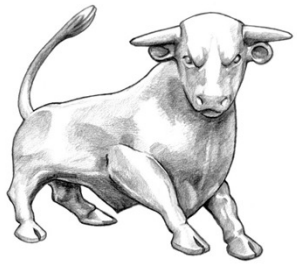

Birmingham Quality

Birmingham Quality

Previously known as the *Wolfson EQA Laboratory*,
Birmingham Quality provides primarily
UK NEQAS External Quality Assessment
Services in Clinical Chemistry

UK NEQAS

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Birmingham
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birminghamquality@uhb.nhs.uk
www.birminghamquality.org.uk

Adam Uldall Lecture

Post-market surveillance of manufacturers' assays and the effects of the revised IVDD

David Bullock

Past President, UK NEQAS
Director, Birmingham Quality
Organiser, UK NEQAS for Clinical Chemistry

40 YEARS OF QUALITY
1969 UK NEQAS 2009

EQALM

EQA: POST-MARKET SURVEILLANCE

Performance surveillance

- general
- manufacturer-related issues
- how EQA can help - examples
- partnership and transparency
- commutability issues

New IVD Directive - proposed Regulations

- proposed changes
  - risk-based classification
  - clinical evidence
- what does it mean for EQA?

Disclaimer: ***"This presentation includes various examples, and mention or exclusion of any manufacturer or product implies neither endorsement nor criticism"***

ADAM ULDALL

ADAM ULDALL

1989- European EQA Organisers' meetings

- convened initially by BCR
  - chemistry
  - endocrinology
  - haematology
  - microbiology
- extended by Adam Uldall
  - in conjunction with international conferences

ADAM ULDALL

1991 Krakow Congress
- creation of EQALM
- formalisation of Working Groups

1996 Incorporation of EQALM
- to ensure continuity and independence

2000 Publication of Working Group outputs
- EQANews vol 11

IFCC Committee on Analytical Quality
- member and Chair

***"Devoted to improving laboratory performance**, but sadly unrecognised by IFCC"*

NEEDS FOR COMPARABILITY

- **Mobility**
  - patients
  - medical staff
  - electronic patient record
- **Common interpretation**
  - reference intervals
  - decision criteria
  - electronic patient record
- **Pursuit of trueness (the right result)**
  - traceability to reference procedures
  - IVD Directive

Performance surveillance

40 YEARS OF QUALITY
1969 UK NEQAS 2009

EQALM

PERFORMANCE SURVEILLANCE

Performance is a <u>professional</u> responsibility

- **Surveillance in the UK:**
  - laboratory Director and staff
  - Scheme Organiser - *CAPA/RCA proforma*
  - National Quality Assessment Advisory Panel - *UKAS/CPA*
  - Joint Working Group on Quality Assessment
  - *Medical Director of Trust/hospital*
  - *Care Quality Commission [able to close hospitals] . . .*

'Failure' prompts investigation and education, <u>NOT</u> an automatic penalty

Learning from 'failures' is important

"BUT IT'S THE INSTRUMENT'S FAULT"

Increasing reliance on IVDs across laboratory medicine

- **instrument is the main determinant of performance**

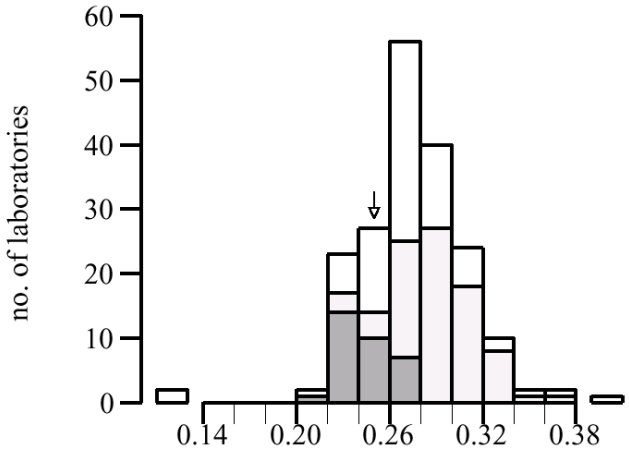
- ***this is <u>not</u> a valid excuse for poor performance!***

It may be the instrument's fault

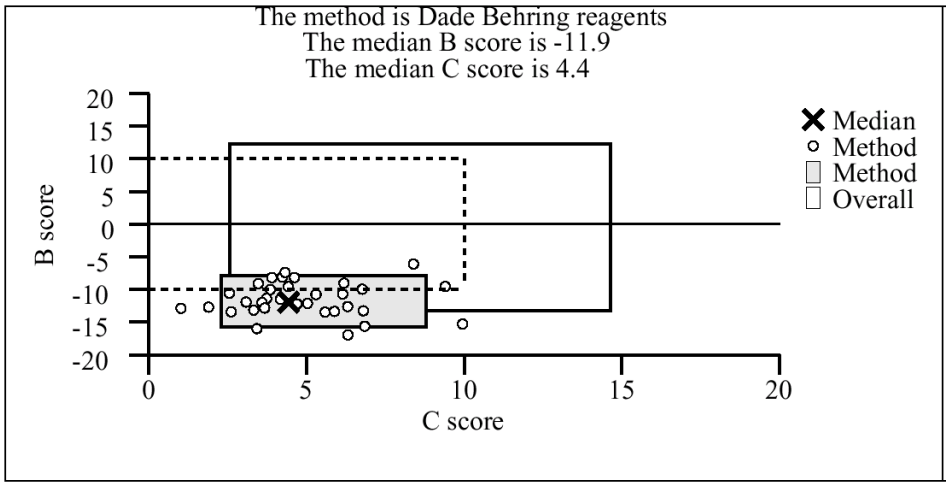
40 YEARS OF QUALITY
1969 UK NEQAS 2009

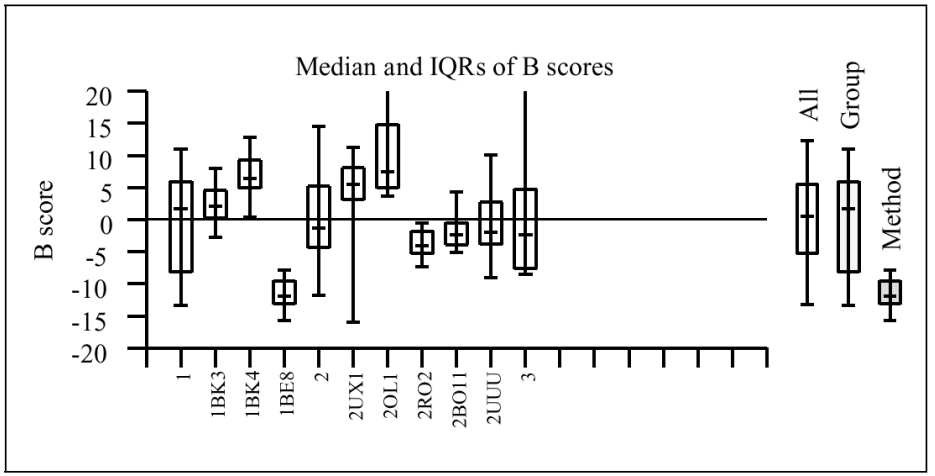
EQALM

Dade Behring C4 - February 2003



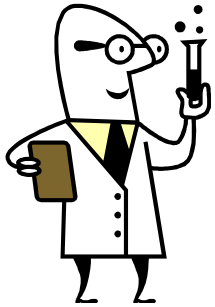
Method mean (Dade Behring reagents)	0.246
Target (ALTM)	0.278
Method bias (%)	-11.8
ALTM	0.278





Post-market surveillance

Medical device regulation



Manufacturer

investigation
action
communication

Other reports:

- **EQA**
- Literature

compliance

Notified Body

Competent Authority

User reports

European market

CE

post market surveillance
vigilance

Harmonised Standards/Common Technical Specification = "presumption of conformity"

EU co-ordination - Competent Authorities

- **Vigilance database (Eudamed)**
- **Vigilance enquiries**
- **Vigilance teleconference**
- **Vigilance Task Forces**
- **IVD Working Group**

plus liaison with N America, Australia and Japan

Manufacturer issues – What do we do? - 1

UK - BIVDA/EQA Forum 2003

- talk to manufacturer first
- is it seen in clinical specimens?
- exclude specimen-related causes (non-commutability)
- report to NQAAP and/or MHRA as appropriate
- assist manufacturer in resolution and confirmation
- wrap up and advise
  - Steering Committee ±NQAAP ±MHRA ±participants

Manufacturer denial = MHRA referral as adverse incident

Manufacturer issues – What do we do? - 2

Europe - EN 14136:2004

- **Use of EQA to assess IVDs** (“examination procedures”)
  - usual EQA design requirements apply
  - additional design requirements:
    - EQA specimens behave like clinical specimens
    - 6+ distributions/year
    - classify by method - **if following manufacturer’s instructions!**
    - procedure-specific processing
    - inform manufacturer first
  - requirements on EQA organisation:
    - independent advisory committee
    - independence – free from commercial conflicting interests

Method classification - UK NEQAS policy

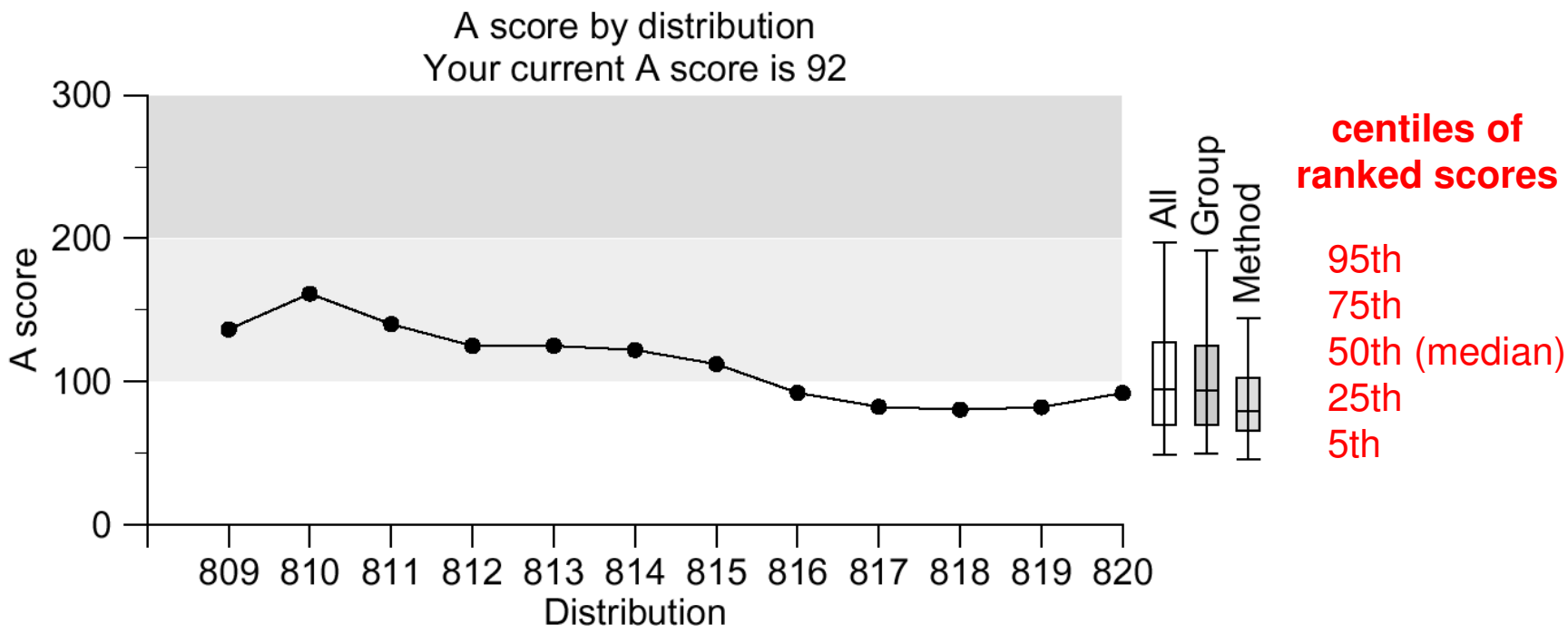
- **UK NEQAS Birmingham assigns a 'named' method code only if the laboratory uses the method according to the manufacturer's instructions**

