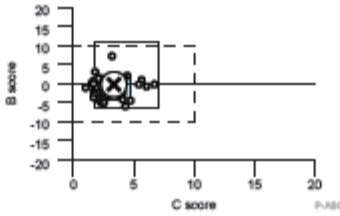
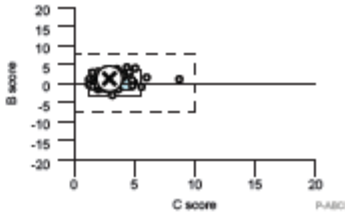
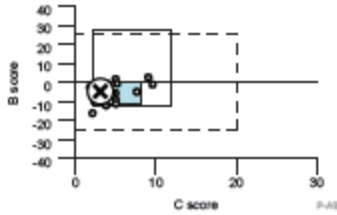
Birmingham Quality

UK NEQAS for Specific Proteins	Laboratory :
Distribution : **383** Date : 15-Aug-2017	Page 2 of 21
Performance Summary Icons (click graph for details)	

IgG	IgA	IgM	Transferrin
			

Caeruloplasmin			
			

Analytical Performance over the last 6 months (rolling time window of 6 distributions)

All our time periods are 'rolling' to give you current information.
You may wish to keep you own log of Calendar Year or Financial Year time points if you require 'year-end' statements for your own internal use.
Any analytes with out of consensus performance will be highlighted in red and can be clicked for further details.

You have out of consensus performance for:	IgA	
You have in consensus performance for:	IgG IgM	Transferrin Caeruloplasmin
You have no performance data for:	*None*	

Participation and Return Rates

This scheme cycle is notionally every four weeks.
Analytically, we assess you over a six month time window (6 Distributions).
For return rates, late and amended results we assess you over a twelve month period (12 distributions).

	Distributions	**Rating**	**Affected Distributions**
Participation	12 distributions out of a possible 12	Satisfactory	
Late Returns	0 distributions from the last 12	Satisfactory	
Amendments	1 distribution accepted from the last 12	Satisfactory	382

Analytical Performance for specimens from distribution 383 only

You can judge, in association with your IQC and other QA measures, if your current performance is a blip or part of a trend.

Out of consensus for at least one specimen for:	IgA		
In consensus for all specimens for:	IgG IgM	Transferrin Caeruloplasmin	
You have no specimen data for:	*None*		
You are not registered for:	C3 C4 Alpha-1-antitrypsin	Alpha-1-acid glycoprot Haptoglobin Transthyretin	Alpha-2 macroglobulin Immunochem Albumin

Birmingham Quality

UK NEQAS for Specific Proteins

Laboratory :

Distribution : 383 Date : 15-Aug-2017

Distribution Summary

If your laboratory is outside of the acceptable limits of performance for any its rolling time-window scores (A, B or C scores), this will be indicated by a red traffic light symbol. It is the responsibility of the laboratory to undertake an internal investigation to establish the underlying cause and put in place corrective and preventive action. Please do not wait to receive a formal notification of performance from the Scheme Organiser or the National Quality Assurance Advisory Panel (NQAAP) before logging the non-conformity and, where necessary, acting upon the data contained in your report. A green traffic light merely reflects that your laboratory is performing as well as the state-of-the-art allows; it does not necessarily mean that your assay / laboratory performance is good enough clinically.

Concentration-dependent degree of difficulty factors have not yet been established for Immunochemical Albumin and so 'A scores' and Specimen Accuracy Indices are currently unavailable for this analyte.

	Specimen	Pool	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
IgG (g/L)	383A	346	5.74	5.96	-3.7 ◆	89	-3.1	1.7	● ↔	● ↔	● ↔
	383B	347	9.84	10.15	-3.0 ◆						
	383C	348	14.24	14.80	-3.8 ◆						
IgA (g/L)	383A	346	1.16	1.282	-9.5 ▼▼	206	-9.3	1.6	● ↘	● ↘	● ↔
	383B	347	1.86	2.104	-11.6 ▼▼						
	383C	348	2.68	3.032	-11.6 ▼▼						
IgM (g/L)	383A	346	0.54	0.572	-5.6 ▽	39	-0.3	3.3	● ↔	● ↗	● ↔
	383B	347	0.93	0.981	-5.2 ▽						
	383C	348	1.38	1.429	-3.4 ◆						
Transferrin (g/L)	383A	346	1.60	1.60	+0.2 ◆	58	+1.2	2.9	● ↔	● ↔	● ↔
	383B	347	2.87	2.73	+5.2 △						
	383C	348	4.14	3.97	+4.3 ◆						
Caeruloplasmin (g/L)	383A	346	0.15	0.149	+0.4 ◆	42	-4.6	3.1	● ↔	● ↔	● ↔
	383B	347	0.25	0.252	-0.7 ◆						

UK NEQAS for Specific Proteins

Laboratory :

Distribution : 383 Date : 15-Aug-2017

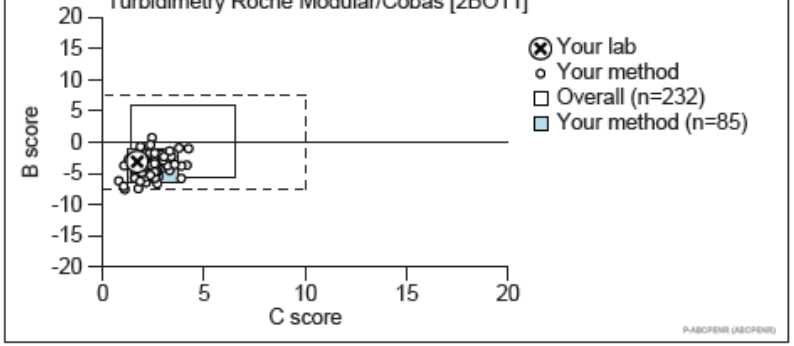
Method Summary

Our method update service is web-based and is accessed online via the 'edit' button on the 'Results and Reports page'. You can select from a dropdown of methods or select the default option from the major manufacturer's products*.

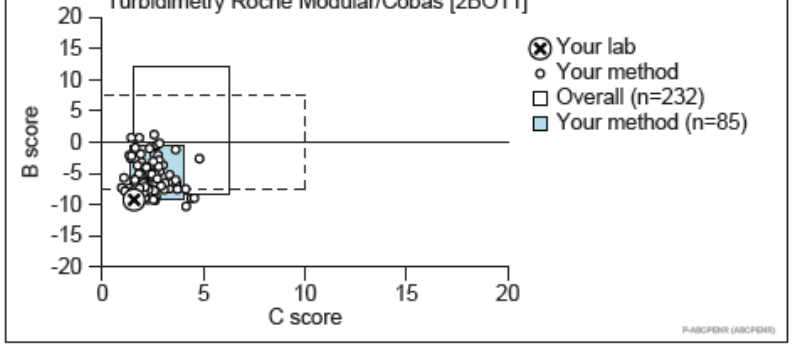
*If you are not using the system according to the manufacturer's instructions, please select the in-house category within your system's method principle.

	Method Principle	Your Method	Units	A score with trend arrow	Method median A score	All lab median A score
IgG	Turbidimetry	Roche Modular/Cobas [2BO11]	g/L	89 ● ↔	112	107
IgA	Turbidimetry	Roche Modular/Cobas [2BO11]	g/L	206 ● ↘	136	113
IgM	Turbidimetry	Roche Modular/Cobas [2BO11]	g/L	39 ● ↔	39	61
Transferrin	Turbidimetry	Roche Modular/Cobas [2BO11]	g/L	58 ● ↔	58	58
Caeruloplasmin	Turbidimetry	Roche Modular/Cobas [2BO11]	g/L	42 ● ↔	48	59

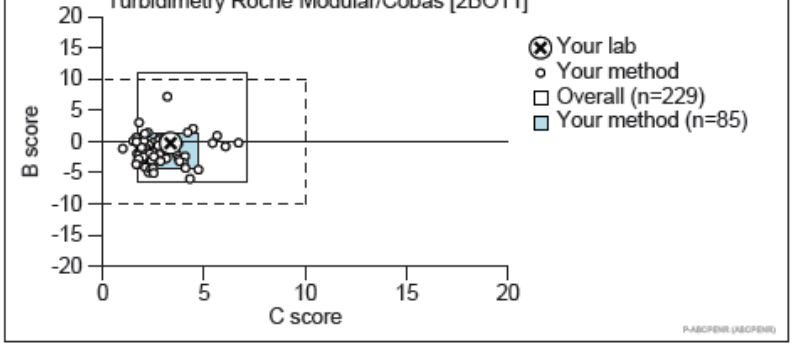
IgG B score is -3.1 and C score is 1.7
Turbidimetry Roche Modular/Cobas [2BO11]



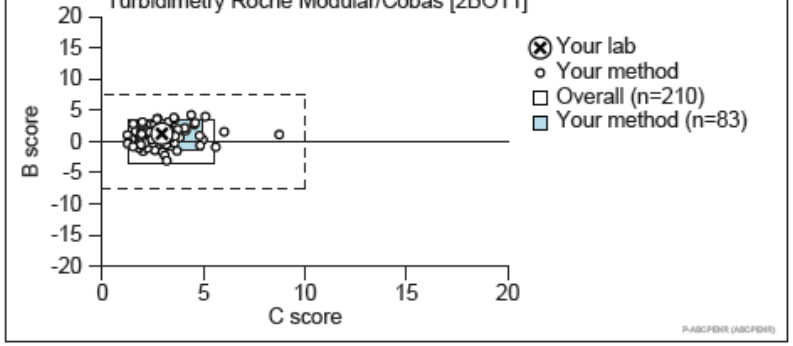
IgA B score is -9.3 and C score is 1.6
Turbidimetry Roche Modular/Cobas [2BO11]



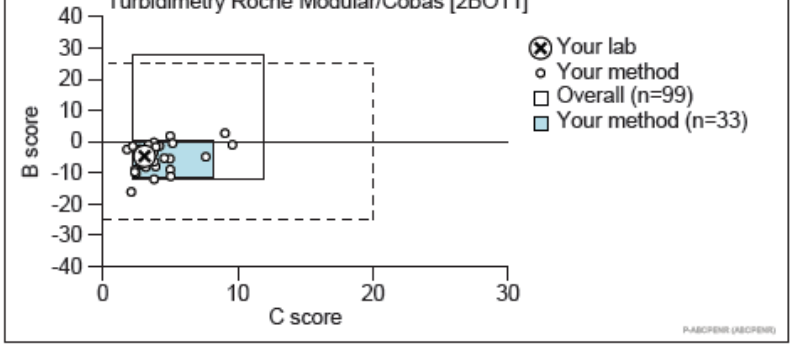
IgM B score is -0.3 and C score is 3.3
Turbidimetry Roche Modular/Cobas [2BO11]



Transferrin B score is +1.2 and C score is 2.9
Turbidimetry Roche Modular/Cobas [2BO11]



Caeruloplasmin B score is -4.6 and C score is 3.1
Turbidimetry Roche Modular/Cobas [2BO11]



Birmingham Quality

UK NEQAS for Specific Proteins | **Laboratory :**

Distribution : 383 Date : 15-Aug-2017 | Page 10 of 21

Analyte : IgA (g/L)

Spec.	Pool	Pool description / Treatments / Additions
383A	346	Dilute serum fractions [M and F]
383B	347	Dilute serum fractions [M and F]
383C	348	Concentrated serum fractions [M and F]

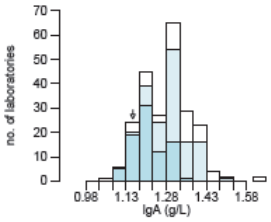
- All methods
- Turbidimetry
- Roche Modular/Cobas [2BO11]

Your A score is 206
Your B score is -9.3
Your C score is 1.6

The A limit is 200
The B limit is +/- 7.5
The C limit is 10.0

Specimen : 383A

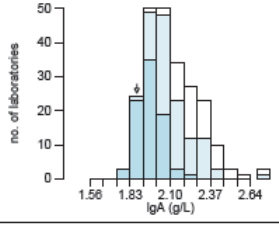
	n	Mean	SD	CV(%)
All methods [ALTM]	228	1.282	0.091	7.1
Nephelometry	50	1.332	0.093	7.0
Beckman Immage [1BK4]	13	1.208	0.068	5.6
Siemens (Dade Behring) [1BE8]	37	1.367	0.054	3.9
Turbidimetry	175	1.269	0.083	6.6
Abbott reagents [2AB14]	36	1.291	0.041	3.2
Olympus AU reagents [2OL1]	30	1.329	0.042	3.2
Randox reagents	4	1.404		
Roche Modular/Cobas [2BO11]	84	1.218	0.063	5.2
Siemens ADVIA reagents [2TE5]	11	1.393	0.013	1.0
The Binding Site reagents	4	1.226		
Vitros Fusion [2JJ1]	5	1.300	0.000	0.0



Your result 1.16
Target value (ALTM) 1.282
Standard Uncertainty 0.008
Your specimen: %bias -9.5
Accuracy Index 196
Method Principle mean [GLTM] 1.269
Method mean [MLTM] 1.218

Specimen : 383B

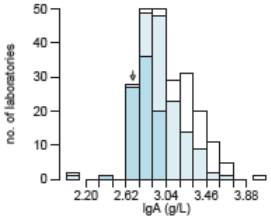
	n	Mean	SD	CV(%)
All methods [ALTM]	228	2.104	0.169	8.1
Nephelometry	50	2.294	0.141	6.2
Beckman Immage [1BK4]	13	2.239	0.228	10.2
Siemens (Dade Behring) [1BE8]	37	2.321	0.116	5.0
Turbidimetry	175	2.053	0.134	6.5
Abbott reagents [2AB14]	36	2.048	0.063	3.1
Olympus AU reagents [2OL1]	30	2.152	0.065	3.0
Randox reagents	4	2.238		
Roche Modular/Cobas [2BO11]	84	1.971	0.082	4.1
Siemens ADVIA reagents [2TE5]	11	2.320	0.041	1.8
The Binding Site reagents	4	2.077		
Vitros Fusion [2JJ1]	5	2.200	0.199	9.0



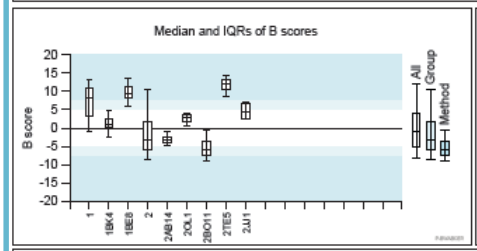
Your result 1.86
Target value (ALTM) 2.104
Standard Uncertainty 0.015
Your specimen: %bias -11.6
Accuracy Index 262
Method Principle mean [GLTM] 2.053
Method mean [MLTM] 1.971

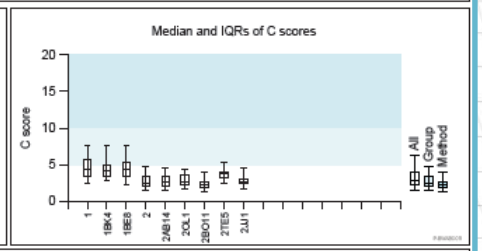
Specimen : 383C

	n	Mean	SD	CV(%)
All methods [ALTM]	228	3.032	0.272	9.0
Nephelometry	50	3.335	0.212	6.4
Beckman Immage [1BK4]	13	3.111	0.163	5.2
Siemens (Dade Behring) [1BE8]	37	3.416	0.159	4.6
Turbidimetry	175	2.951	0.204	6.9
Abbott reagents [2AB14]	36	2.962	0.087	3.0
Olympus AU reagents [2OL1]	30	3.107	0.109	3.5
Randox reagents	4	3.142		
Roche Modular/Cobas [2BO11]	84	2.821	0.110	3.9
Siemens ADVIA reagents [2TE5]	11	3.412	0.055	1.6
The Binding Site reagents	4	2.993		
Vitros Fusion [2JJ1]	5	3.200	0.200	6.2