- **If the procedure or results are modified, adjusted, 'tweaked', 'modified' or 'fiddled' in some way, it automatically becomes an in house system**
  - it will be classified (and scored) by method principle
  - it will be identified as 'in house'

[BS EN 14136:2004]

Trend data with *Box and Whisker* plots

Rolling time window score



centiles of ranked scores

95th
75th
50th (median)
25th
5th

Time →

'THE ABC OF EQA'

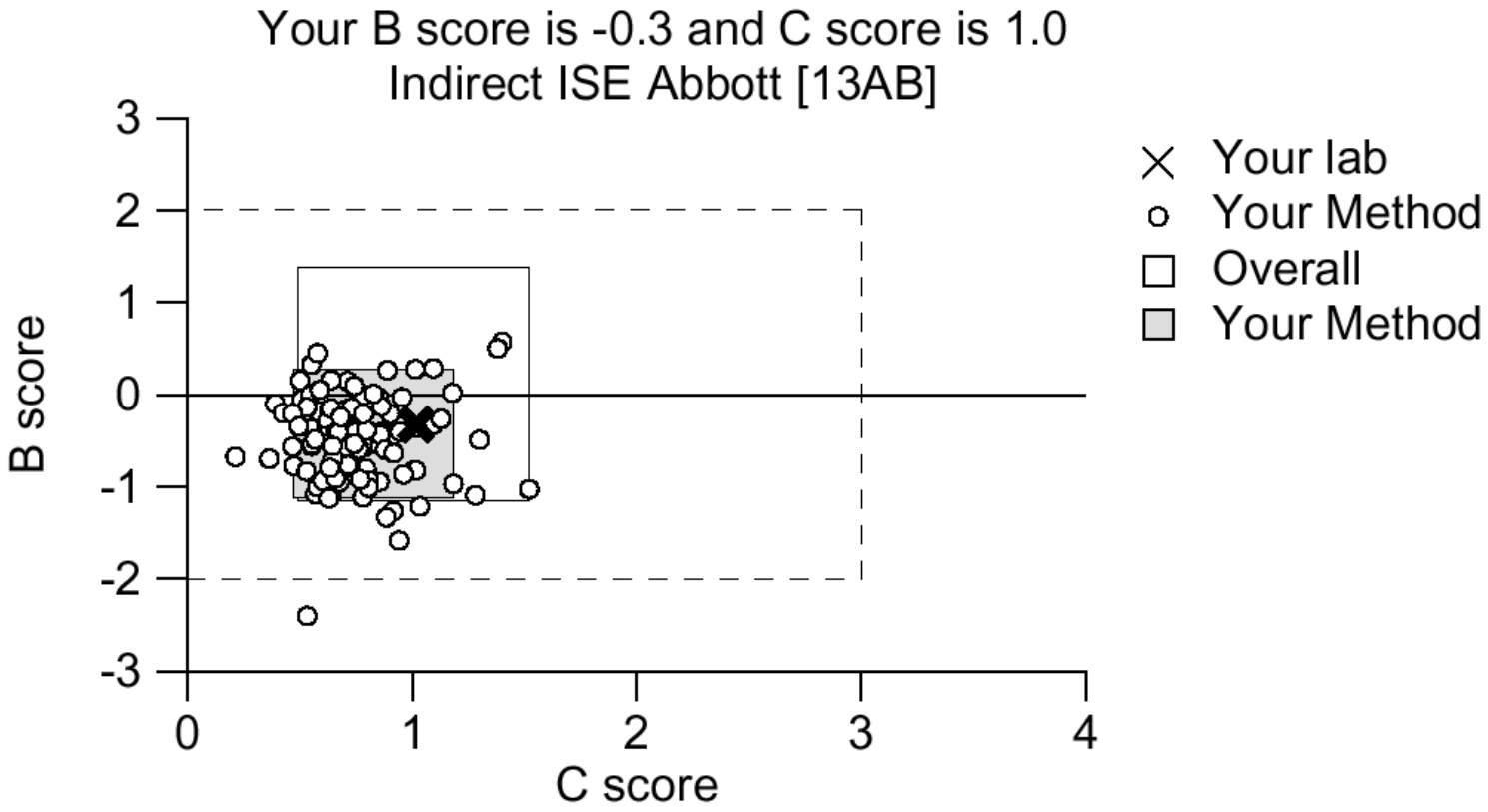
A set of three complementary scores:

- **A** is for **A**ccuracy (total error)
- **B** is for **B**ias
- **C** is for **C**onsistency of bias

Penalty Box Plot

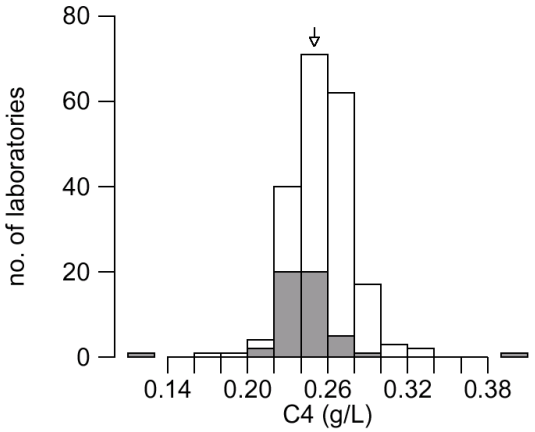
(rolling time-window data; one data point per laboratory)

Average bias from target

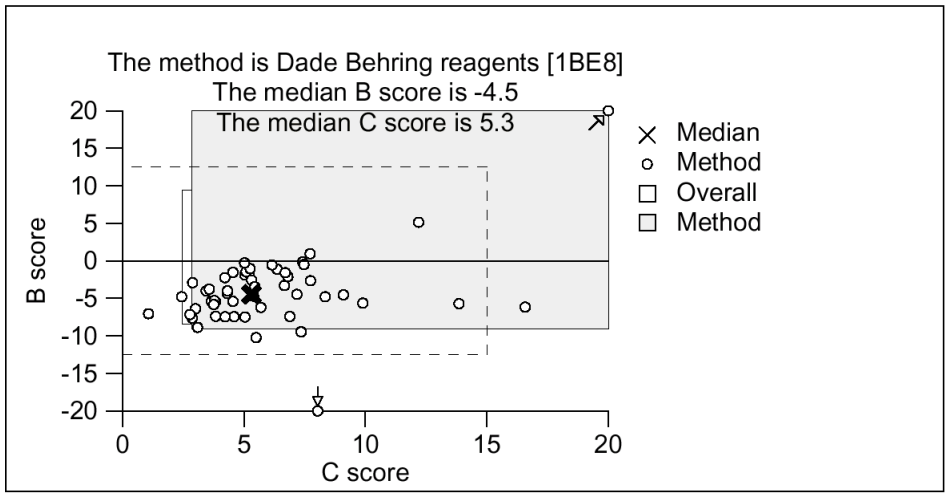


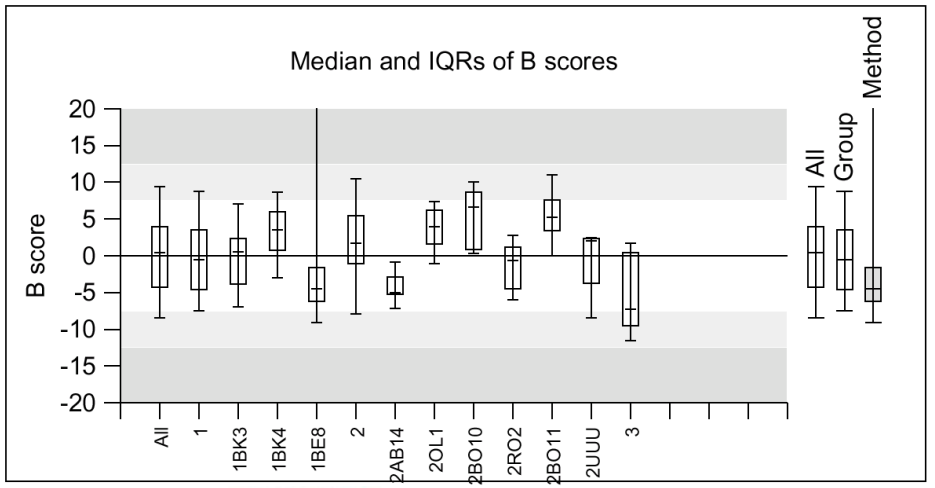
Consistency of bias

Dade Behring C4 - March 2006



Method mean (Dade Behring reagents [1BE8])	0.245
Target (ALTM)	0.259
Method bias (%)	-5.4
ALTM	0.259





EQA provides valuable data

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 MPROVEMENT

- FOR LABORATORIES AND FOR MANUFACTURERS!

ADVANTAGES OF USING EQA DATA

- **Available in real time - *almost !***
  - reflects current situation
  - can follow trends
  - changes can be detected quickly (dependent on frequency)
- **Reflects reality**
  - routine performance
  - clinical service laboratories, using
    - multiple batches
    - multiple operators
    - multiple instruments

Overview of method performance - 'Top ten' snapshots

Birmingham Quality

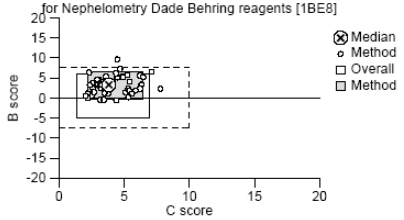
UK NEQAS for Specific Proteins

Method Report

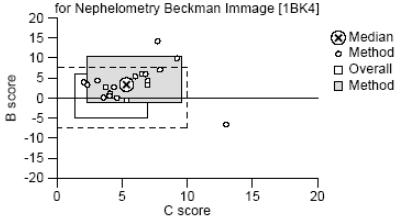
Distribution : **347** Date : 17-Jun-2014

IgG (g/L)

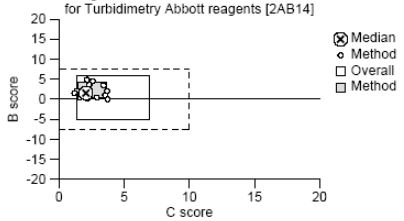
IgG Median B is +3.3 and C is 3.8
for Nephelometry Dade Behring reagents [1BE8]



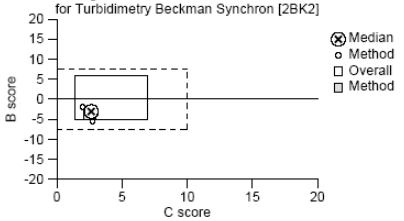
IgG Median B is +3.3 and C is 5.3
for Nephelometry Beckman Immage [1BK4]



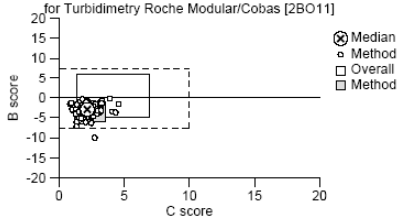
IgG Median B is +1.6 and C is 2.0
for Turbidimetry Abbott reagents [2AB14]



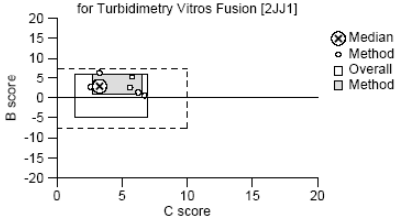
IgG Median B is -3.1 and C is 2.6
for Turbidimetry Beckman Synchron [2BK2]



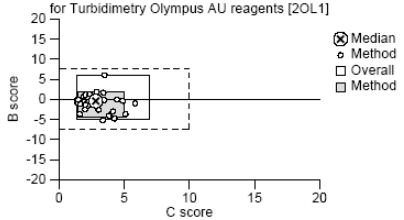
IgG Median B is -2.9 and C is 2.2
for Turbidimetry Roche Modular/Cobas [2BO11]



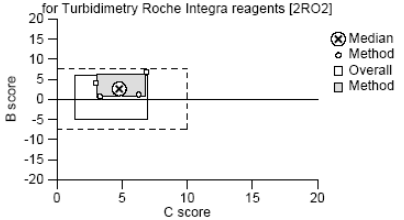
IgG Median B is +2.8 and C is 3.3
for Turbidimetry Vitros Fusion [2JJ1]



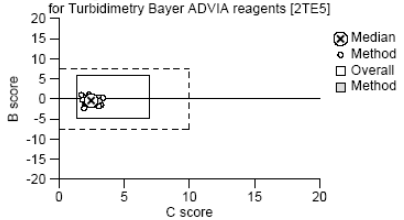
IgG Median B is -0.4 and C is 2.8
for Turbidimetry Olympus AU reagents [2OL1]



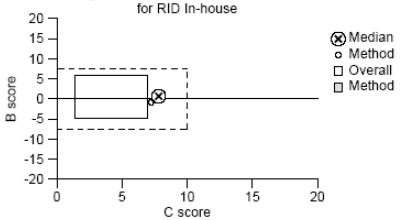
IgG Median B is +2.6 and C is 4.8
for Turbidimetry Roche Integra reagents [2RO2]



IgG Median B is -0.4 and C is 2.4
for Turbidimetry Bayer ADVIA reagents [2TE5]



IgG Median B is +0.7 and C is 7.8
for RID In-house



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Please return your results and view your reports via the Online Results and Reports Service https://results.ukneqas.org.uk or via www.birminghamquality.org.uk

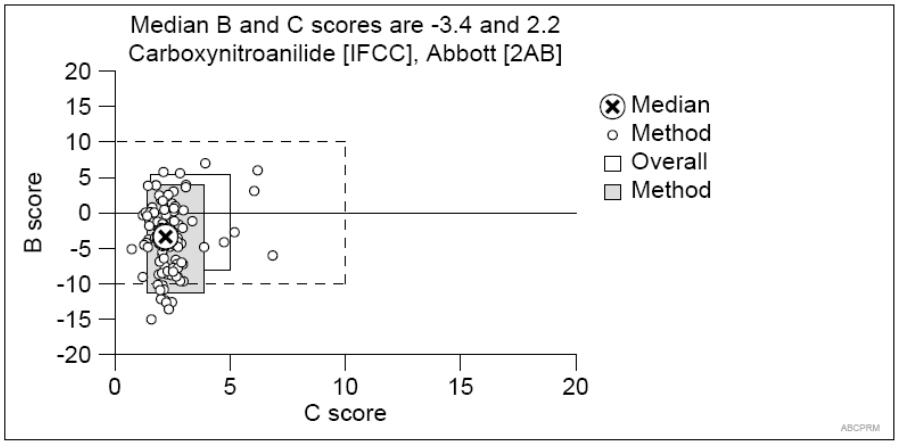
For this Scheme, the Organiser is David Bullock.