Your result 2.68
Target value (ALTM) 3.032
Standard Uncertainty 0.024
Your specimen: %bias -11.6
Accuracy Index 257
Method Principle mean [GLTM] 2.951
Method mean [MLTM] 2.821





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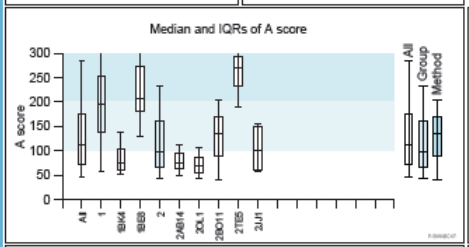
UK NEQAS for Specific Proteins | **Laboratory :**

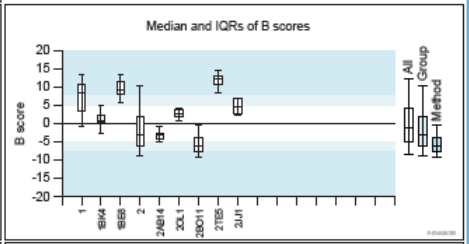
Distribution : 383 Date : 15-Aug-2017 | Page 11 of 21

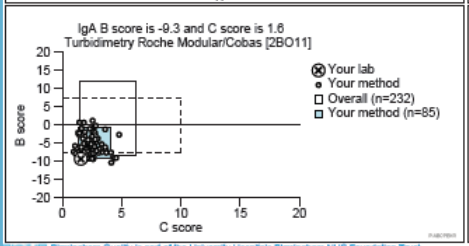
Analyte : IgA (g/L)

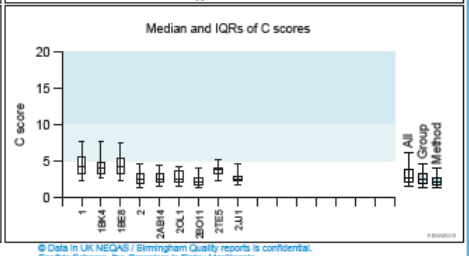
Pool (exclusion) [Type]	Distribution 378 14-Mar-2017 result	target	%bias	Distribution 379 11-Apr-2017 result	target	%bias	Distribution 380 16-May-2017 result	target	%bias	Distribution 381 20-Jun-2017 result	target	%bias	Distribution 382 18-Jul-2017 result	target	%bias	Distribution 383 15-Aug-2017 result	target	%bias
(312) [B,V]	(0.59)	**0.589**	(+0.2)															
346 [B,V]																1.16	**1.282**	-9.5
363 [F,V]													1.52	**1.642**	-7.4			
357 [B,V]				1.75	**1.920**	-8.9												
362 [F,V]													1.81	**1.962**	-7.8			
347 [B,V]																1.86	**2.104**	-11.6
345 [F,V]	1.99	**2.172**	-8.4				1.91	**2.174**	-12.1									
360 [F]	2.17	**2.380**	-8.8				2.11	**2.360**	-10.6									
358 [B,V]				2.15	**2.381**	-9.7												
366 [F,V]										2.29	**2.514**	-8.9						
364 [F,V]													2.46	**2.670**	-7.9			
367 [F,V]										2.48	**2.705**	-8.3						
368 [F,V]										2.76	**3.017**	-8.5						
348 [B,V]																2.68	**3.032**	-11.6
359 [B,V]				2.75	**3.058**	-10.1												
372 [F,V]							3.08	**3.389**	-9.1									
Method mean	2BO11		-8.6	2BO11		-9.6	2BO11		-10.6	2BO11		-8.6	2BO11		-7.7	2BO11		-10.9
A score	153			155			179			184			191			206		
B score	-6.9			-6.9			-8.0			-8.2			-8.5			-9.3		
C score	2.4			2.4			2.2			2.0			1.3			1.6		

B Male and Female
F Female only
V Preservative free









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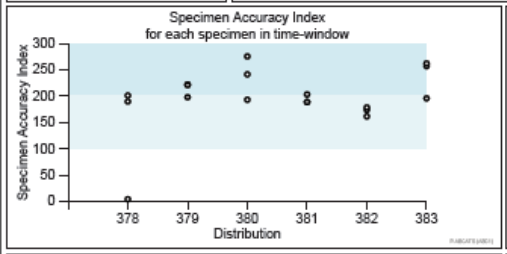
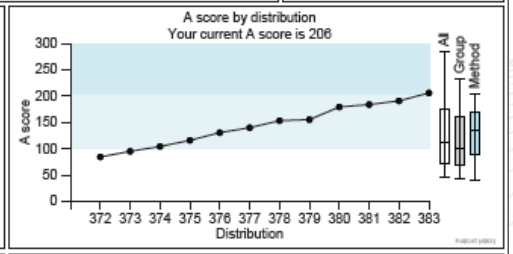
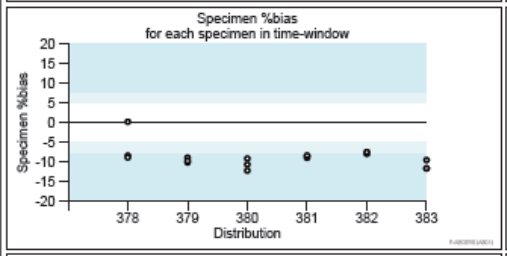
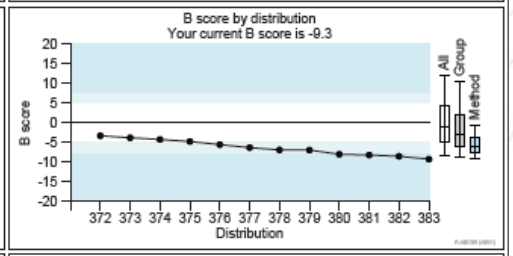
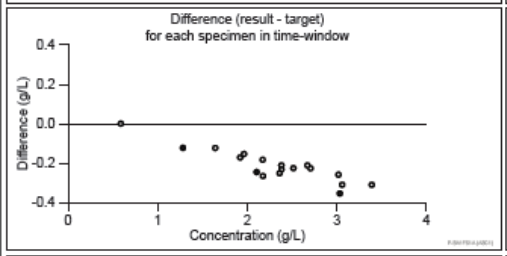
IgA g/L

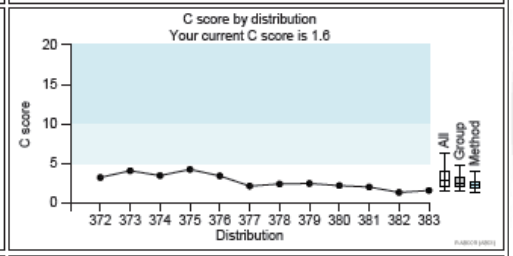


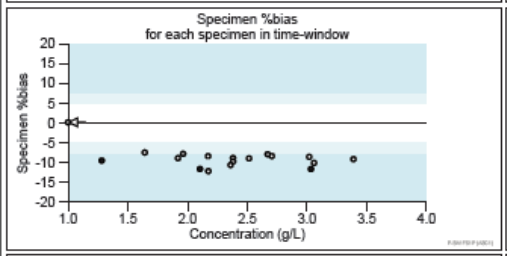


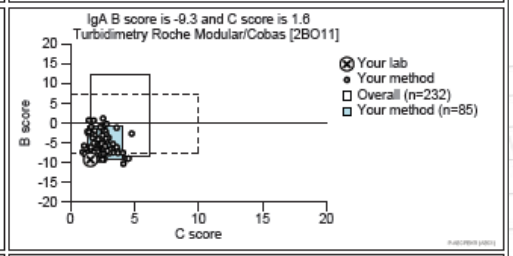


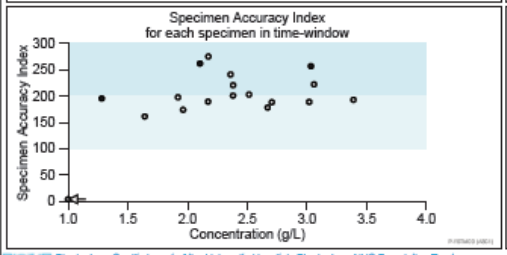


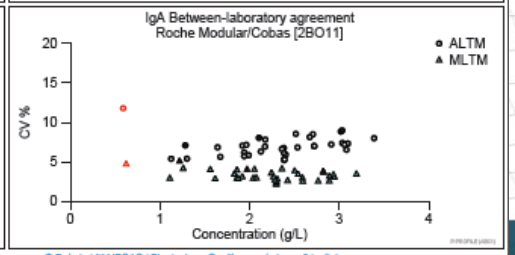












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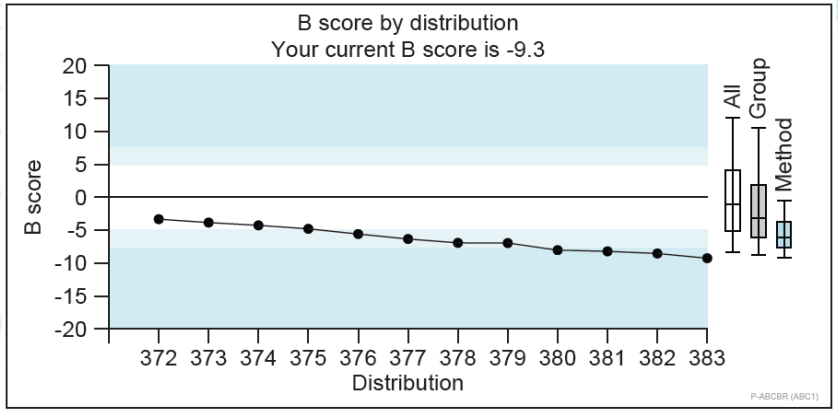
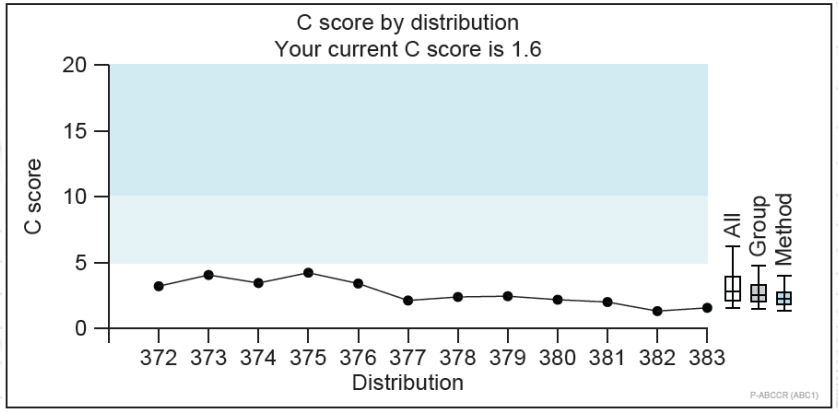
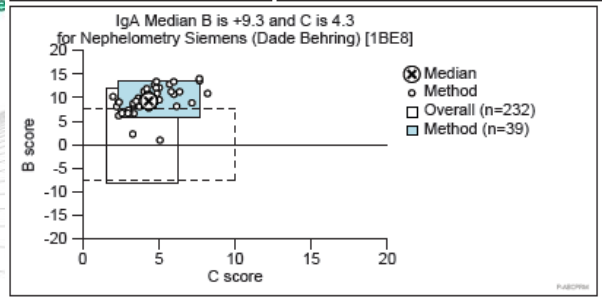
International Quality Expertise

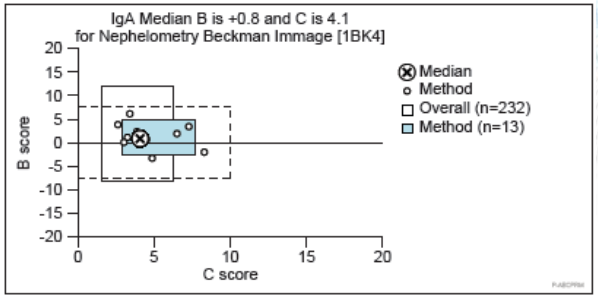


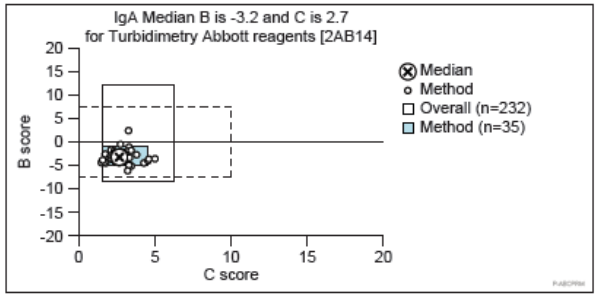


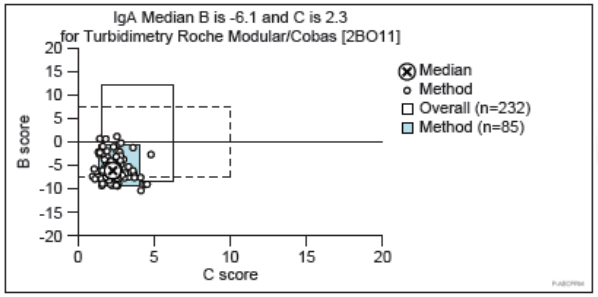
UK NEQAS International Quality Expertise

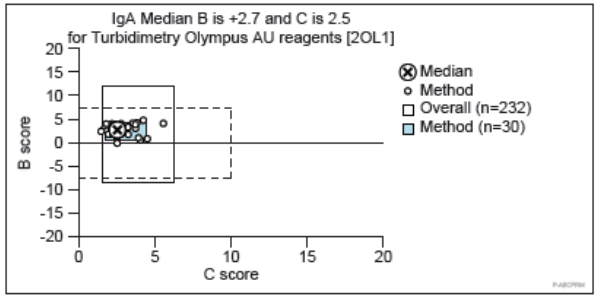
UK NEQAS for Specific Proteins	Method Report
Distribution : **383** Date : 15-Aug-2017	
IgA (g/L)	

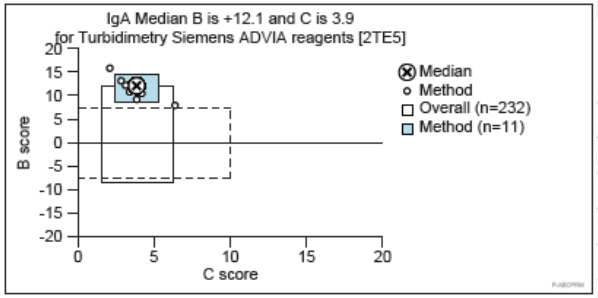


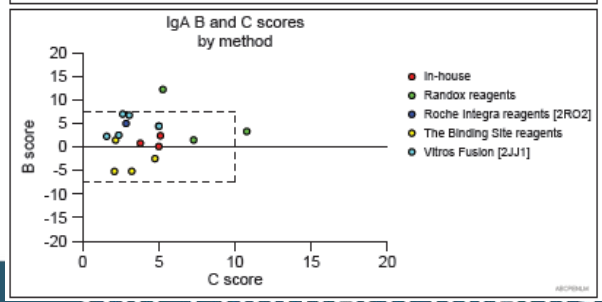












UK NEQAS for GFR Estimations [eGFR]

Laboratory :

Distribution : 130 Date : 19-Mar-2017

Analyte : Serum creatinine (umol/L)