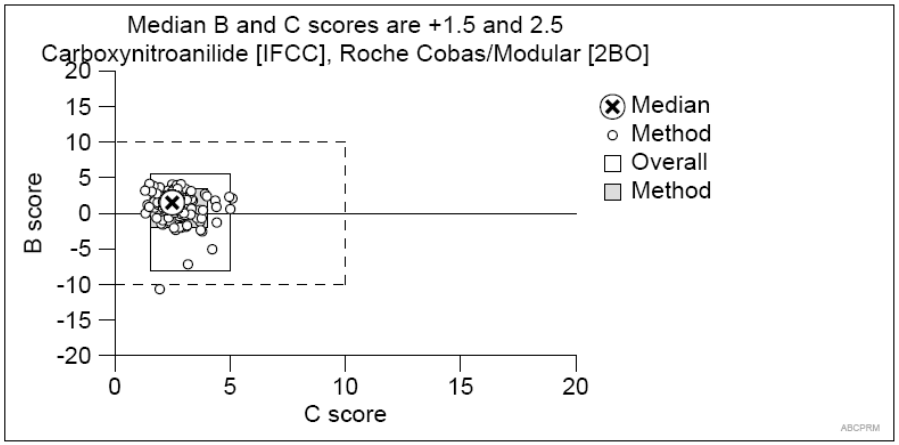
www.birminghamquality.org.uk

Published at 10:41 on Thursday 19 June 2014

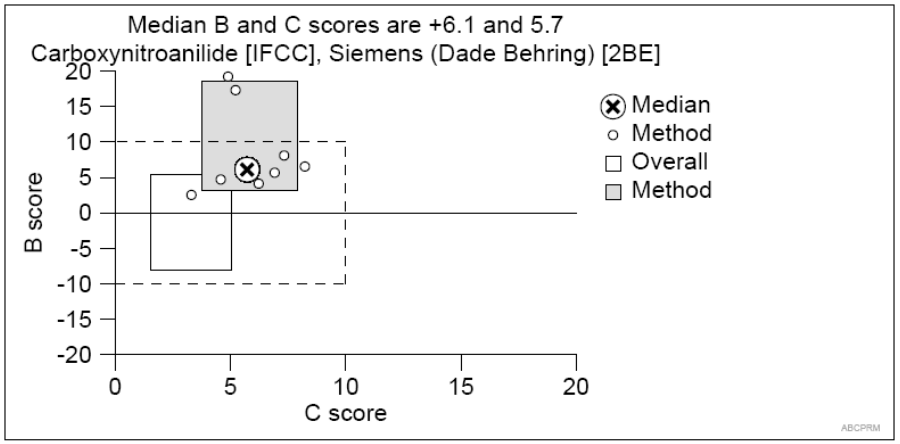
GGT

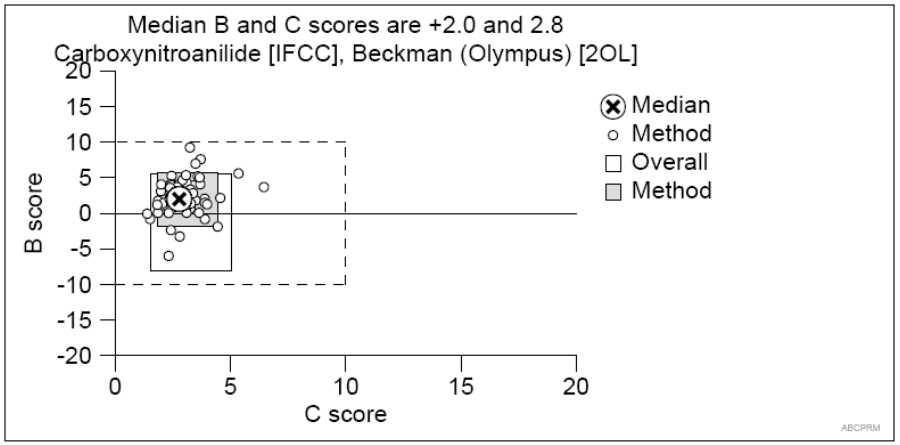
Wide spread of users' bias





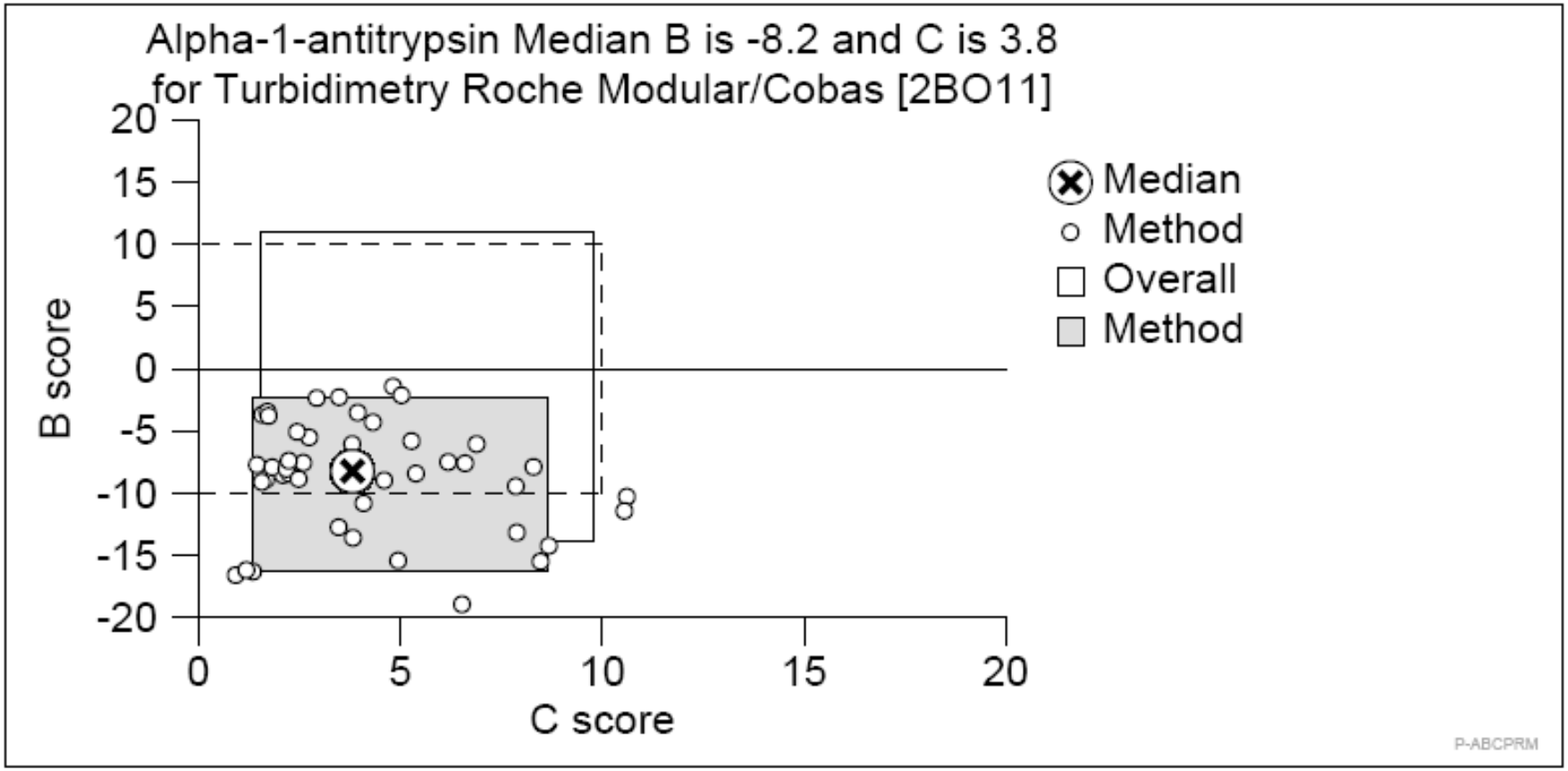
Positive bias





Minimal bias, with tight clustering of users

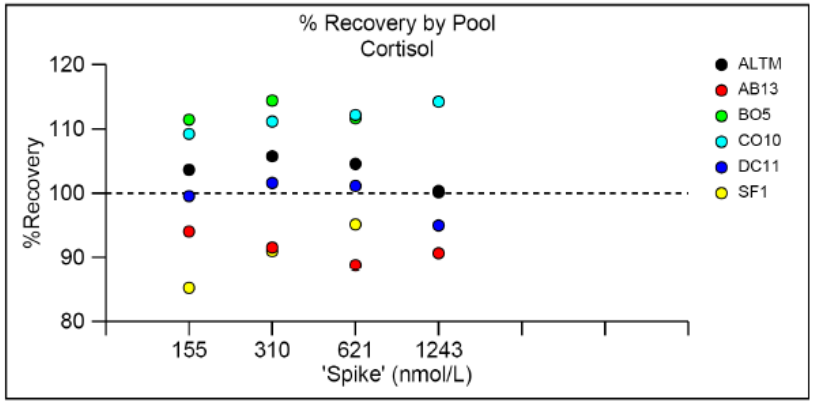
Alpha-1-antitrypsin

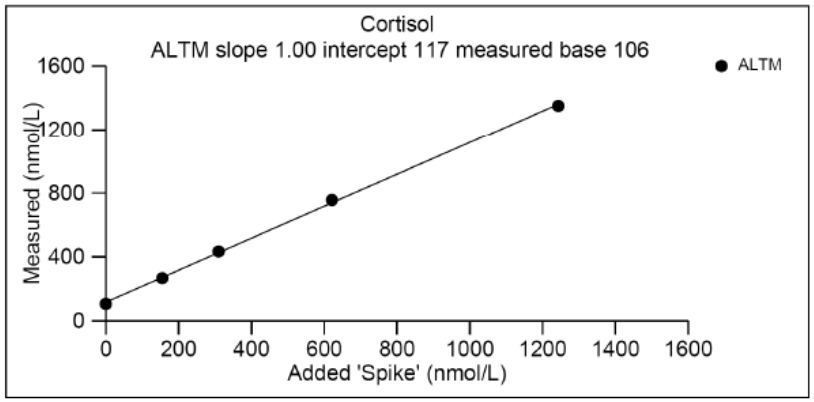


Recovery

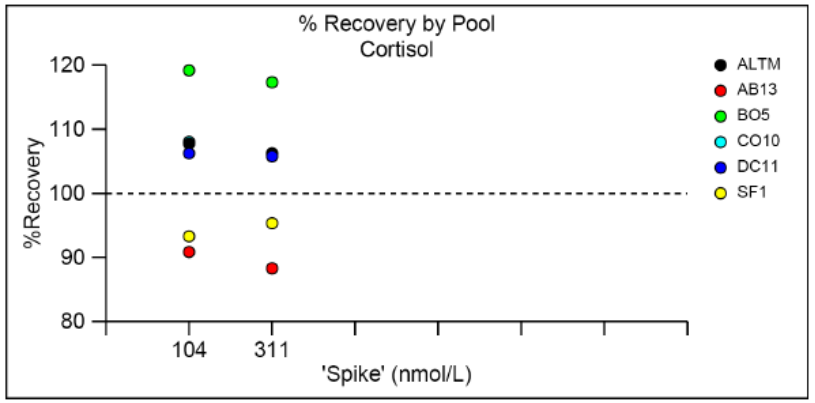
Cortisol Recovery

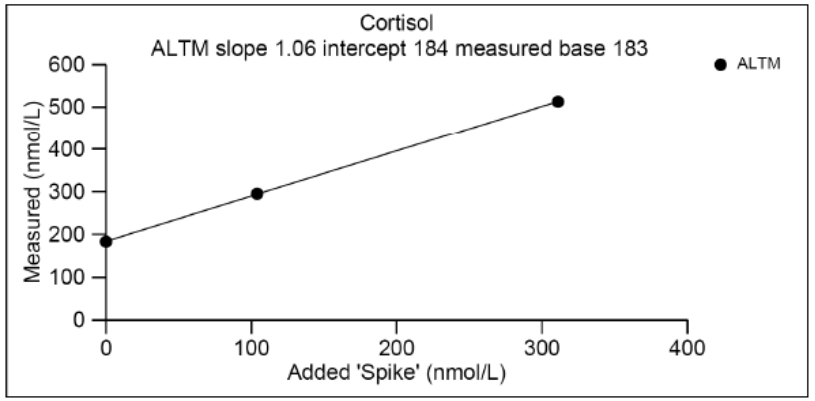
Distribution 395





Distribution 404

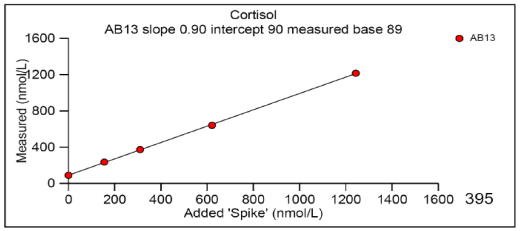


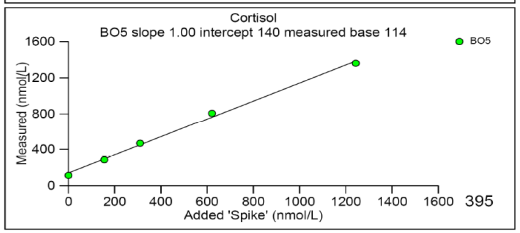


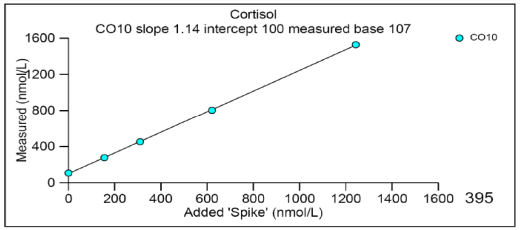
40 YEARS OF QUALITY
1969 UK NEQAS 2009

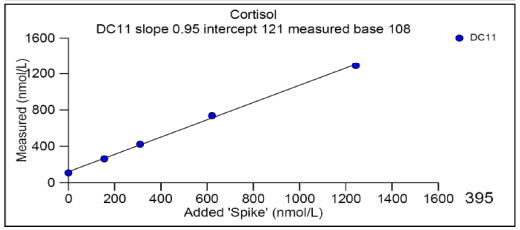
EQALM

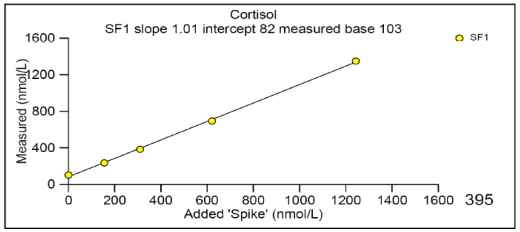
Distribution 395



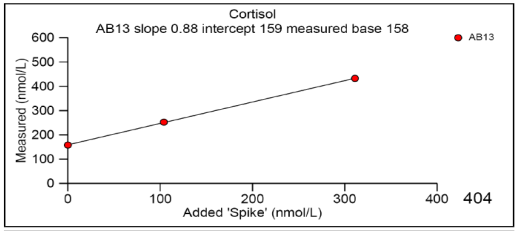


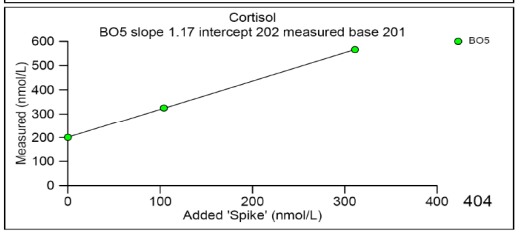


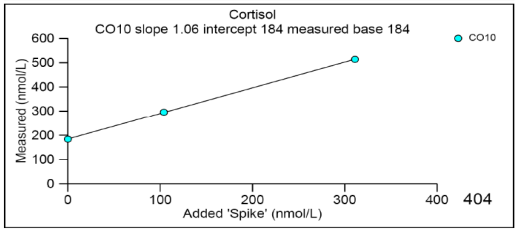


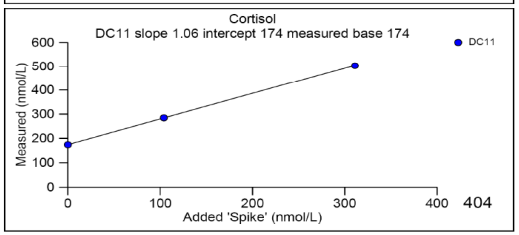


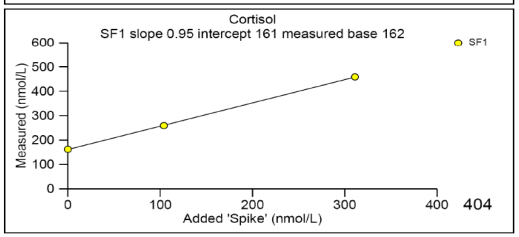
Distribution 404





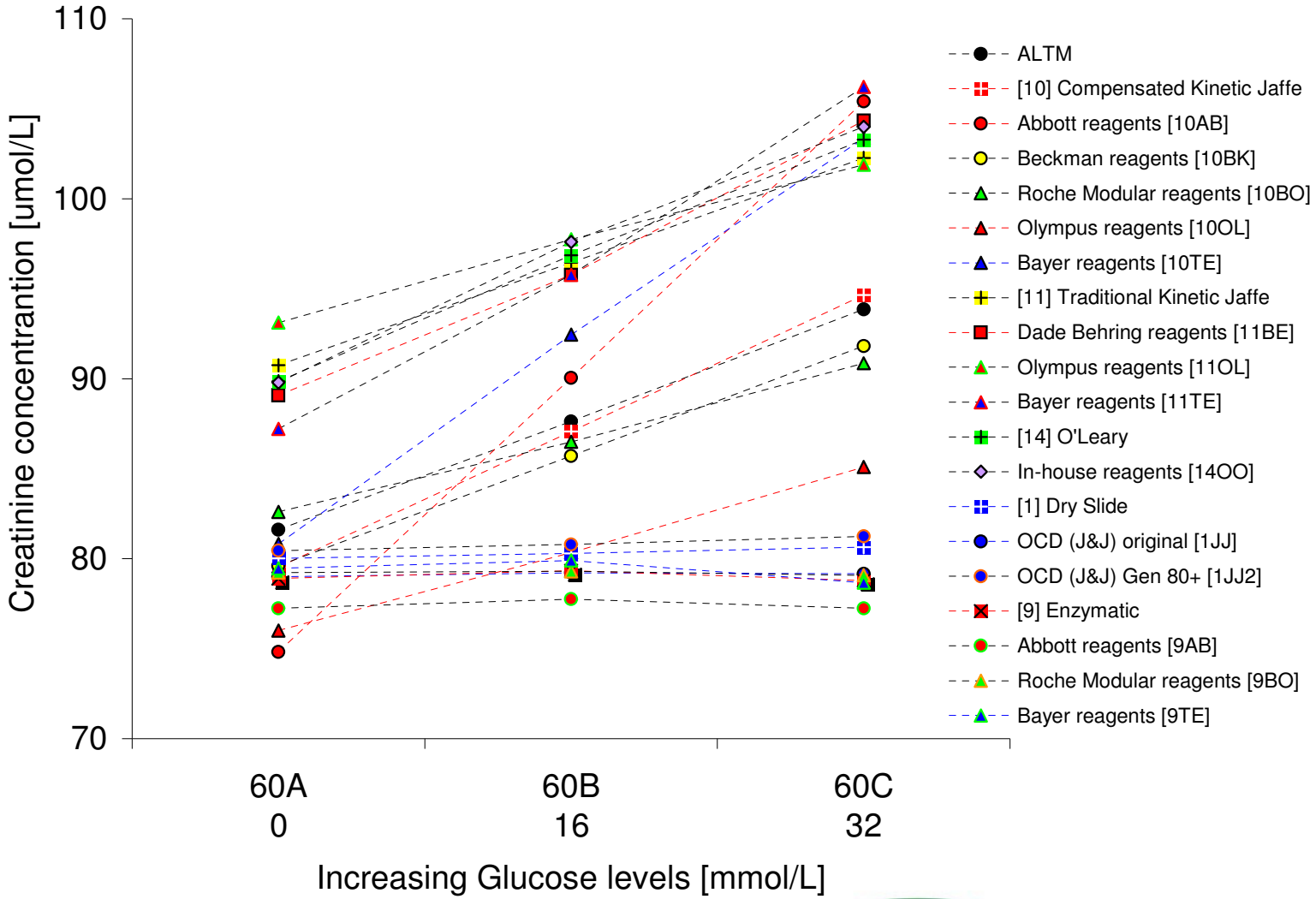






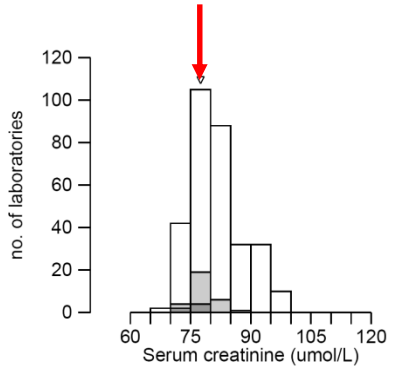
Interference

Glucose and Creatinine



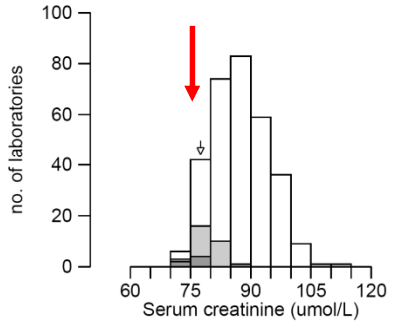
Glucose and Creatinine

Specimen : 60A	n	Mean	SD	CV(%)
All methods	311	81.6	6.4	7.8
Dry slide	23	80.0	2.2	2.7
OCD (J&J) Gen 80+ [1JJ2]	15	80.5	2.1	2.6
Compensated Kinetic Jaffe	190	79.5	4.8	6.0
Abbott reagents [10AB]	45	74.8	2.3	3.1
Beckman reagents [10BK]	32	79.6	4.0	5.0
Roche Modular reagents [10BO]	82	82.6	3.2	3.9
Traditional Kinetic Jaffe	56	90.8	5.9	6.5
Olympus reagents [11OL]	34	93.1	2.8	3.0
Enzymatic	30	78.9	2.7	3.5
Abbott reagents [9AB]	6	77.3	3.5	4.6
Roche Modular reagents [9BO]	15	79.2	2.5	3.2



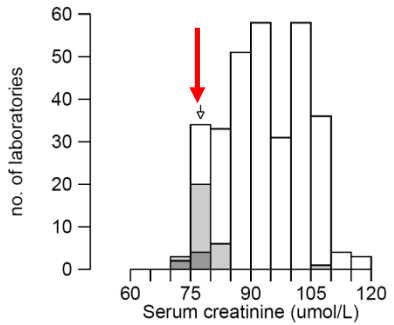
neat

Specimen : 60B	n	Mean	SD	CV(%)
All methods	311	87.6	7.2	8.2
Dry slide	23	80.3	2.3	2.8
OCD (J&J) Gen 80+ [1JJ2]	15	80.8	2.2	2.7
Compensated Kinetic Jaffe	190	87.1	4.5	5.1
Abbott reagents [10AB]	45	90.1	2.5	2.7
Beckman reagents [10BK]	32	85.7	3.8	4.4
Roche Modular reagents [10BO]	82	86.5	3.6	4.2
Traditional Kinetic Jaffe	56	96.5	5.0	5.2
Olympus reagents [11OL]	34	97.8	2.8	2.8
Enzymatic	30	79.3	2.4	3.1
Abbott reagents [9AB]	6	77.8	3.1	3.9
Roche Modular reagents [9BO]	15	79.3	2.0	2.5



+16 mmol/L glucose

Specimen : 60C	n	Mean	SD	CV(%)
All methods	311	93.9	11.0	11.7
Dry slide	23	80.6	2.9	3.6
OCD (J&J) Gen 80+ [1JJ2]	15	81.3	2.9	3.5
Compensated Kinetic Jaffe	190	94.7	8.4	8.8
Abbott reagents [10AB]	45	105.4	2.4	2.3
Beckman reagents [10BK]	32	91.8	3.9	4.2
Roche Modular reagents [10BO]	82	90.9	3.3	3.6
Traditional Kinetic Jaffe	56	102.3	5.1	5.0
Olympus reagents [11OL]	34	101.9	3.2	3.2
Enzymatic	30	78.8	2.3	3.0
Abbott reagents [9AB]	6	77.3	3.5	4.6
Roche Modular reagents [9BO]	15	79.1	2.1	2.7