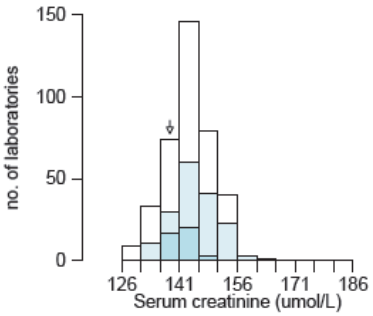
Spec.	Pool	Pool description / Treatments / Additions
130A	221	Normal serum (Pool 220) + 75 umol/L Creatinine
130B	222	Normal serum (Pool 220) + 75 umol/L Creatinine + 20 mmol/L Glu
130C	223	Normal serum (Pool 220) + 75 umol/L Creatinine + 40mmol/L Glu

All methods
Enzymatic [9]
Abbott reagents [9AB]

Your A score is	93 ↘
Your B score is	-3.6 ↘
Your C score is	3.4 ↔
The A limit is	200
The B limit is +/-	10.0
The C limit is	10.0

Specimen : 130A

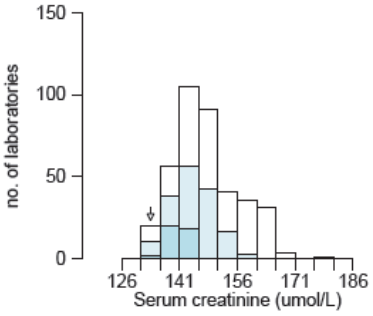
	n	Mean	SD	CV(%)
All methods [ALTM]	385	144.2	5.9	4.1
Dry slide [1]	10	138.9	3.6	2.6
Compensated Kinetic Jaffe [10]	196	143.4	6.0	4.2
Abbott reagents [10AB]	56	144.3	3.4	2.3
Beckman (Olympus) [10OL]	22	138.9	5.5	3.9
Roche Cobas/Modular [10BO]	90	145.4	5.8	4.0
Siemens ADVIA [10TE]	20	135.5	6.4	4.7
Enzymatic [9]	168	145.4	5.9	4.0
Abbott reagents [9AB]	40	142.0	2.7	1.9
Beckman (Olympus) [9OL]	11	142.9	1.6	1.1
Roche Cobas/Modular [9BO]	91	149.1	4.3	2.9
Siemens ADVIA [9TE]	21	136.7	3.1	2.3



Your result	137
Target value (Enzymatic [9])	145.4
Standard Uncertainty	0.6
Your specimen: %bias	-5.8 ▽
Accuracy Index	227
'True' value	
Abbott reagents [9AB] (reagent)	142.0

Specimen : 130B

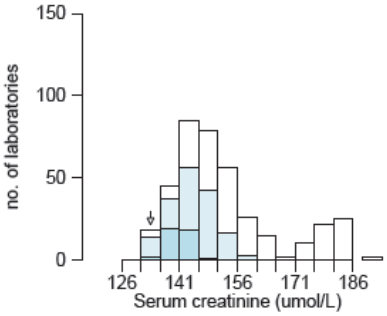
	n	Mean	SD	CV(%)
All methods [ALTM]	385	148.2	8.5	5.7
Dry slide [1]	10	137.2	3.1	2.2
Compensated Kinetic Jaffe [10]	196	152.0	9.1	6.0
Abbott reagents [10AB]	56	162.0	3.3	2.0
Beckman (Olympus) [10OL]	22	143.8	3.8	2.6
Roche Cobas/Modular [10BO]	90	148.6	5.6	3.8
Siemens ADVIA [10TE]	20	148.2	7.0	4.7
Enzymatic [9]	168	144.8	5.9	4.1
Abbott reagents [9AB]	40	141.3	2.8	2.0
Beckman (Olympus) [9OL]	11	142.3	1.9	1.3
Roche Cobas/Modular [9BO]	91	148.6	4.2	2.8
Siemens ADVIA [9TE]	21	136.9	2.6	1.9



Your result	135
Target value (Enzymatic [9])	144.8
Standard Uncertainty	0.6
Your specimen: %bias	-6.8 ▽
Accuracy Index	267
'True' value	
Abbott reagents [9AB] (reagent)	141.3

Specimen : 130C

	n	Mean	SD	CV(%)
All methods [ALTM]	385	152.3	13.4	8.8
Dry slide [1]	10	137.6	2.9	2.1
Compensated Kinetic Jaffe [10]	196	160.7	15.6	9.7
Abbott reagents [10AB]	56	180.5	3.5	1.9
Beckman (Olympus) [10OL]	22	147.9	3.3	2.2
Roche Cobas/Modular [10BO]	90	152.3	6.6	4.4
Siemens ADVIA [10TE]	20	161.0	6.4	4.0
Enzymatic [9]	168	144.5	5.8	4.0
Abbott reagents [9AB]	40	141.3	2.8	2.0
Beckman (Olympus) [9OL]	11	141.6	2.2	1.6
Roche Cobas/Modular [9BO]	91	148.2	4.1	2.8
Siemens ADVIA [9TE]	21	136.5	2.6	1.9



Your result	135
Target value (Enzymatic [9])	144.5
Standard Uncertainty	0.6
Your specimen: %bias	-6.6 ▽
Accuracy Index	260
'True' value	
Abbott reagents [9AB] (reagent)	141.3

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International Quality Expertise

Interference in Creatinine assays

~ not some obscure medication or drug, but simple, plain old Glucose

This is mentioned in the OFU, but does everyone read these?

Are diabetics being over treated for kidney problems that aren't there?

The Narrative of EQA

- I am going to talk about:
  - Definitions and nomenclature
  - What is the EQA process?
  - Regulatory systems and structure of the NHS in the UK
  - What does EQA look like in practice?
  - Performance surveillance of Laboratories and post-market surveillance of kits/methods/products
  - Numbers, numbers and interpretation
  - Reference methods and commutability
  - Scoring systems and Scheme design

Folate®~ change in assay from major manufacturer

Figure 4

Histogram for a Roche Gen III user and the method mean table for Specimen 229B

Specimen : 229B	n	Mean	SD	CV(%)
All methods [ALTM]	305	3.93	1.12	28.6
Abbott Architect [AB13]	78	3.07	0.34	11.0
Beckman Access [SF6]	10	4.47	0.15	3.3
Beckman DxI [SF5]	38	4.71	0.29	6.1
In-house [OOO]	1	2.08		
Ortho Vitros [AM12]	2	3.05		
Roche Cobas/Modular [BO5]	110	4.75	0.62	13.2
Folate III (restandardised)	6	3.40	0.47	13.9
Siemens Centaur XP/CP [CO10]	61	3.10	0.43	13.9
Siemens Dimension/Vista [BE9]	2	4.61		
Siemens Imm 2000/XPi [DC11]	3	2.53		

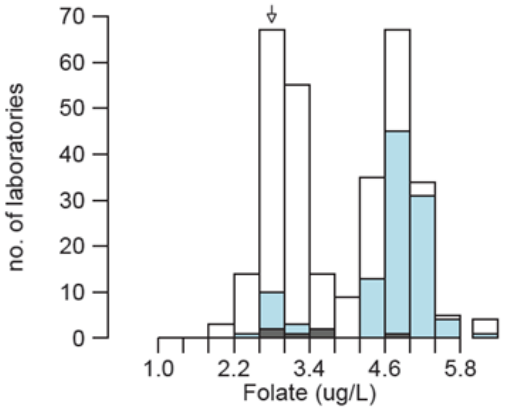
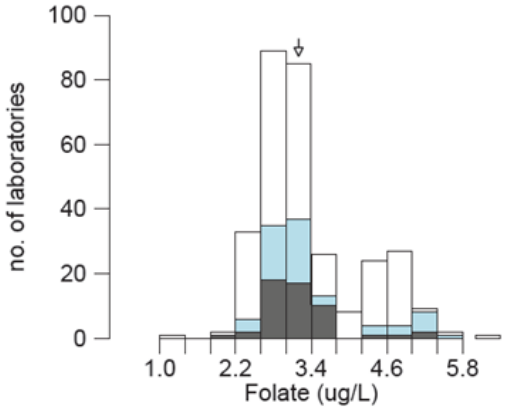


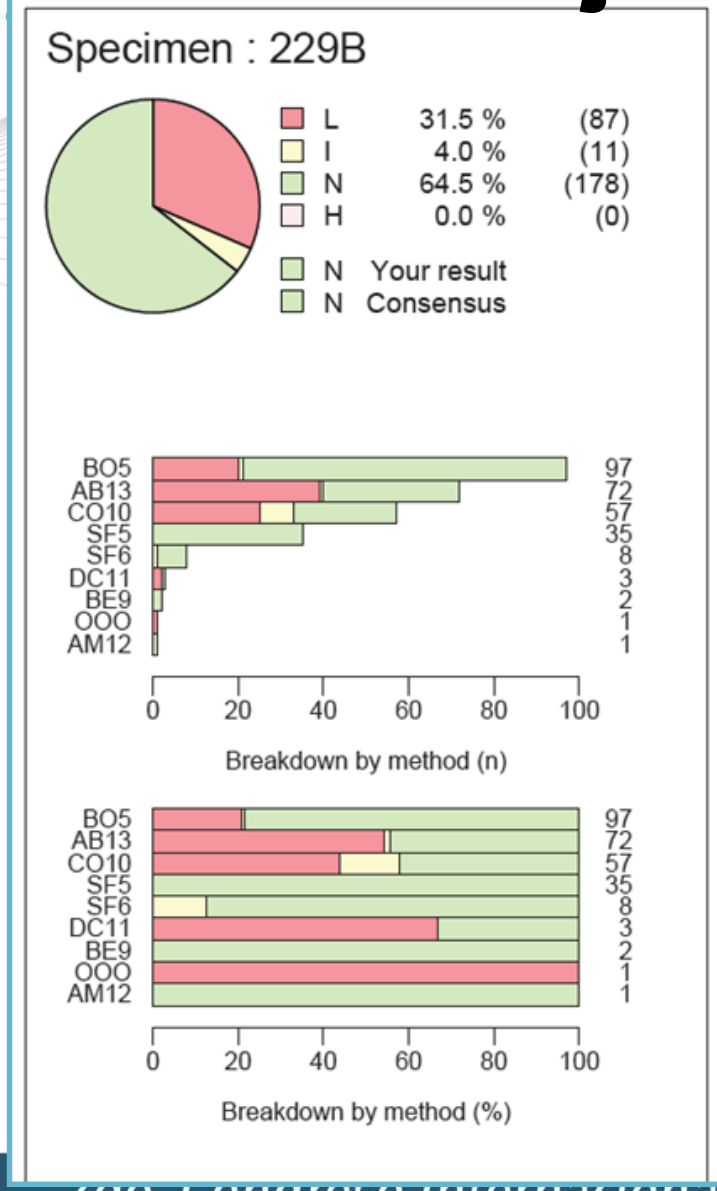
Figure 5

Histogram for a Roche Gen III user and the method mean table for Specimen 234B

Specimen : 234B	n	Mean	SD	CV(%)
All methods [ALTM]	307	3.35	0.78	23.3
Abbott Architect [AB13]	83	2.97	0.29	9.7
Beckman Access [SF6]	9	4.40	0.15	3.3
Beckman DxI [SF5]	37	4.67	0.33	7.1
In-house [OOO]	1	1.31		
Ortho Vitros [AM12]	2	2.75		
Roche Cobas/Modular [BO5]	109	3.31	0.67	20.3
Folate III (restandardised)	52	3.19	0.43	13.3
Siemens Centaur XP/CP [CO10]	61	3.08	0.54	17.4
Siemens Dimension/Vista [BE9]	2	4.31		
Siemens Imm 2000/XPi [DC11]	3	2.70		



Folate ~ change in assay from major manufacturer



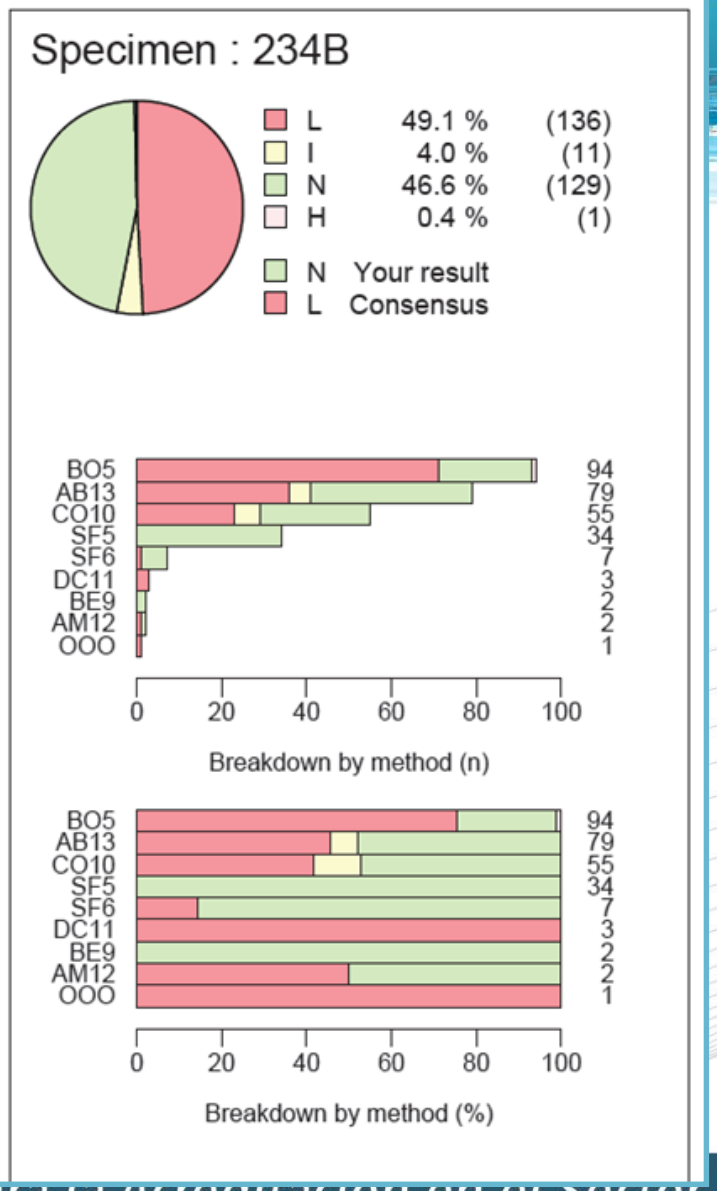


Figure 6

The scatterplot by method, colour coded by interpretation, for Specimen 229B. The full expansion of the method code giving the manufacturer's name and/or product is given on the report in the table next to the histogram.