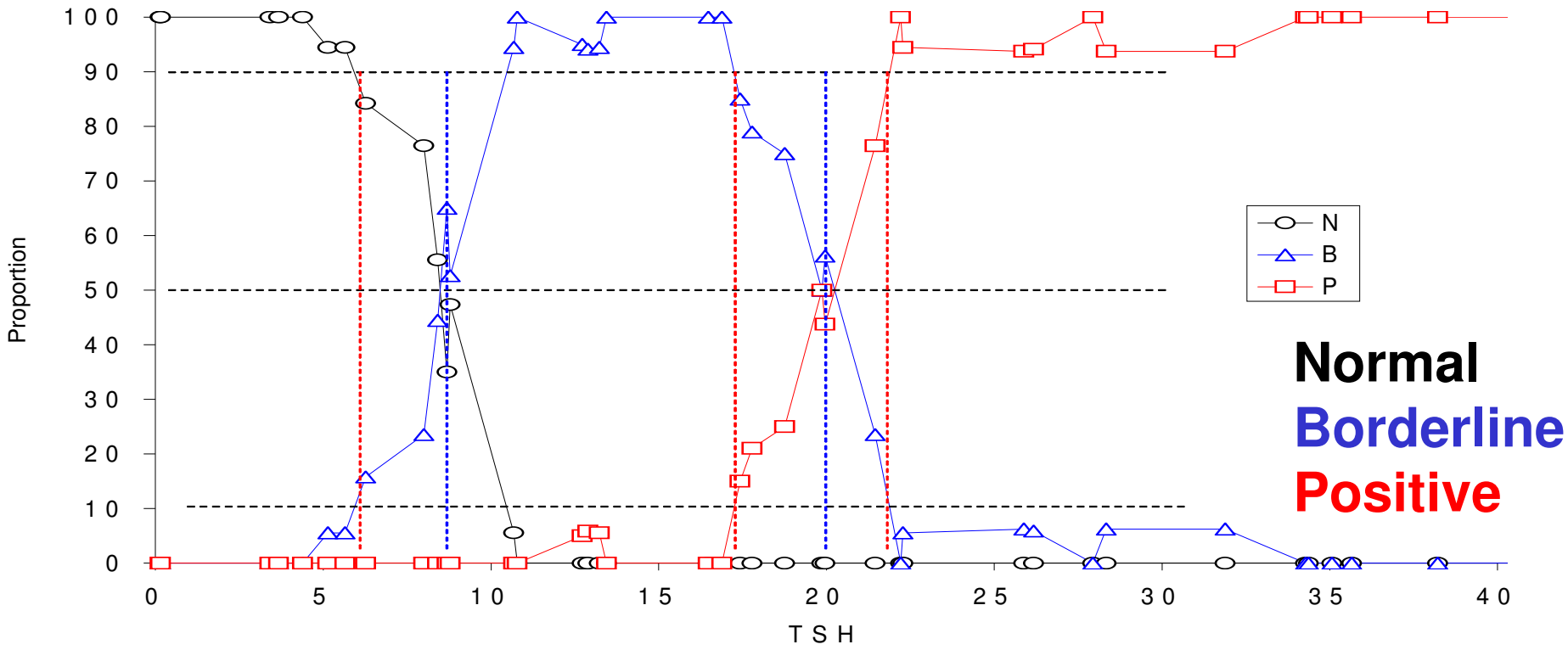
+32 mmol/L glucose

40 YEARS OF QUALITY
1969 UK NEQAS 2009

EQALM

Sensitivity

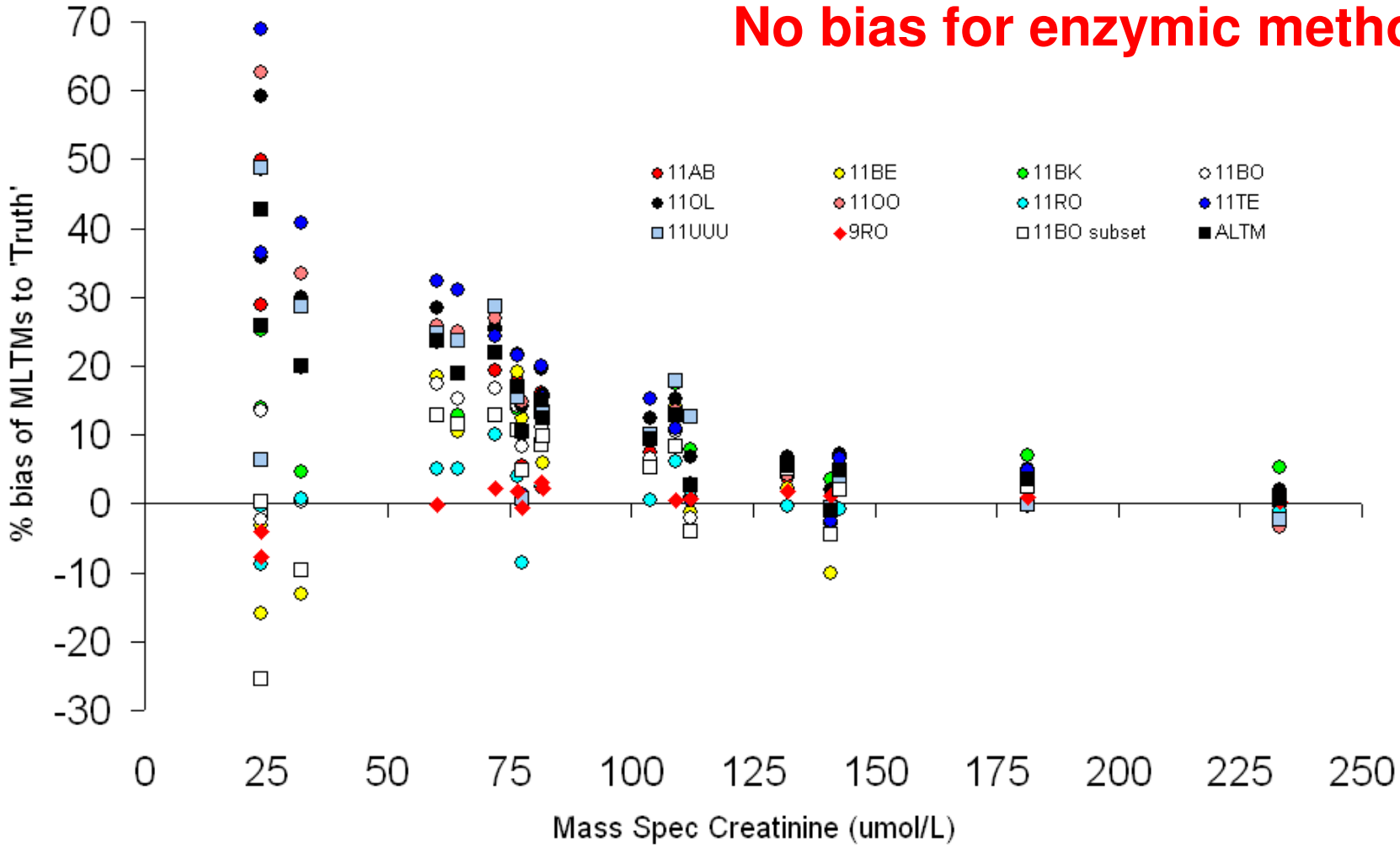
Example Proportions and Empirical Cut-offs TSH/Congenital Hypothyroidism



Specificity

Method bias (%) relative to mass spectrometry

No bias for enzymic methods



40 YEARS OF QUALITY
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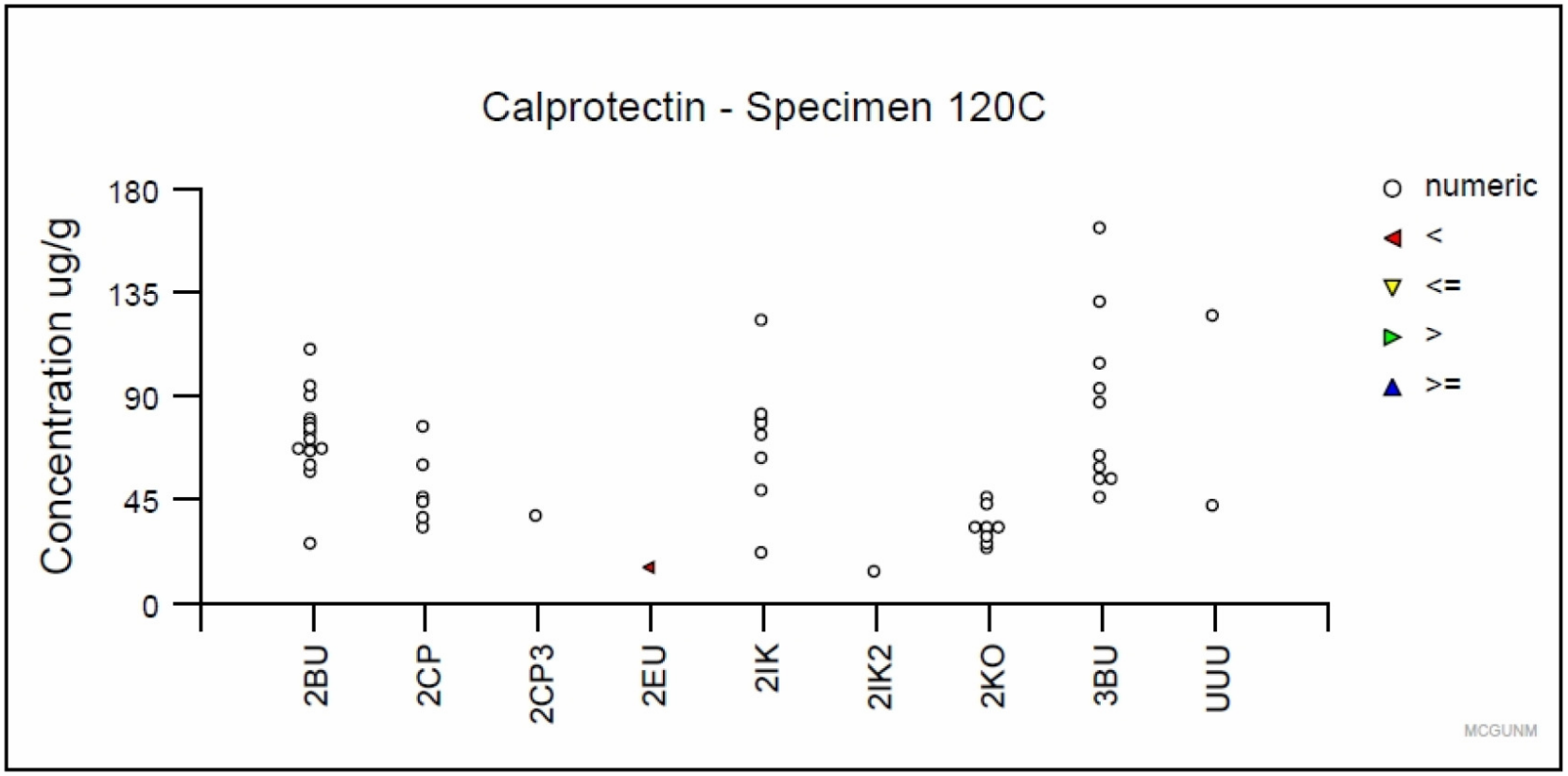
Faecal calprotectin

Specimen 120C



Decision limits at 50 and 150 for <u>all</u> methods ?

A European success story!

CRM 470

40 YEARS OF QUALITY
1969 UK NEQAS 2009

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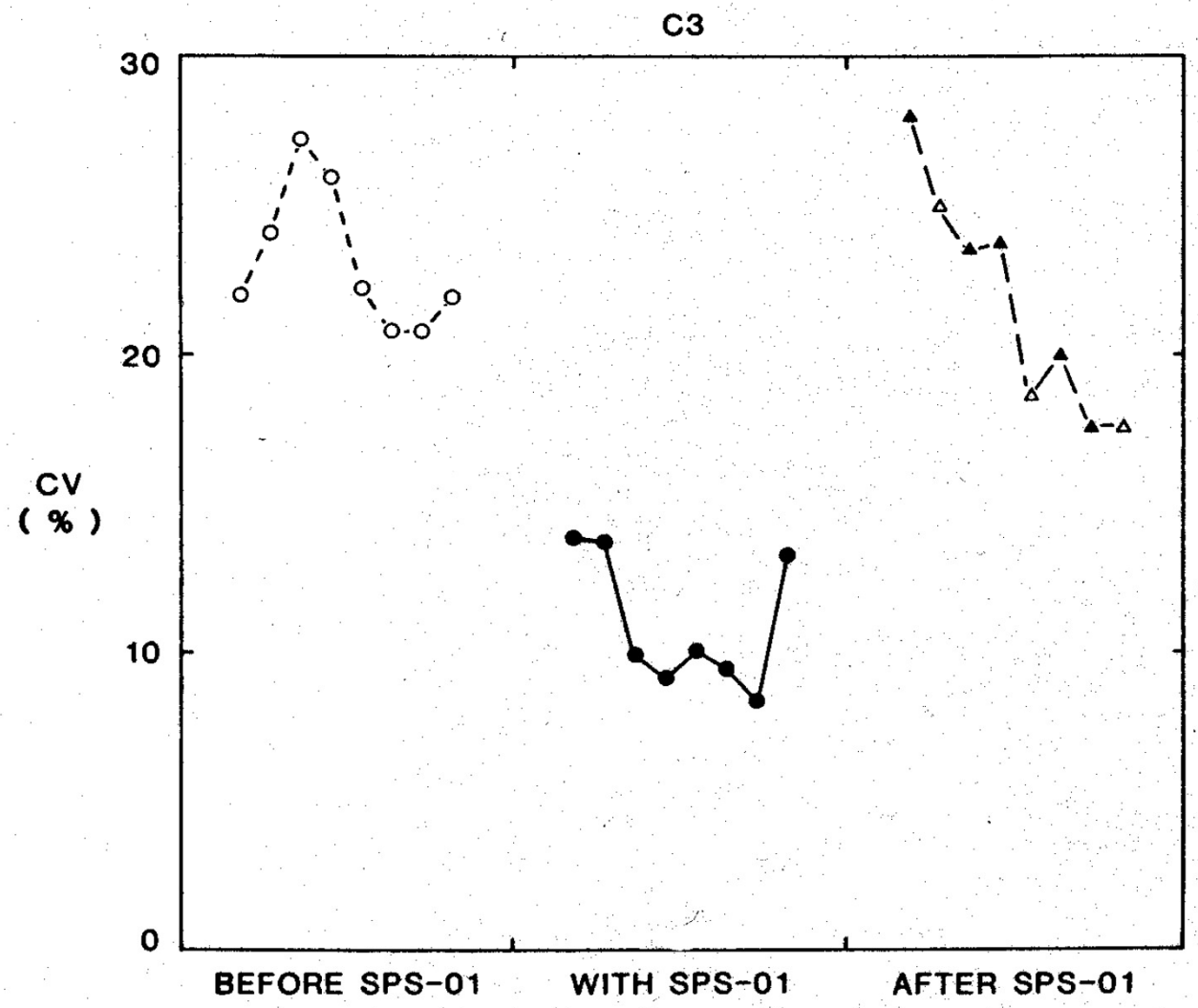
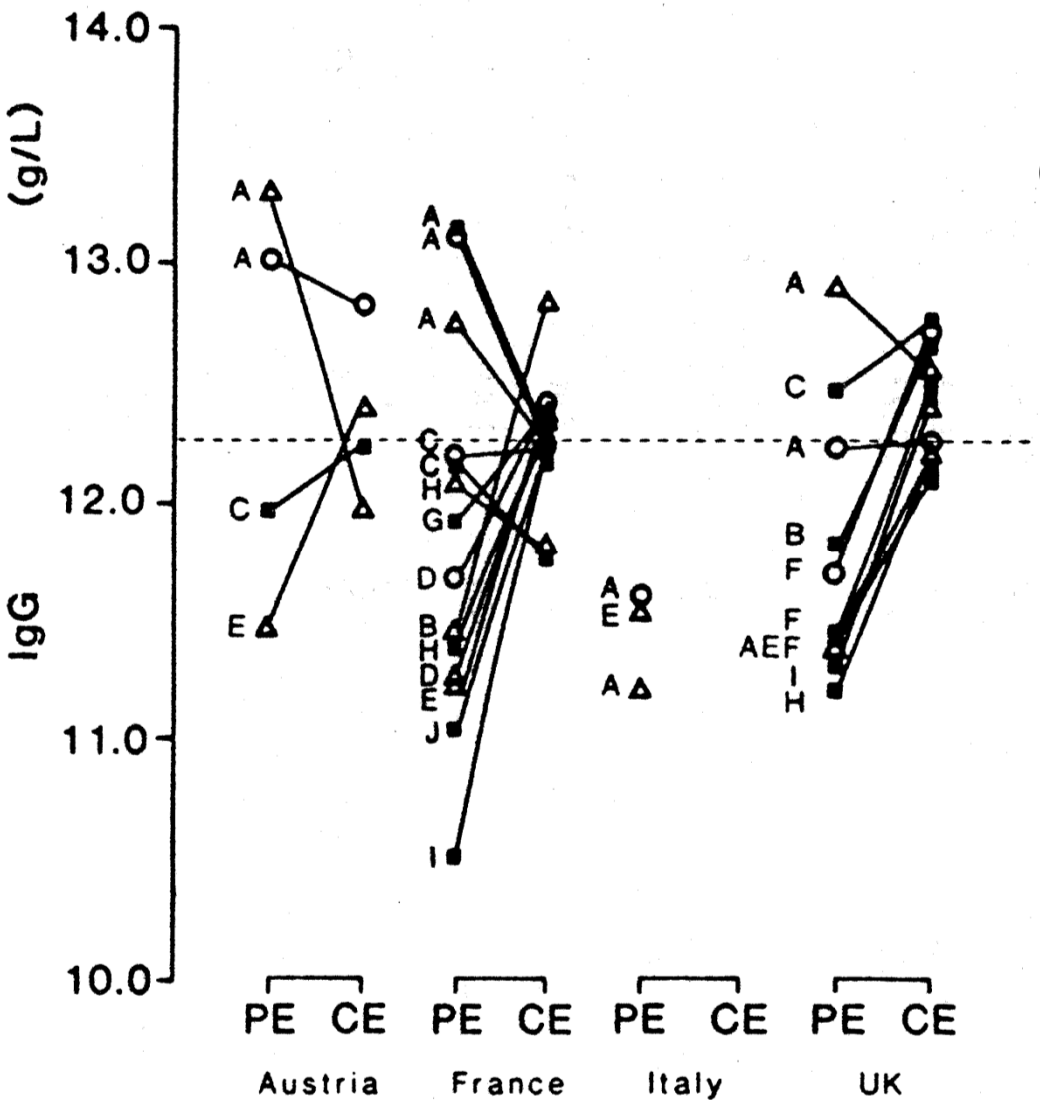
UK NEQAS common calibration study - C3



European calibration study - IgG



PE = raw

CE = 'calibrated'

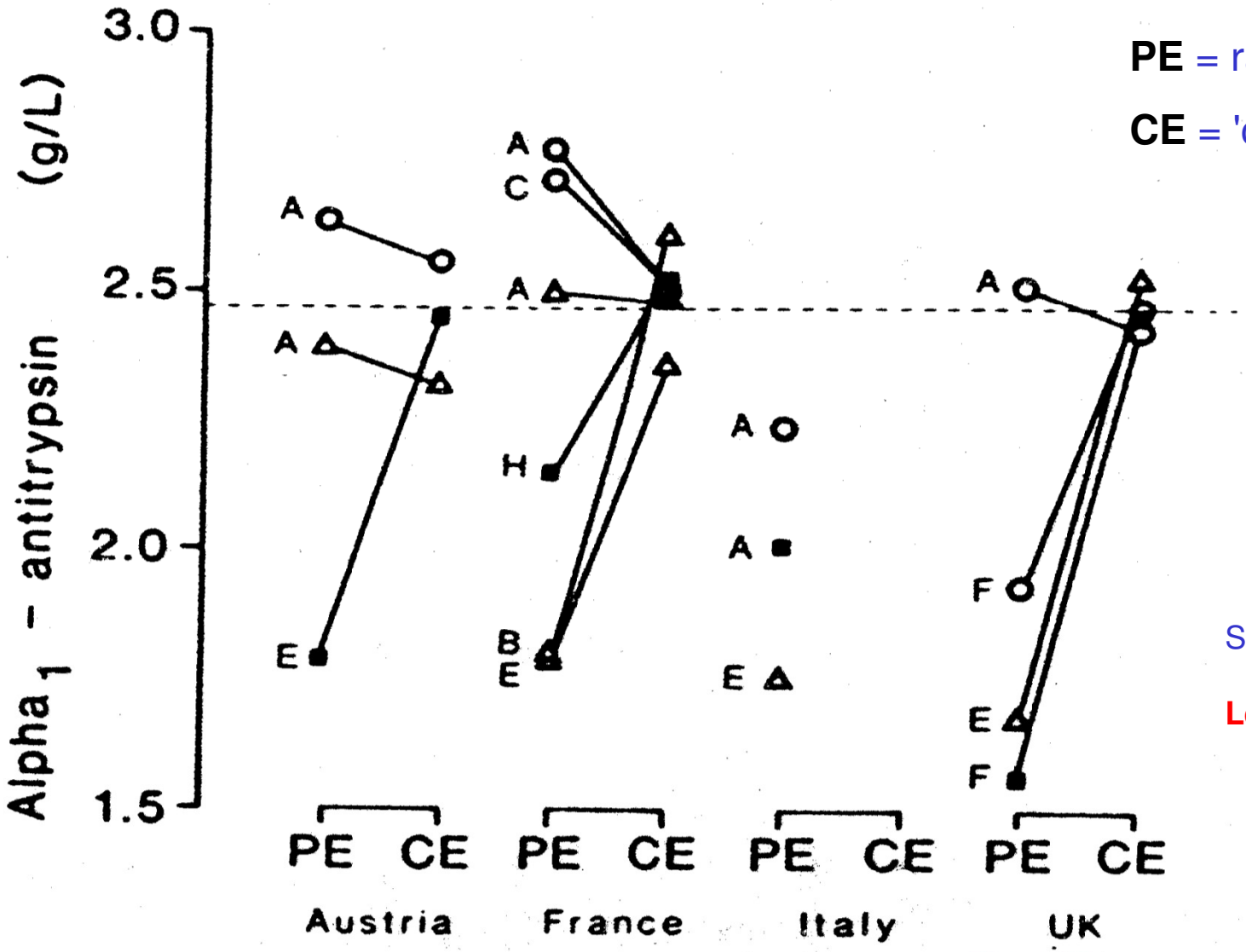
Symbols = procedures

Letters = calibrants

A high

E low

European common calibration study - AT



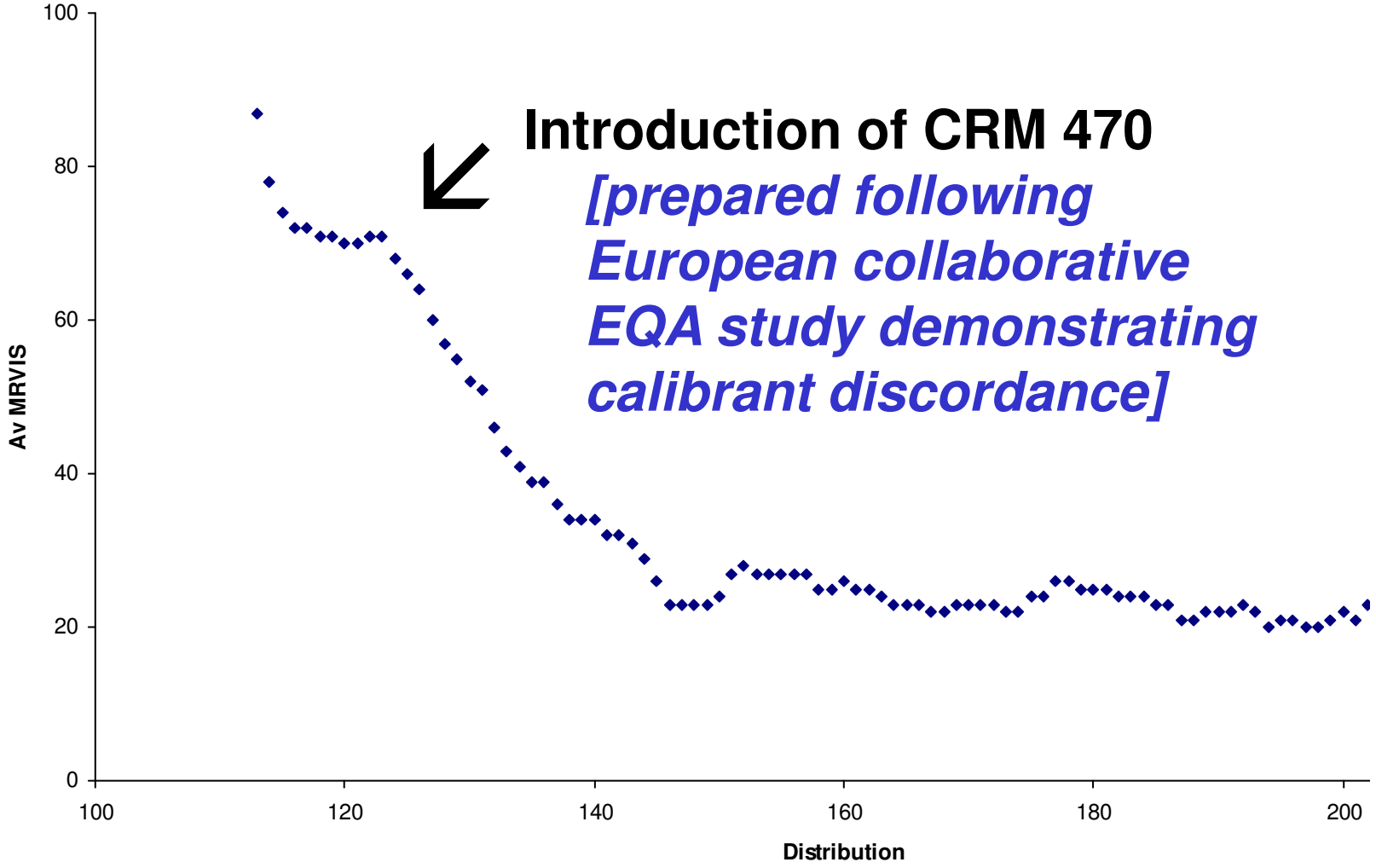
PE = raw

CE = 'calibrated'

Symbols = methods

Letters = calibrants

UK NEQAS for Specific Proteins
Orosomucoid, 1994 - 2001



But success may not last . . .