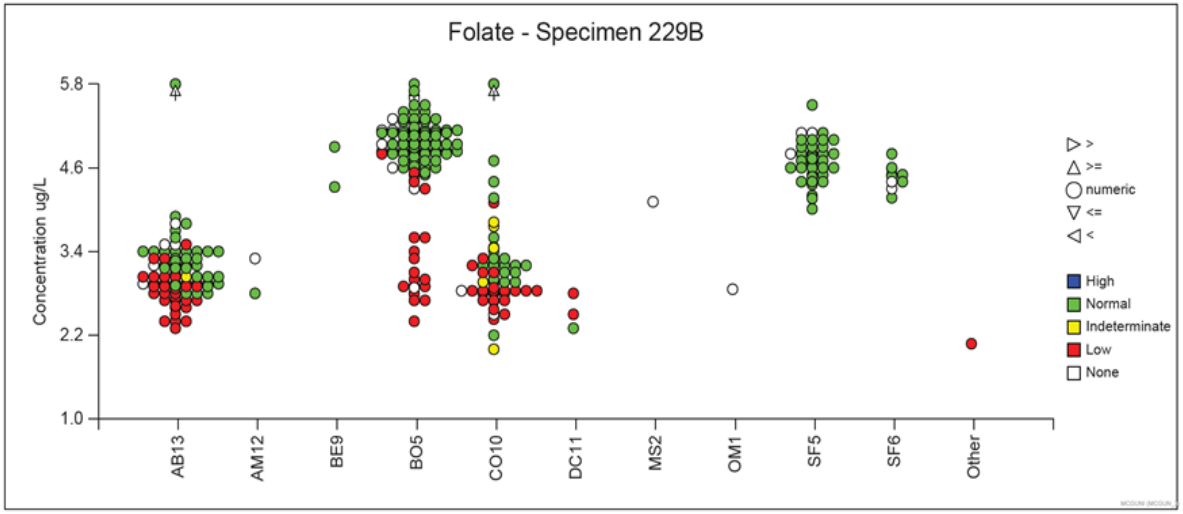
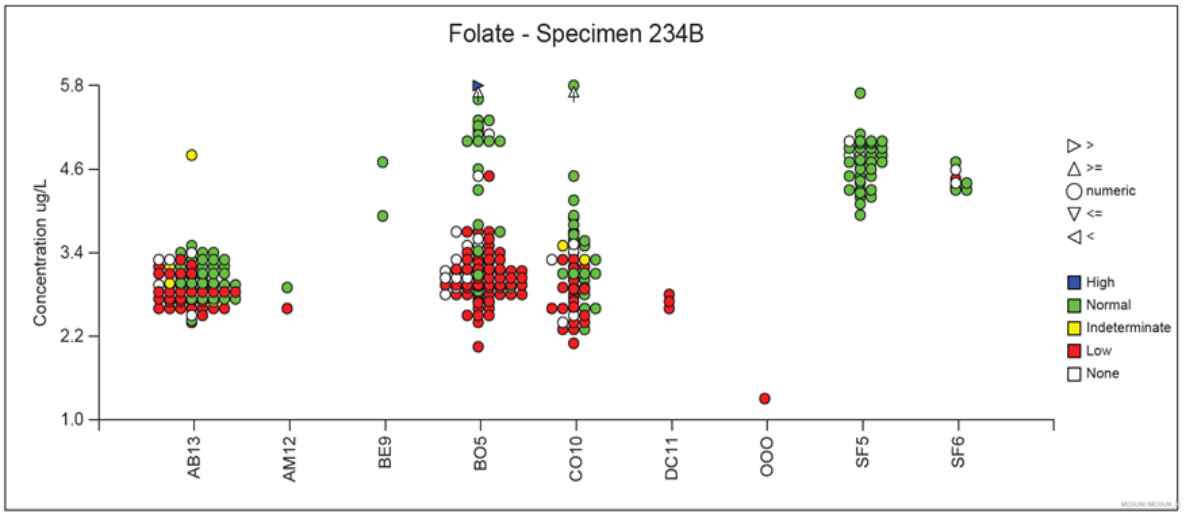


Figure 7

The scatterplot by method, colour coded by interpretation, for Specimen 234B. The full expansion of the method code giving the manufacturer's name and/or product is given on the report in the table next to the histogram.



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Finlay MacKenzie's world famous 'Rainbow Trout Plot'!

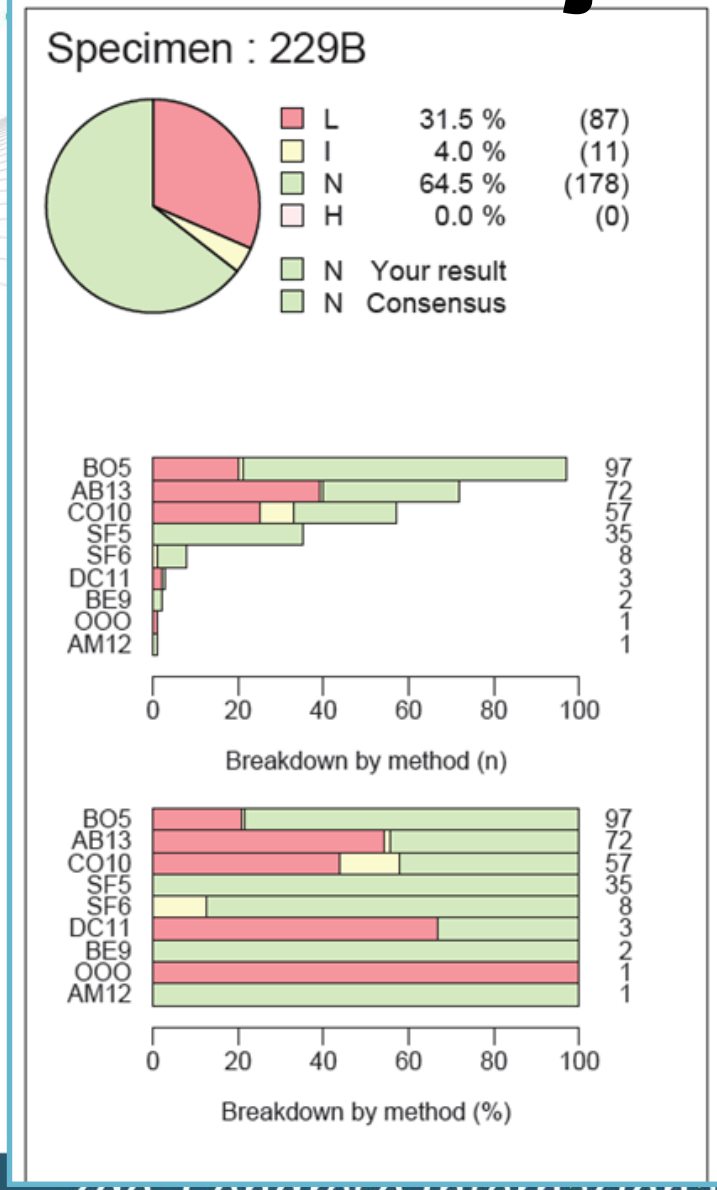
The data is plotted by method across the x-axis.

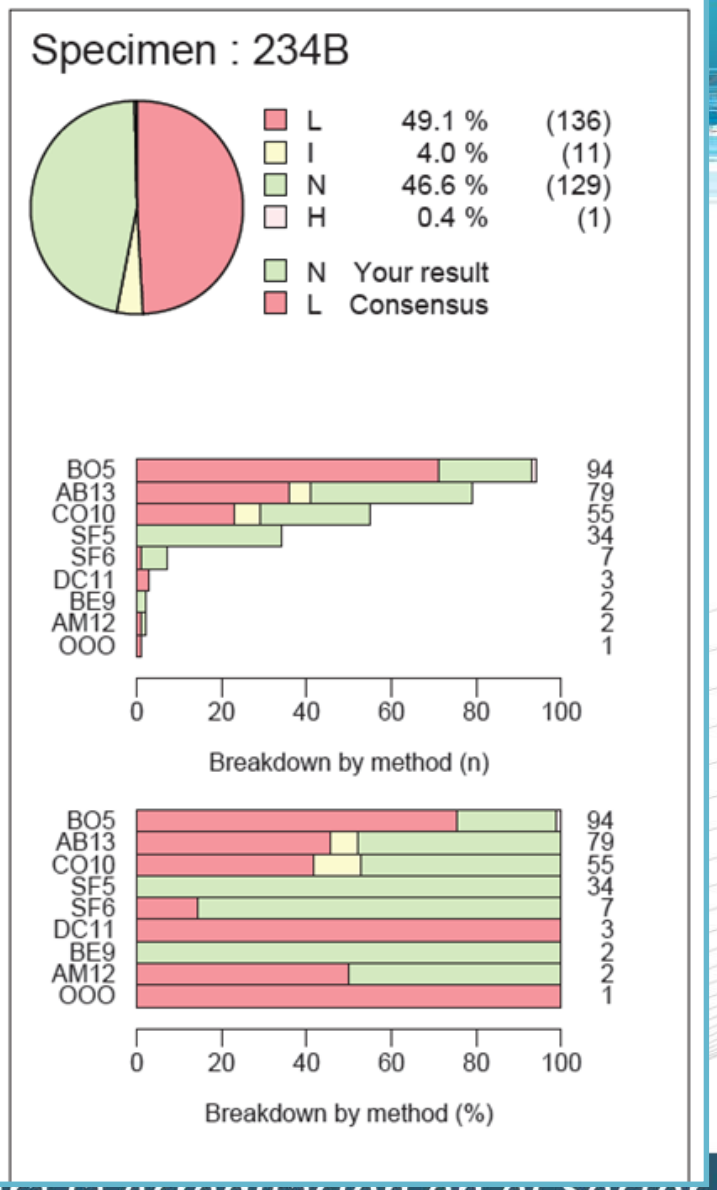
The concentration is on the y-axis. Every result is plotted.

The symbol shape is different for numeric and non-numeric data points.

The colour of each symbol represents the *interpretation* that the participating Laboratory itself has categorised their own result.

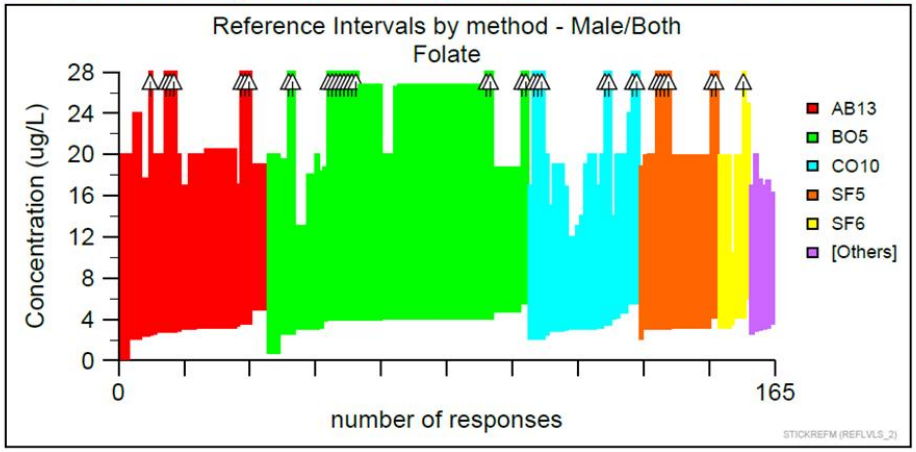
Folate ~ change in assay from major manufacturer

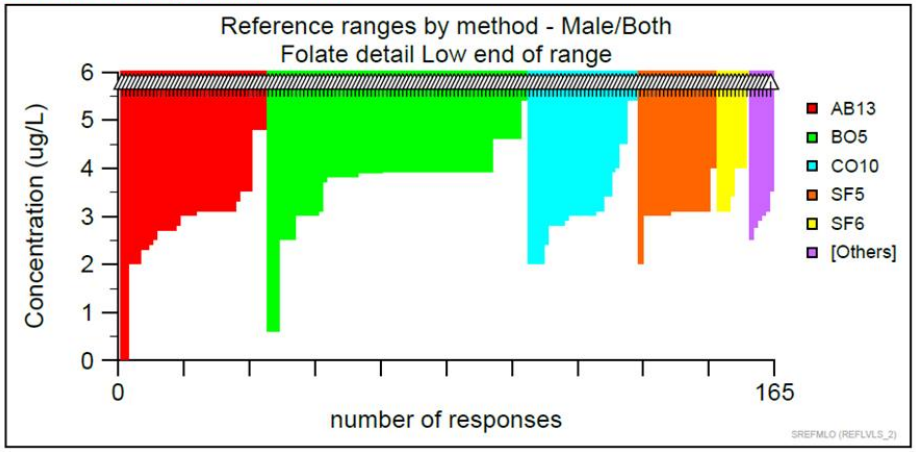




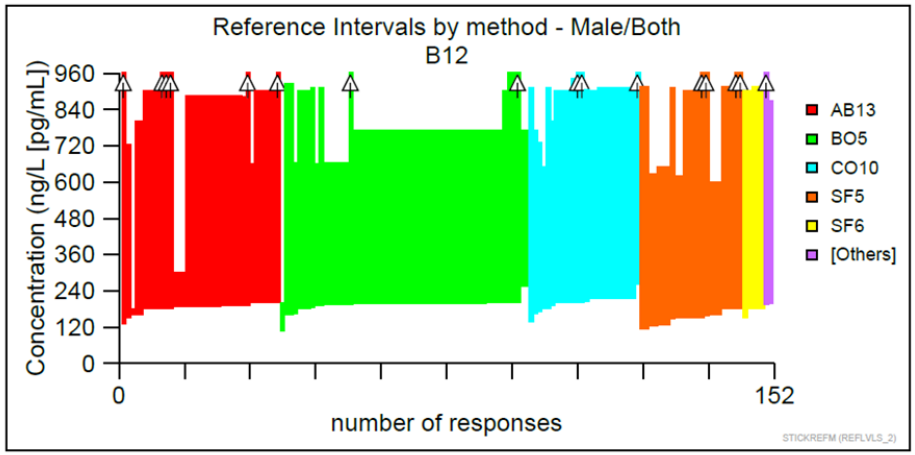
Folate ~ Reference Intervals ~ [with B12 as an other example]

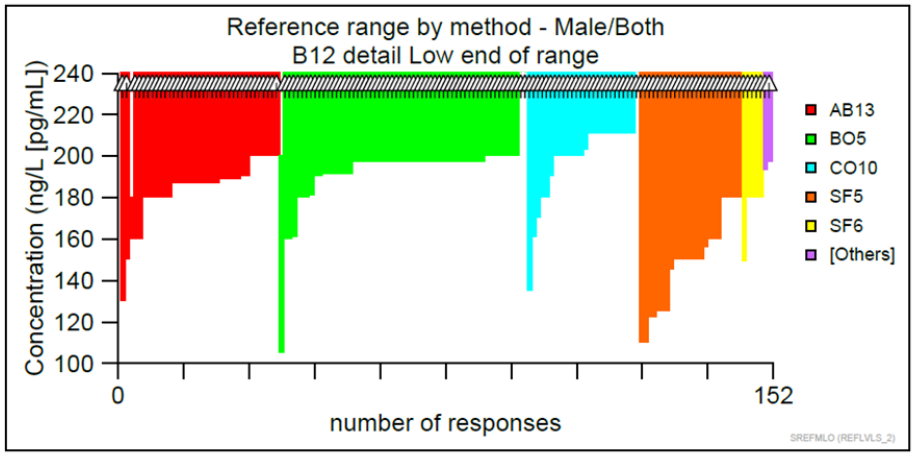
Folate: Full range and Low end of range, ranked by method and increasing lower end

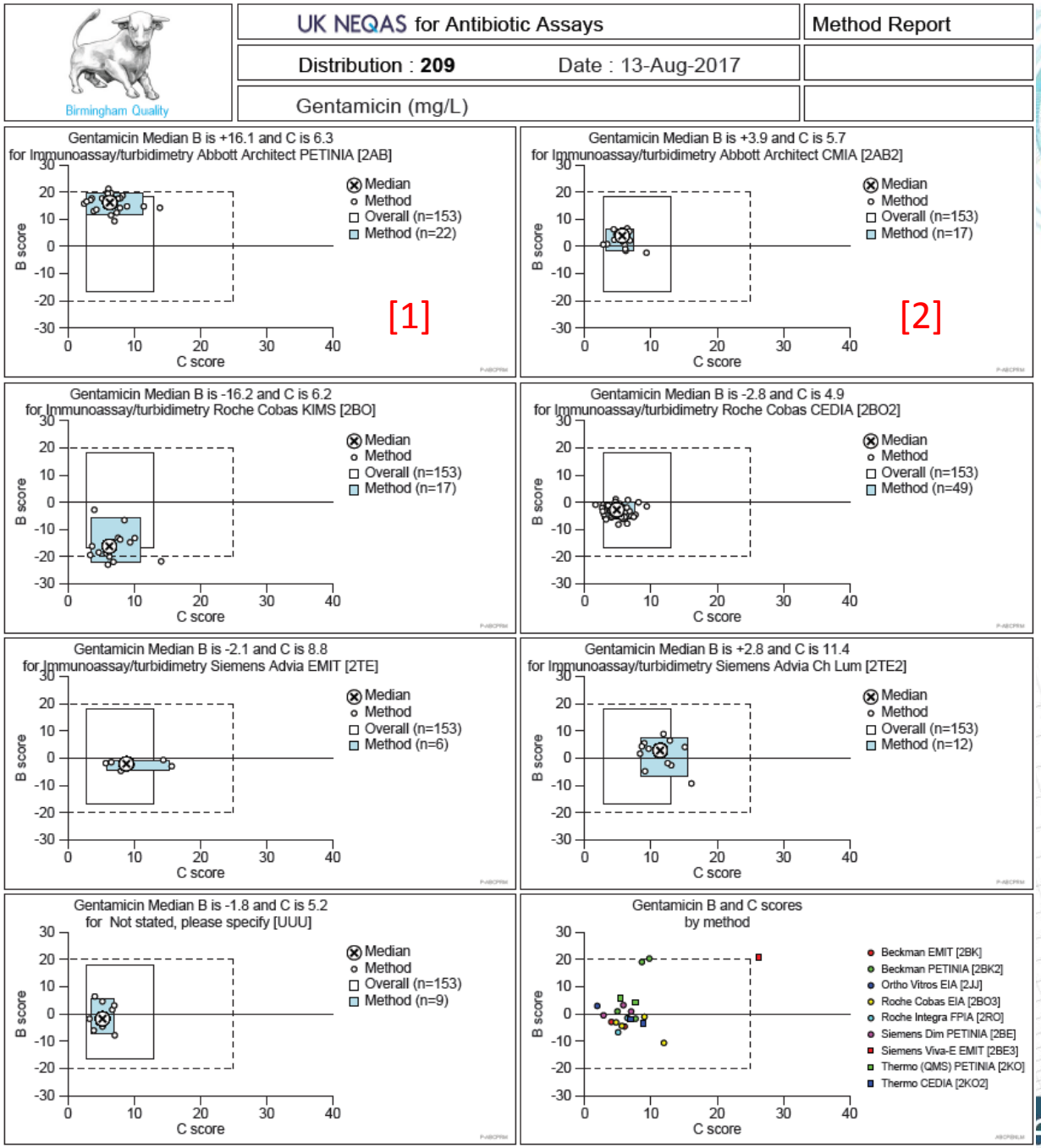




B12: Full range and Low end of range, ranked by method and increasing lower end







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International Quality Expertise

Gentamicin

The top two plots [1] and [2] are both from the same manufacturer.

One has a bias of +4% whilst the other has a bias of +16%.

Which one of its two methods does the manufacturer believe to be correct?

The Narrative of EQA

- I am going to talk about:
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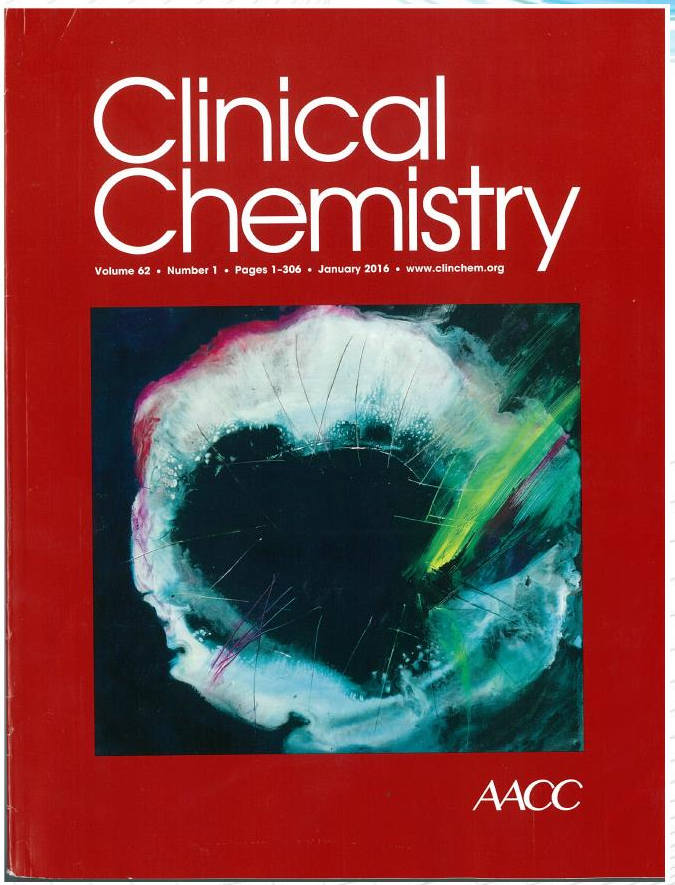
  - What does EQA look like in practice?
  - Performance surveillance of Laboratories and post-market surveillance of kits/methods/products
  - Numbers, numbers and interpretation
  - Reference methods and commutability
  - Scoring systems and Scheme design

Clinical Chemistry

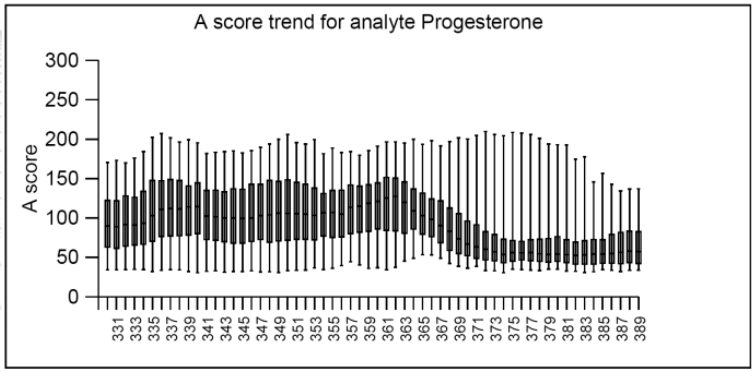
Candidate Reference Method Procedure for the Quantification of Total Serum Cortisol with LC-MS/MS.

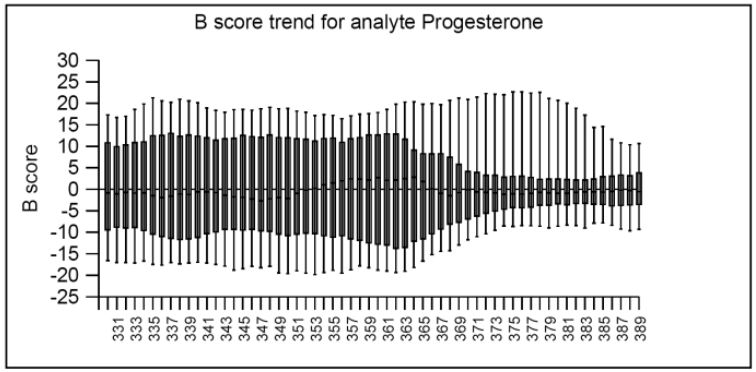


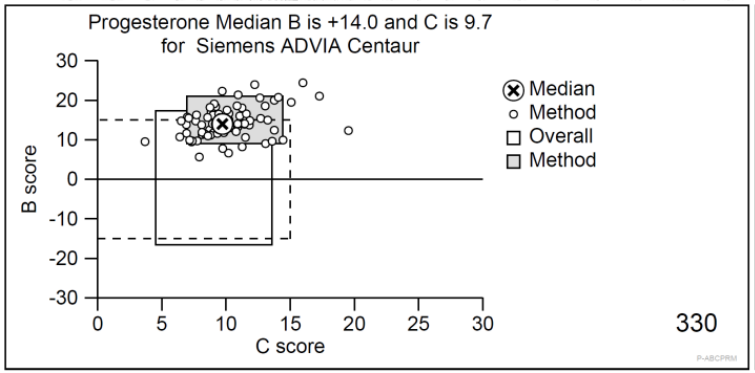
Hawley JM, Owen LJ, MacKenzie F, Mussell C, Cowen S, Keevil BG.

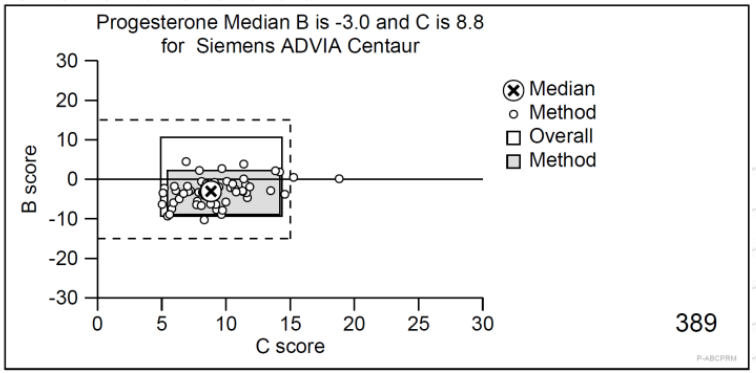
Clin Chem. 2016 Jan;62(1):262-269.

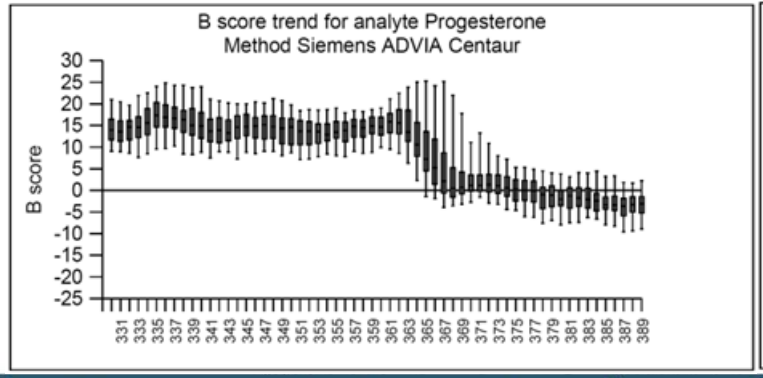
Progesterone Harmony

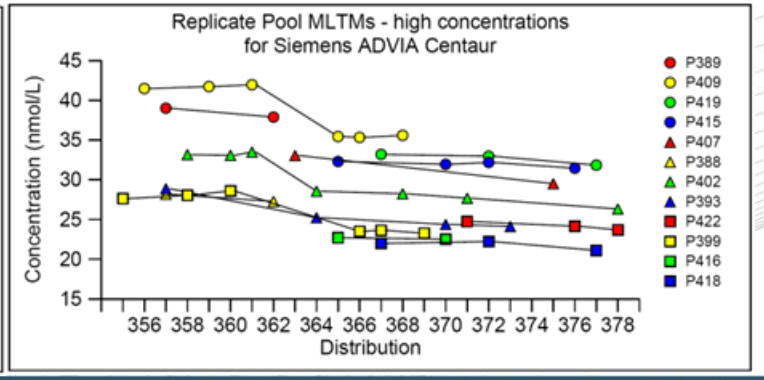








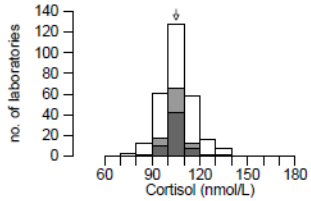




Gender differences Cortisol

Specimen : 367A

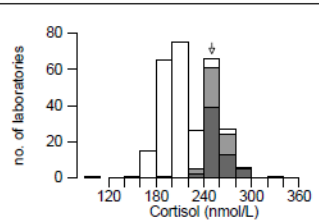
	n	Mean	SD	CV(%)
All methods	282	106	10	9.2
Abbott Architect	35	95	8	7.9
Bayer Advia:Centaur	67	106	8	7.8
Beckman Access	28	110	11	9.6
DPC Immulite 2000	48	111	12	11.1
Roche Elecsys E170 Modular	99	105	6	5.3
	61	105	5	4.8



Your result	101
Target (ALTM)	106
Your specimen:	
%bias	-4.6
transformed bias	-45
Accuracy Index	45
Your method mean Roche Elecsys E170 Modular	105

Specimen : 367B

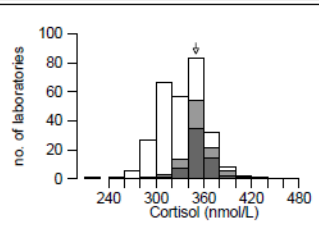
	n	Mean	SD	CV(%)
All methods	282	222	34	15.2
Abbott Architect	35	210	12	5.5
Bayer Advia:Centaur	67	203	18	8.9
Beckman Access	28	189	18	9.7
DPC Immulite 2000	48	206	19	9.1
Roche Elecsys E170 Modular	99	257	12	4.6
	61	257	11	4.4



Your result	254
Target (ALTM)	222
Your specimen:	
%bias	+14.4
transformed bias	+160
Accuracy Index	160
Your method mean Roche Elecsys E170 Modular	257

Specimen : 367C

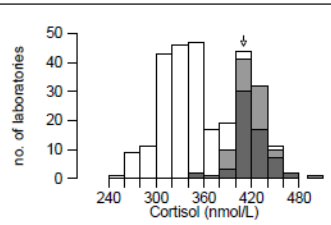
	n	Mean	SD	CV(%)
All methods	282	333	28	8.5
Abbott Architect	35	306	22	7.1
Bayer Advia:Centaur	67	331	23	6.9
Beckman Access	28	315	17	5.4
DPC Immulite 2000	48	325	30	9.3
Roche Elecsys E170 Modular	99	353	15	4.4
	61	353	14	3.9



Your result	346
Target (ALTM)	333
Your specimen:	
%bias	+3.9
transformed bias	+46
Accuracy Index	46
Your method mean Roche Elecsys E170 Modular	353

Specimen : 367D

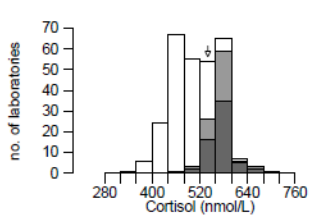
	n	Mean	SD	CV(%)
All methods	282	363	54	14.9
Abbott Architect	35	326	21	6.4
Bayer Advia:Centaur	67	339	23	6.9
Beckman Access	28	299	33	11.1
DPC Immulite 2000	48	341	29	8.6
Roche Elecsys E170 Modular	99	419	18	4.4
	61	419	18	4.2



Your result	407
Target (ALTM)	363
Your specimen:	
%bias	+12.2
transformed bias	+146
Accuracy Index	146
Your method mean Roche Elecsys E170 Modular	419

Specimen : 367E

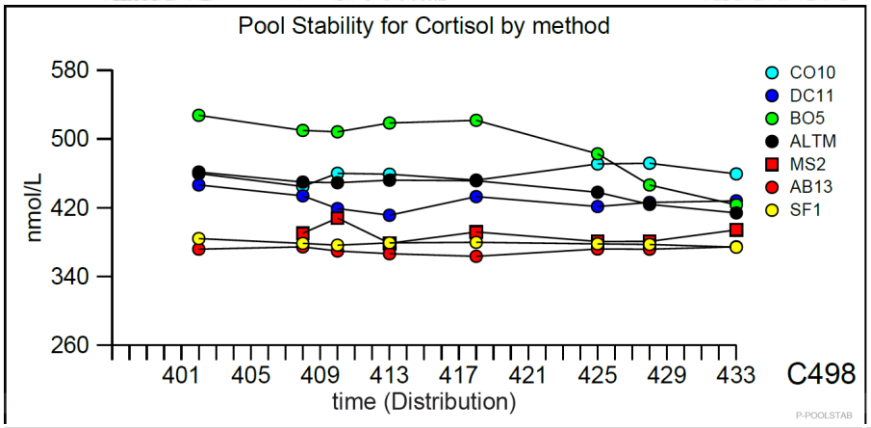
	n	Mean	SD	CV(%)
All methods	282	513	64	12.5
Abbott Architect	35	438	32	7.2
Bayer Advia:Centaur	67	484	38	7.9
Beckman Access	28	476	30	6.4
DPC Immulite 2000	48	506	41	8.1
Roche Elecsys E170 Modular	99	572	24	4.2
	61	573	24	4.2

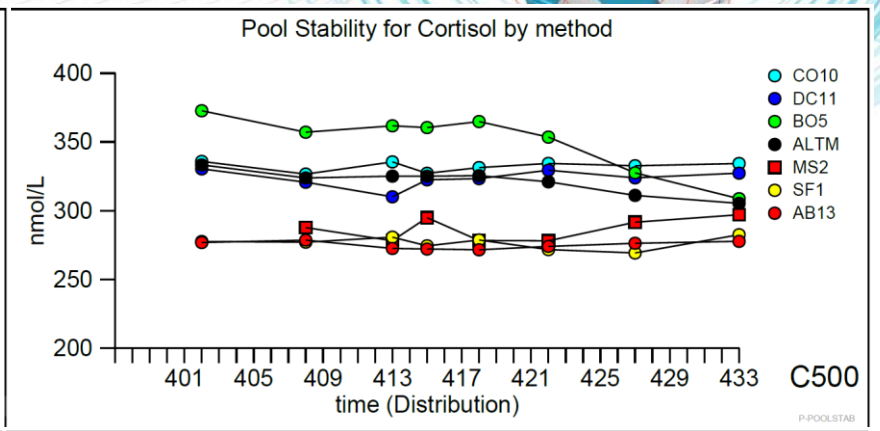


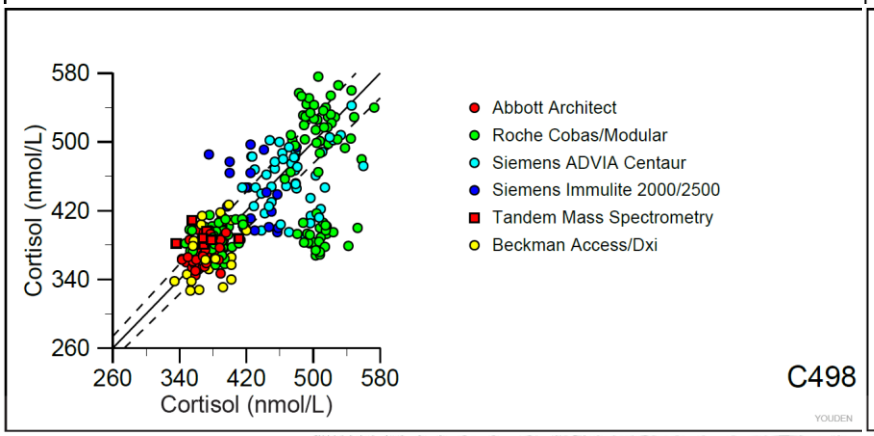
Your result	554
Target (ALTM)	513
Your specimen:	
%bias	+8.0
transformed bias	+90
Accuracy Index	90
Your method mean Roche Elecsys E170 Modular	572

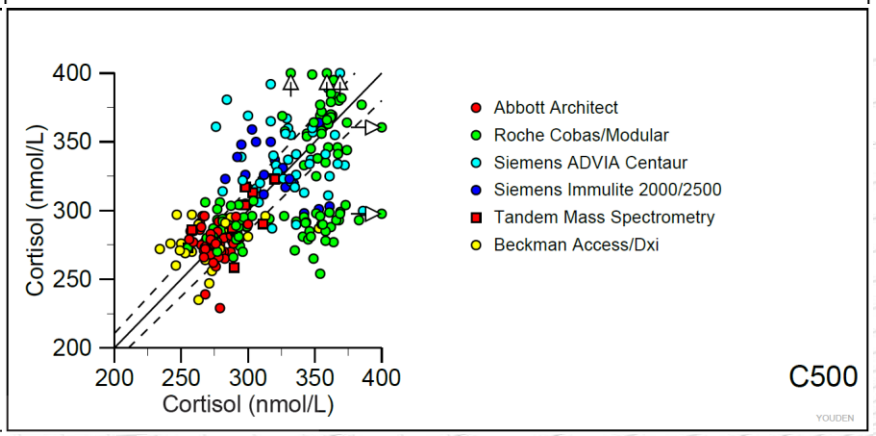
The nature of the beast is that since we want to use exciting endogenous levels in the Scheme, the male donations we get in through the door get used for Cortisol (and now General chemistry) so the effect that has always been there was largely over-looked/ignored although my predecessor and some participants were aware of the potential problem

Cortisol
Lets look at a couple of pools over time





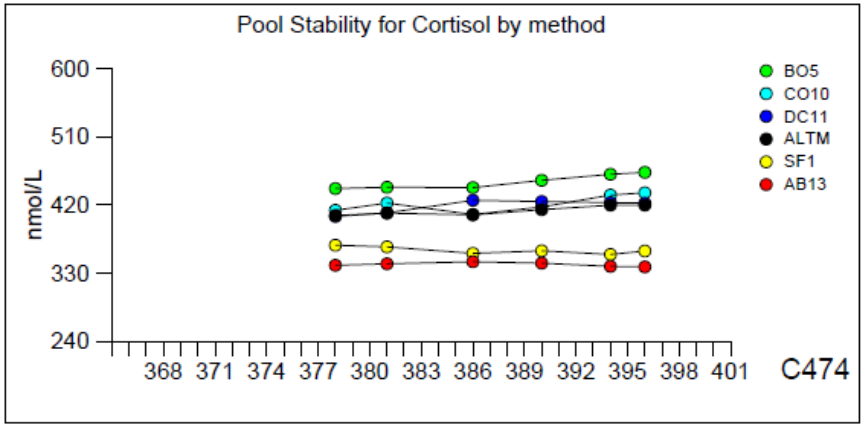


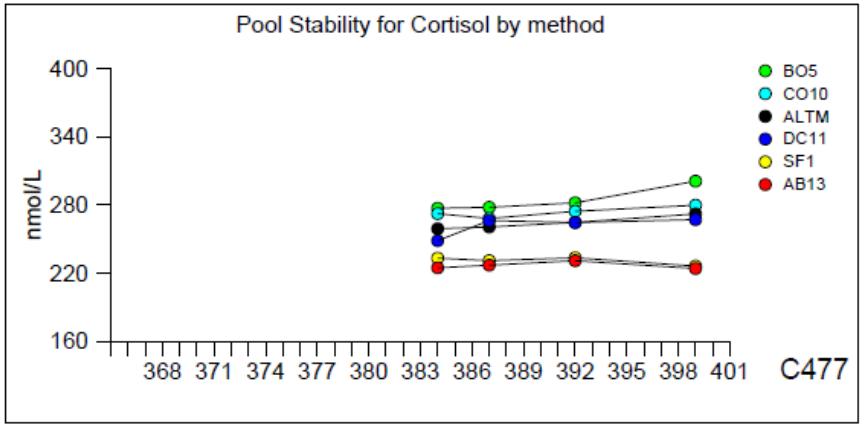


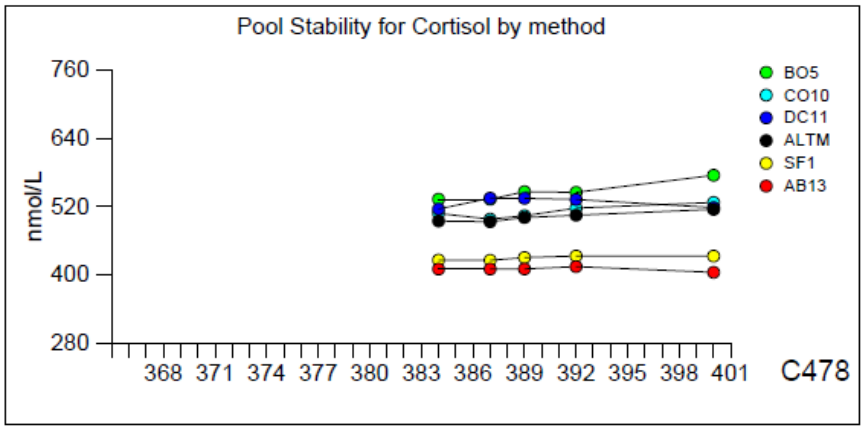
Look at the 3 domains that Roche exhibits for Pool C498 on a Youden Plot. The 520/520 group used Gen I for both Distributions. The 390/390 group used Gen II for both Distributions The 520/390 group changed from Gen I to Gen II between Distributions.

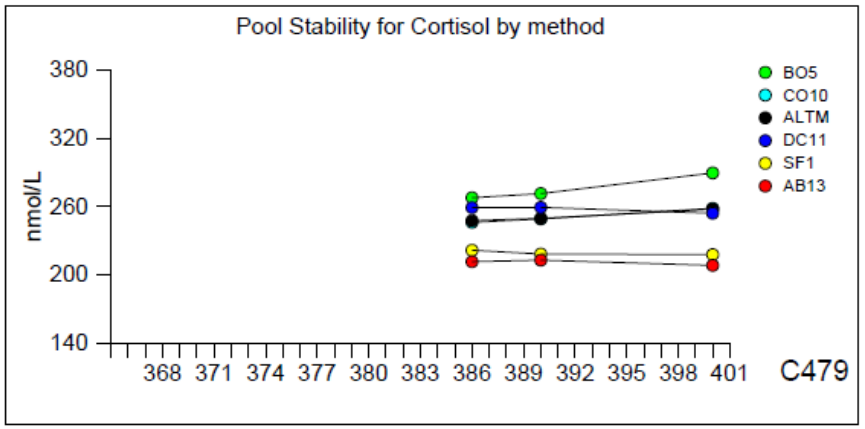
Pool Stability

each graph is one pool with multiple methods



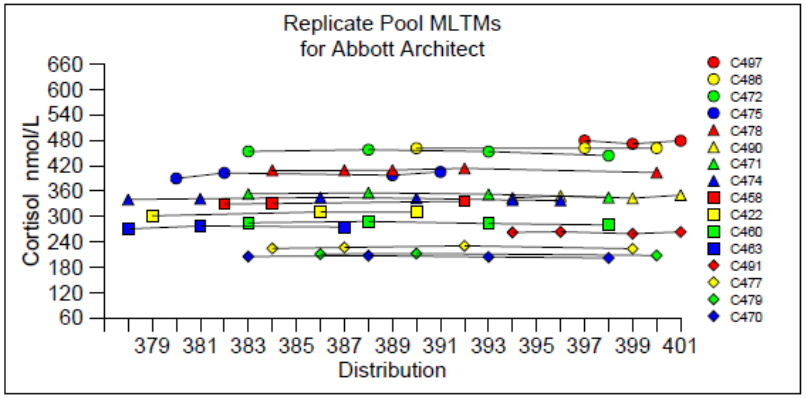


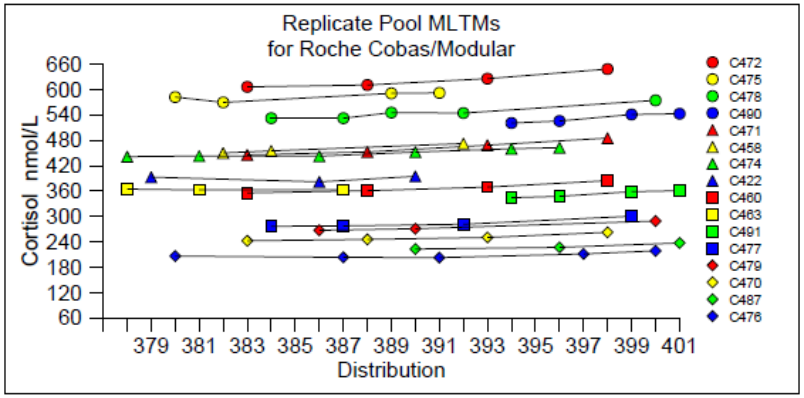


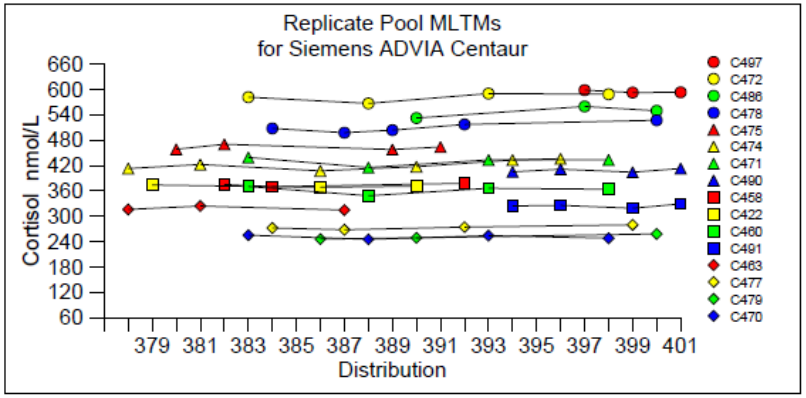


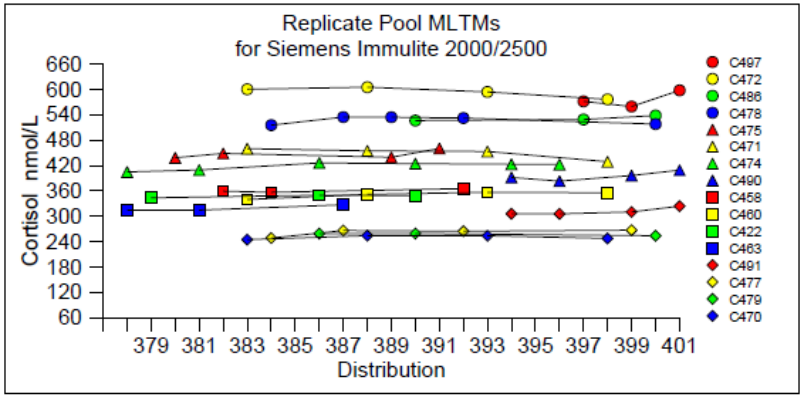
Pool Stability

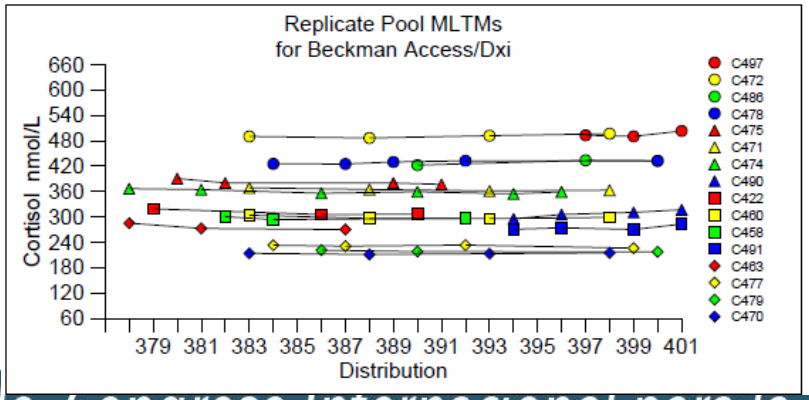
each graph is one method with multiple pools



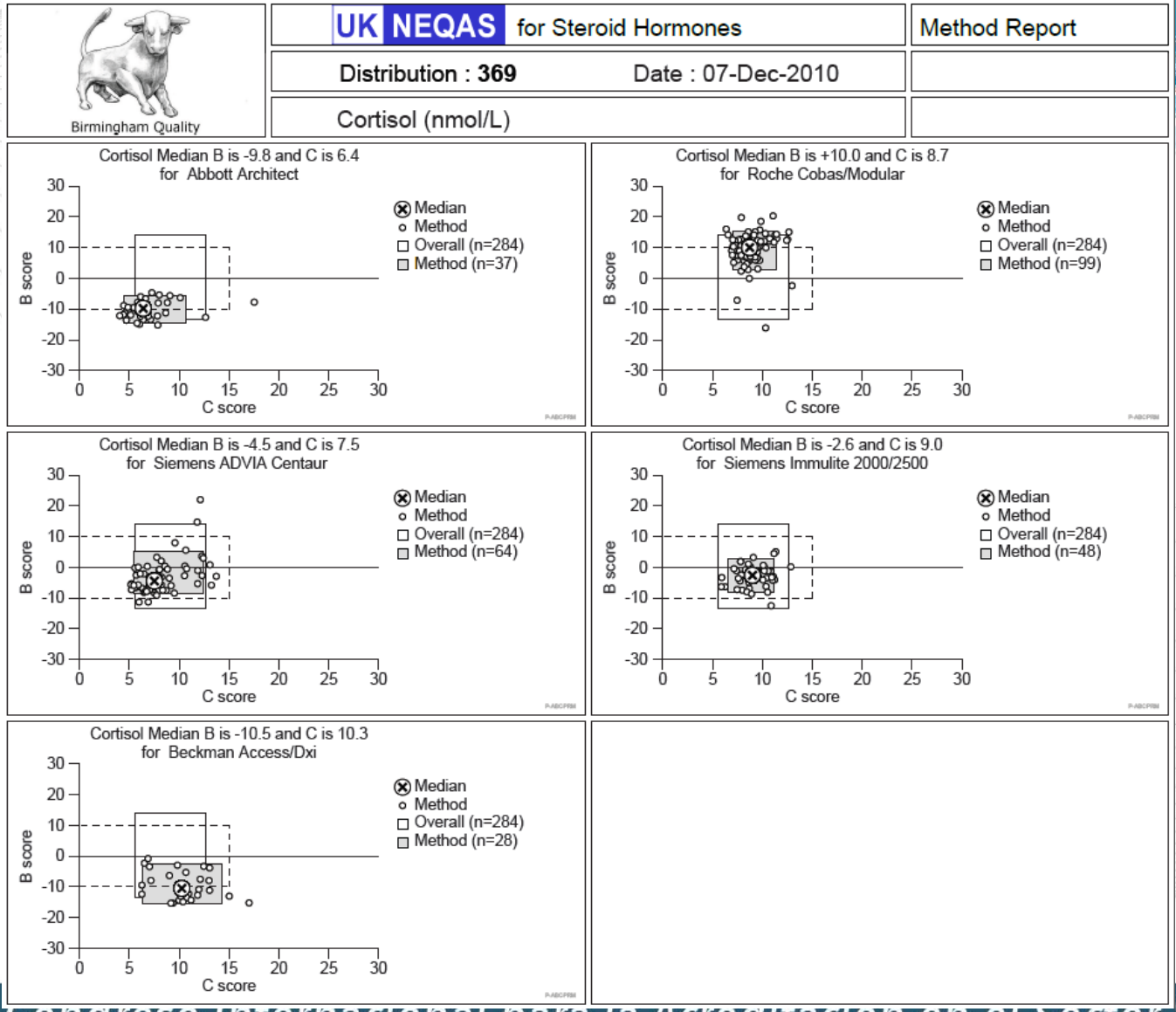






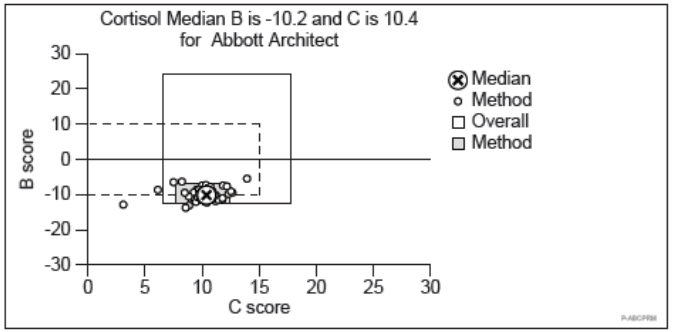


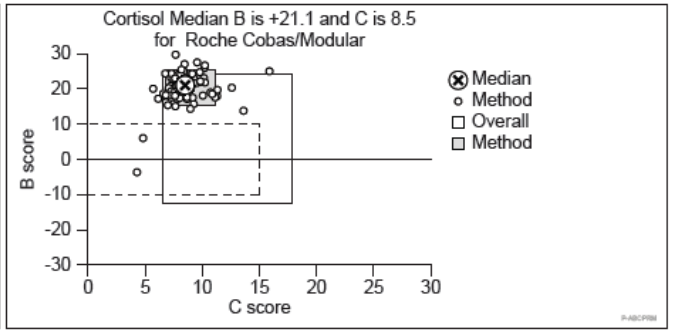
December 2010

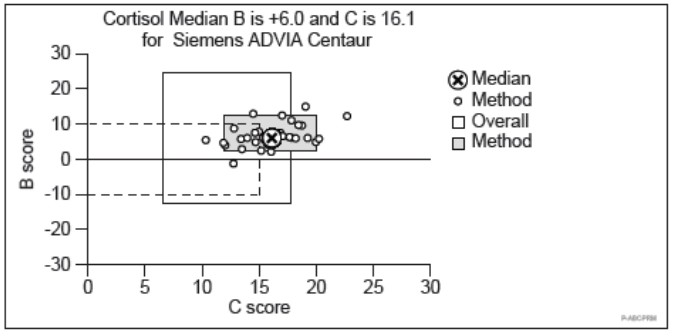


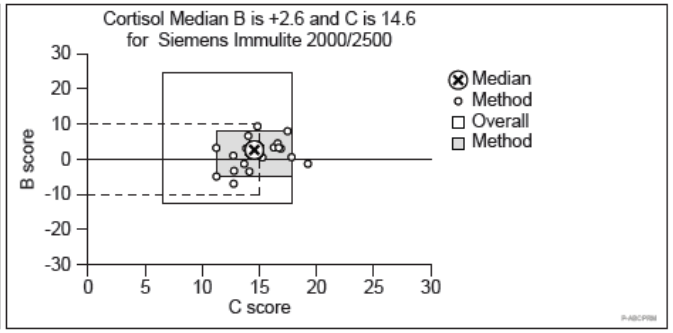
What-if Mass Spec Candidate Reference Method Target August 2015

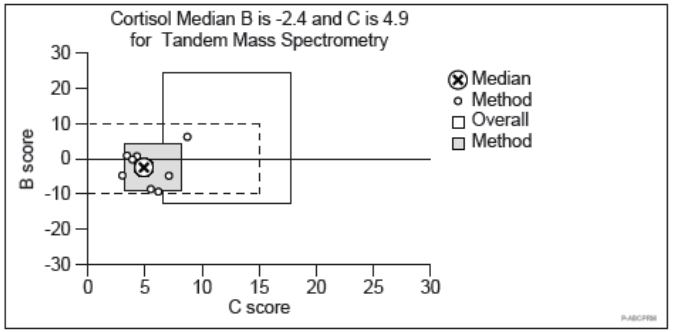
What-if MassSpec	Method Report
Distribution : **422** Date : 18-Aug-2015	
Cortisol (nmol/L)	

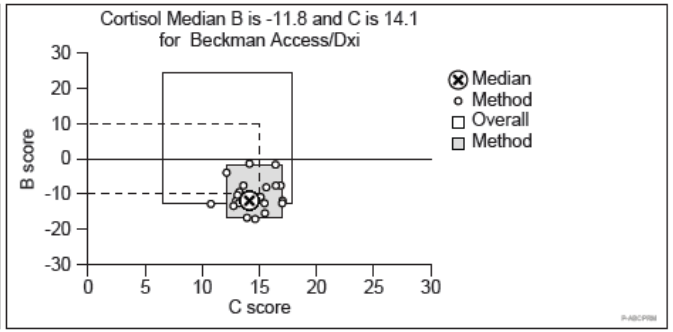




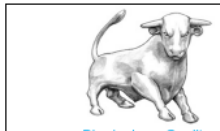








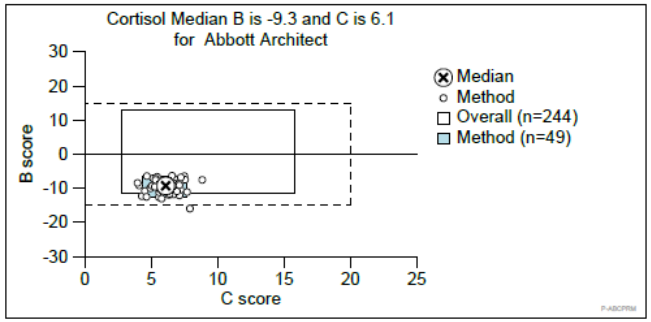
Mass Spec Field Method Target replaces ALTM July 2017

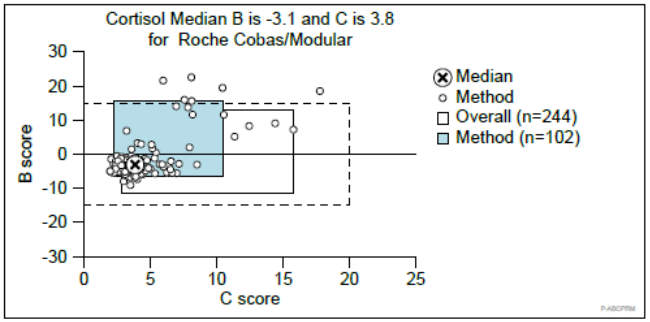


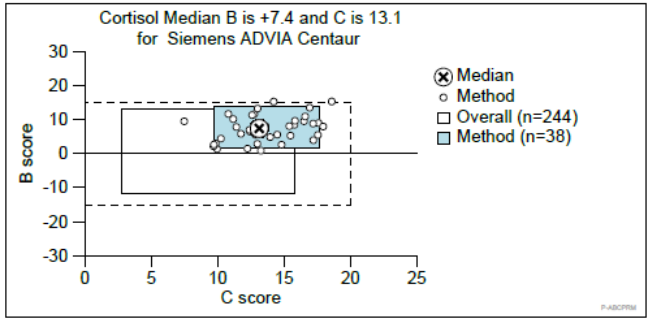
UK NEQAS for Steroid Hormones | Method Report

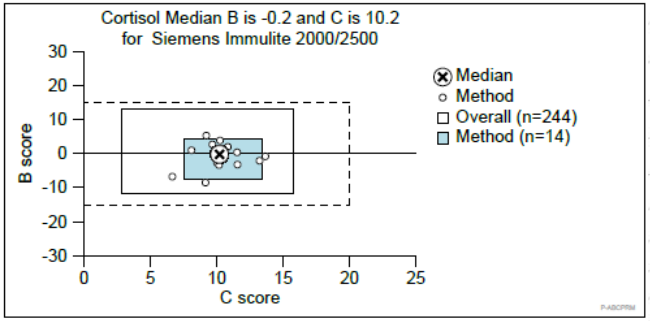
Distribution : 443 Date : 04-Jul-2017

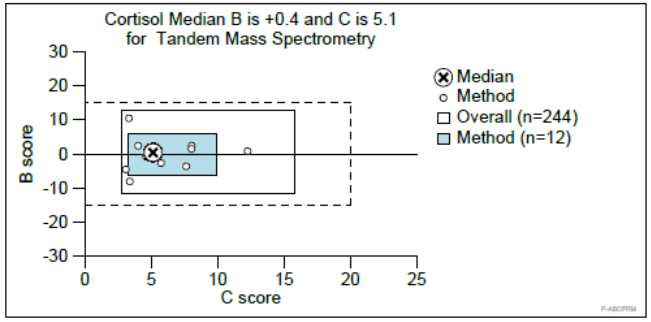
Cortisol (nmol/L)

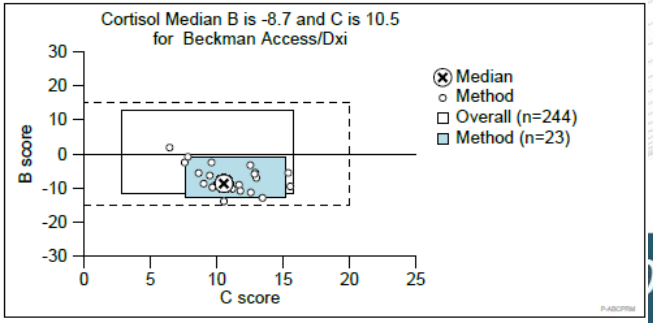




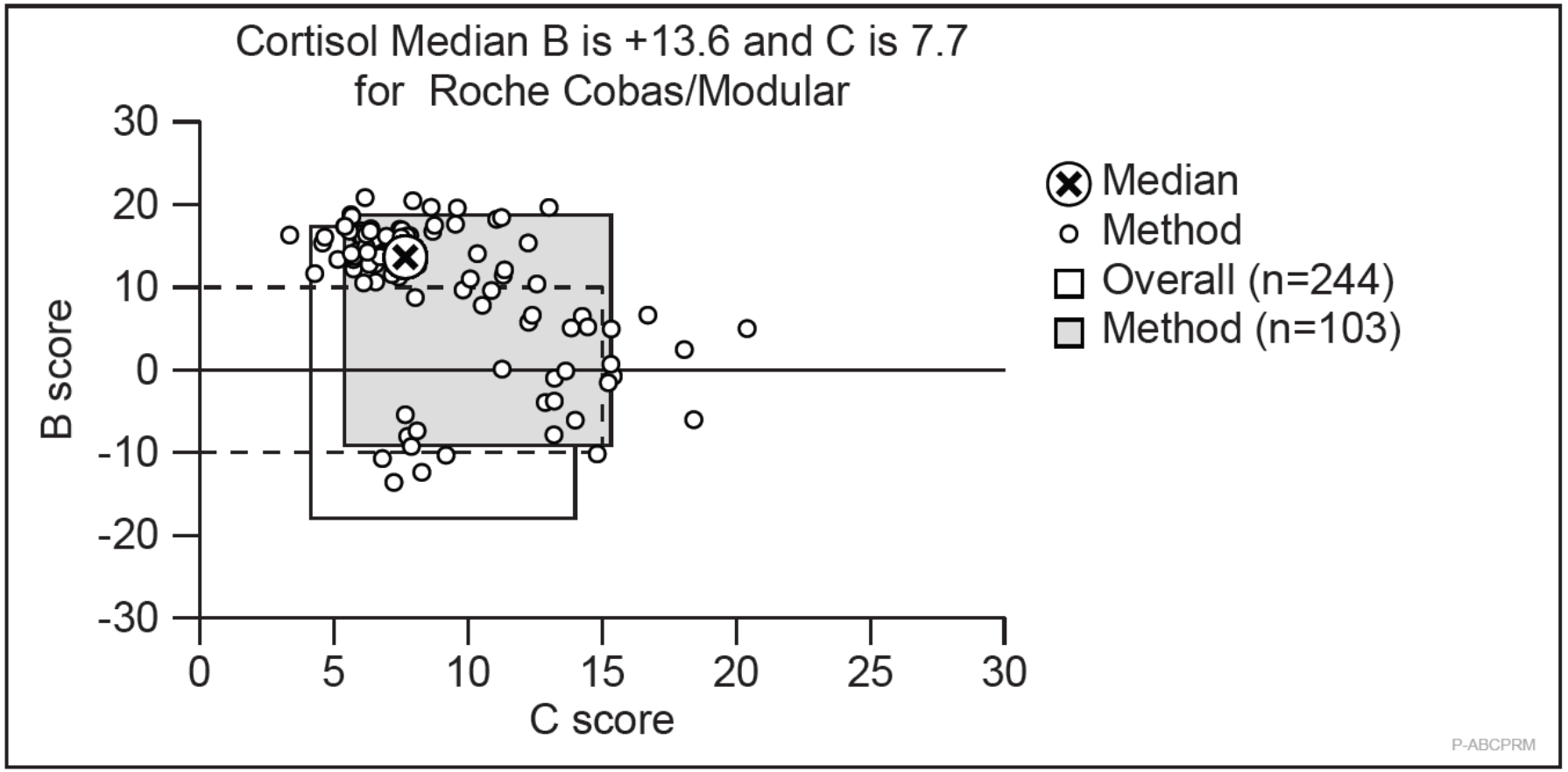




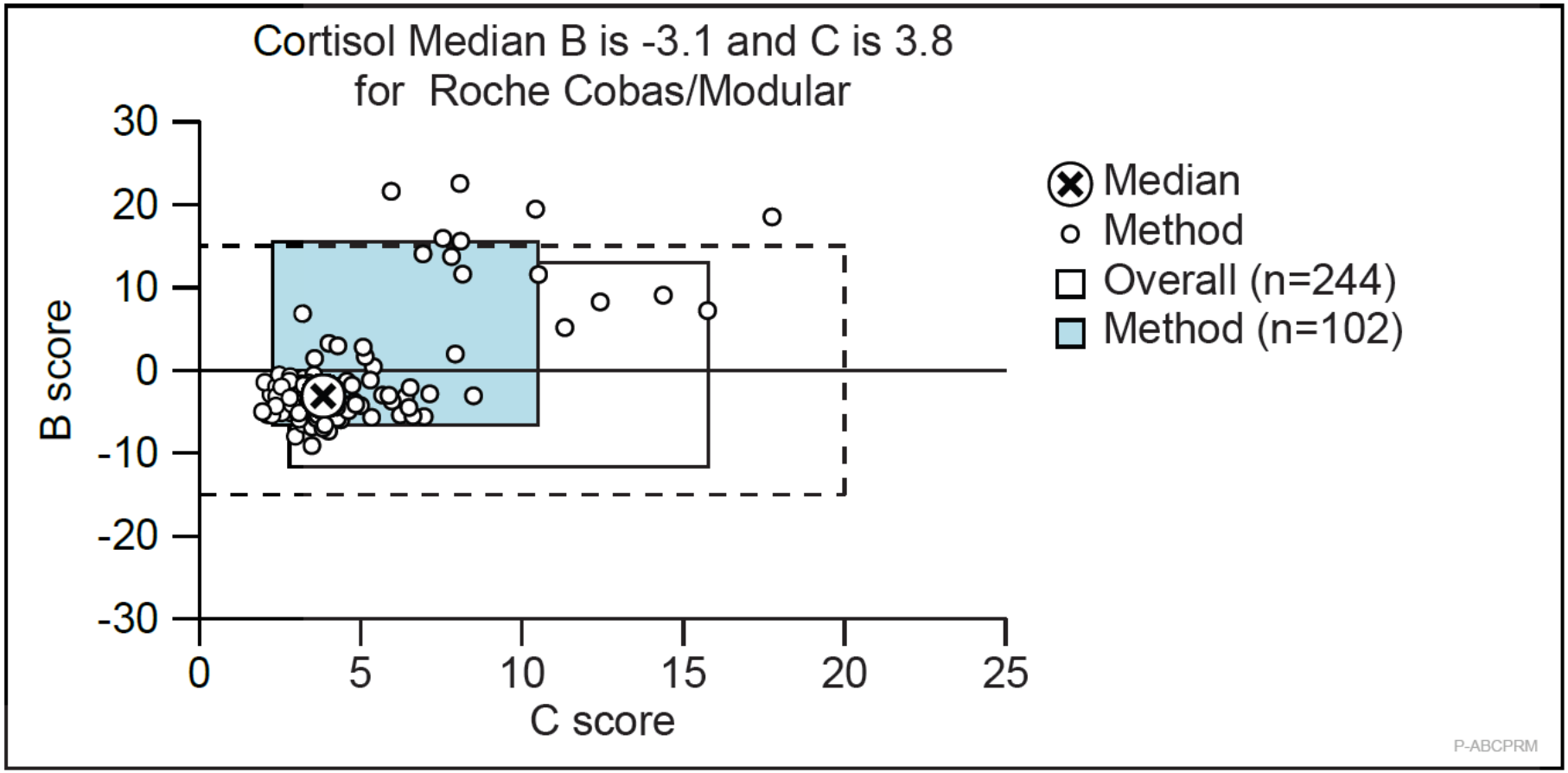




Roche Gen I and Gen II Feb 2016

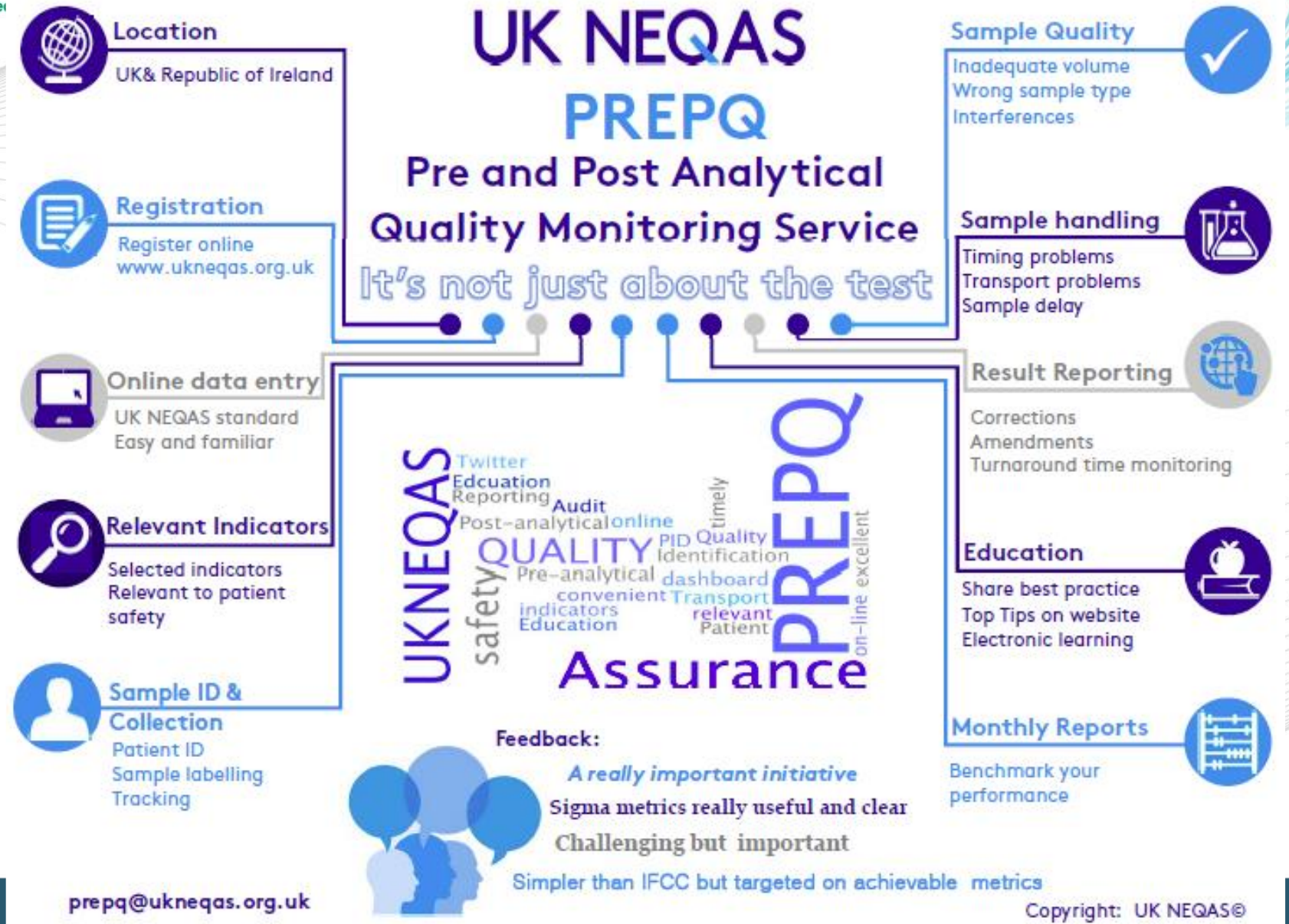


Roche Gen I and Gen II July 2017



Summing Up

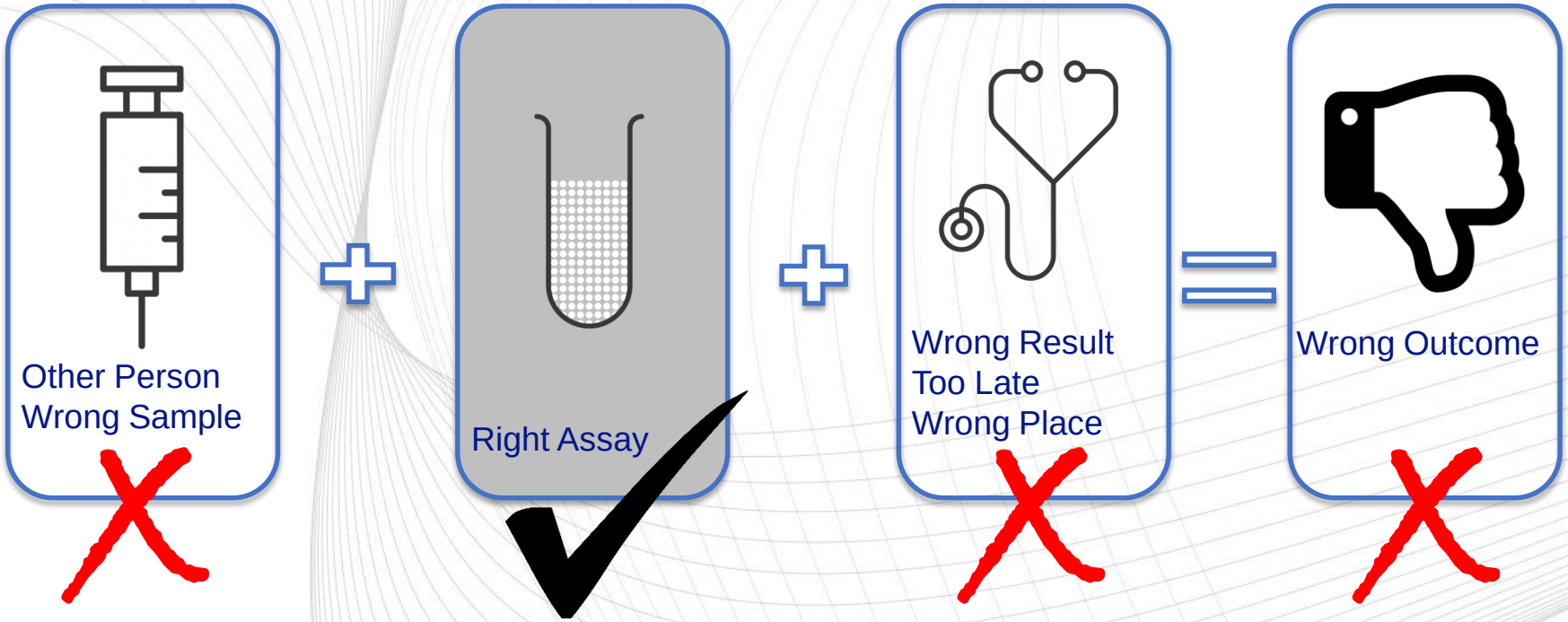
- **EQA gives information on *relative* bias**
- **If the specimens are commutable and reference methods are available, EQA can give information on *absolute* bias**
- **EQA can give trend data over many years**
- **EQA can underpin specificity, sensitivity and standardisation of assay systems**
- **EQA can ensure Guidelines are evidence-based and achievable**
- **EQA must be independent and scientifically and clinically driven**


UK NEQAS
PREPQ
Pre and Post Analytical
Quality Monitoring Service
It's not just about the test
Location
UK& Republic of Ireland
Registration
Register online
www.ukneqas.org.uk
Online data entry
UK NEQAS standard
Easy and familiar
Relevant Indicators
Selected indicators
Relevant to patient
safety
Sample ID &
Collection
Patient ID
Sample labelling
Tracking
Sample Quality
Inadequate volume
Wrong sample type
Interferences
Sample handling
Timing problems
Transport problems
Sample delay
Result Reporting
Corrections
Amendments
Turnaround time monitoring
Education
Share best practice
Top Tips on website
Electronic learning
Monthly Reports
Benchmark your
performance
UKNEQAS
PREPQ
Assurance
Twitter
Edcuation
Reporting
Audit
Post-analytical
online
timely
QUALITY
PID
Quality
Identification
safety
Pre-analytical
dashboard
convenient
Transport
indicators
relevant
Education
Patient
on-line excellent
Feedback:
A really important initiative
Sigma metrics really useful and clear
Challenging but important
Simpler than IFCC but targeted on achievable metrics
prepq@ukneqas.org.uk
Copyright: UK NEQAS©

PREPQ

End to End Quality

It's not just about the Quality of the test



A UK NEQAS Pre & Post Analytical Quality Monitoring Service

The Narrative of EQA

- I am going to talk about:
  - Definitions and nomenclature
  - What is the EQA process?
  - Regulatory systems and structure of the NHS in the UK
  - What does EQA look like in practice?
  - Performance surveillance of Laboratories and post-market surveillance of kits/methods/products
  - Numbers, numbers and interpretation
  - Reference methods and commutability
  - Scoring systems and Scheme design

Performance surveillance

Performance Surveillance

- **Performance surveillance is a professional responsibility**
- **In the UK:**
  - **laboratory Director and staff**
  - **Scheme Organiser**
  - **National Quality Assurance Advisory Panel**
  - **Joint Working Group on Quality Assurance**
  - ***[Medical Director of Trust/hospital]***

'Failure' prompts investigation and education, NOT an automatic penalty

"But it's the Instrument's Fault"

- Increasing reliance on IVDs
  - ***not a valid excuse for poor performance!***
- In Europe:
  - **BS EN 14136:2004** Use of external quality assessment schemes in the assessment of the the performance of in vitro diagnostic examination procedures
- In the UK:
  - JWG guidelines for EQA scheme organisers in the management of problems with EQA performance of IVDs
- Scheme Organisers do contact suppliers
  - more likely to be effective
  - ?in parallel with contact to users

Manufacturer divergences

- The bad news
  - individual manufacturers' methods do diverge
  - method principles may also diverge
    - some problems may be specimen-related
  - some manufacturers deny there is a problem
    - denial may last a long time

- The good news
  - manufacturers do respond (eventually)
    - (proactive) constructive dialogue with UK NEQAS
    - responsiveness increases with experience