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1969 UK NEQAS 2009

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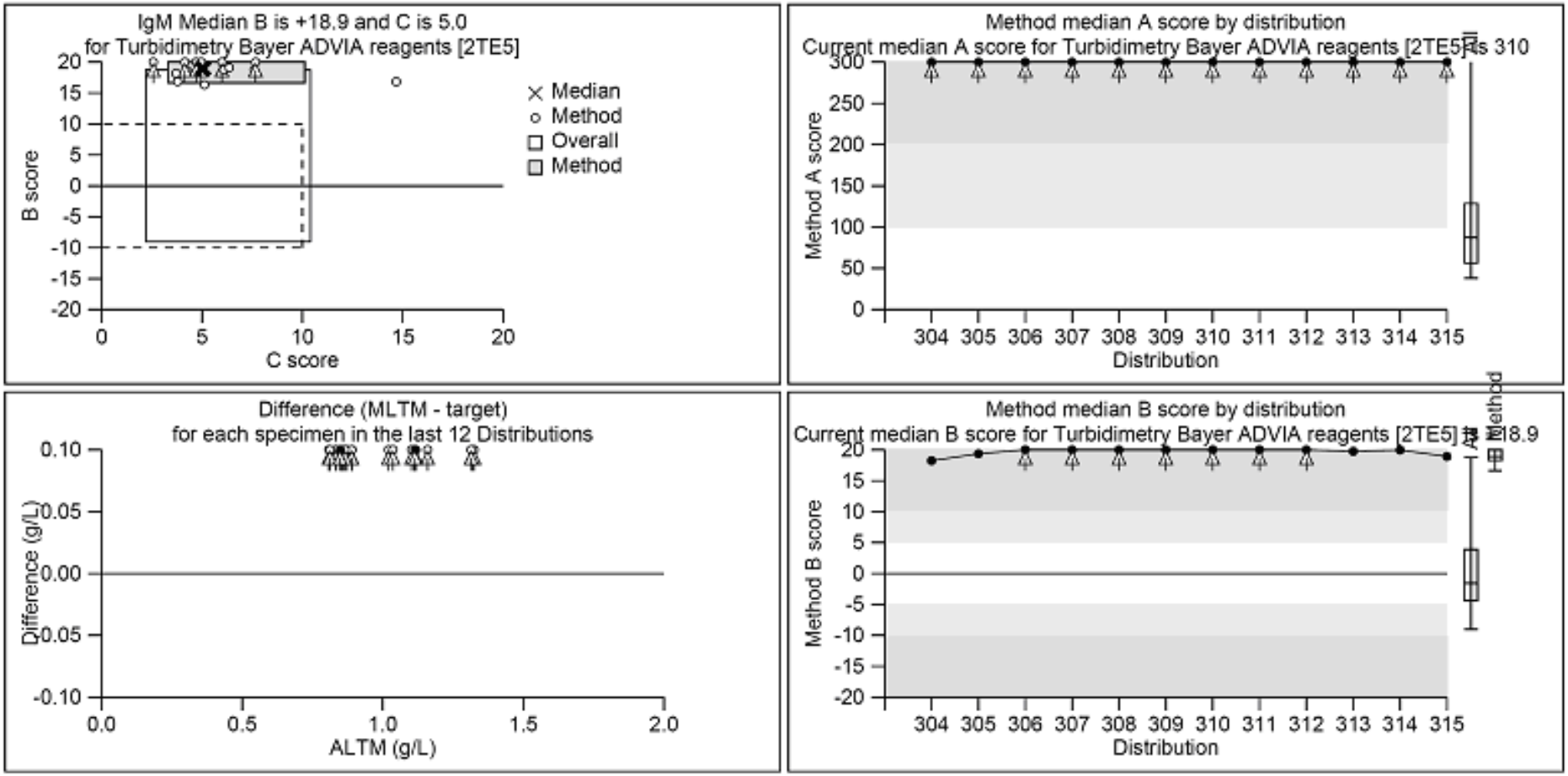
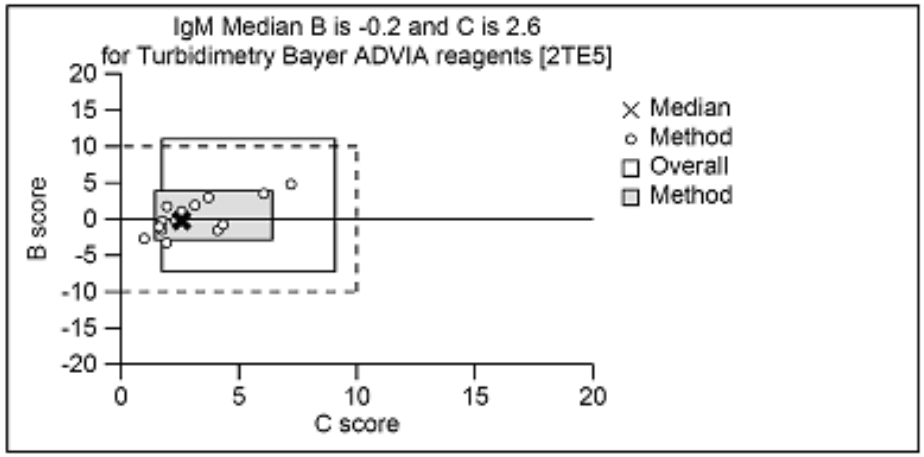
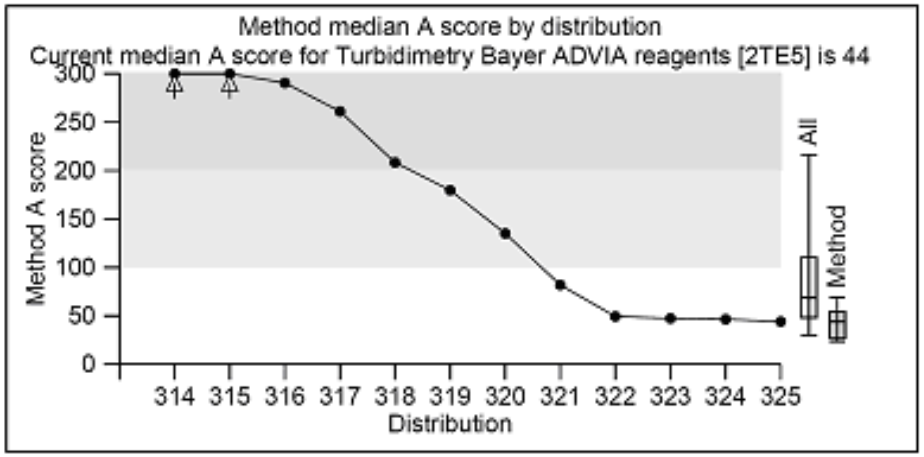
Advia IgM - August 2011

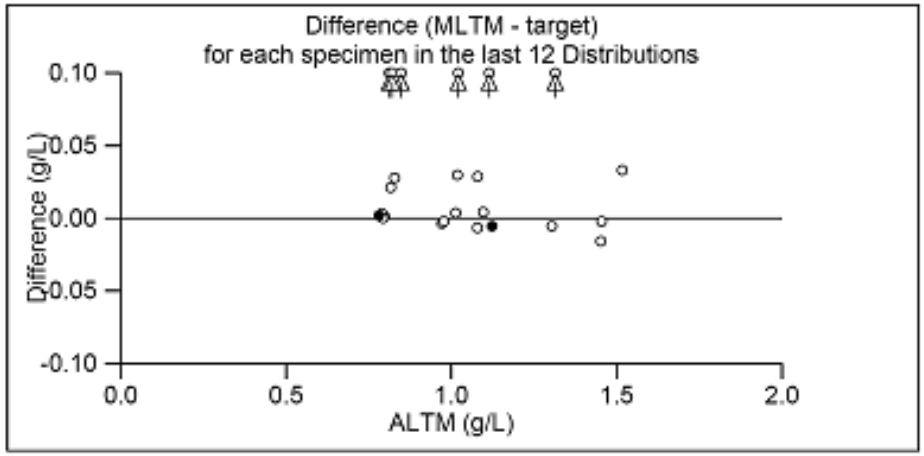


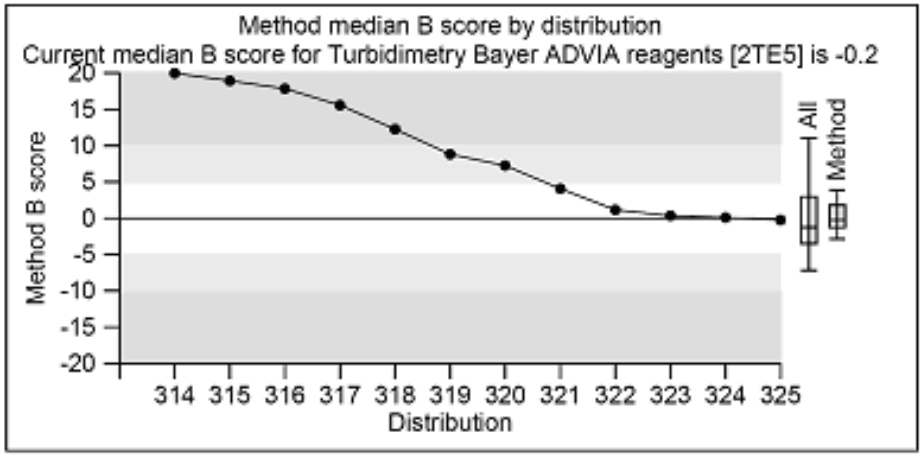
- 20% positive bias - "It's a matrix effect" . . .

Advia IgM - July 2012



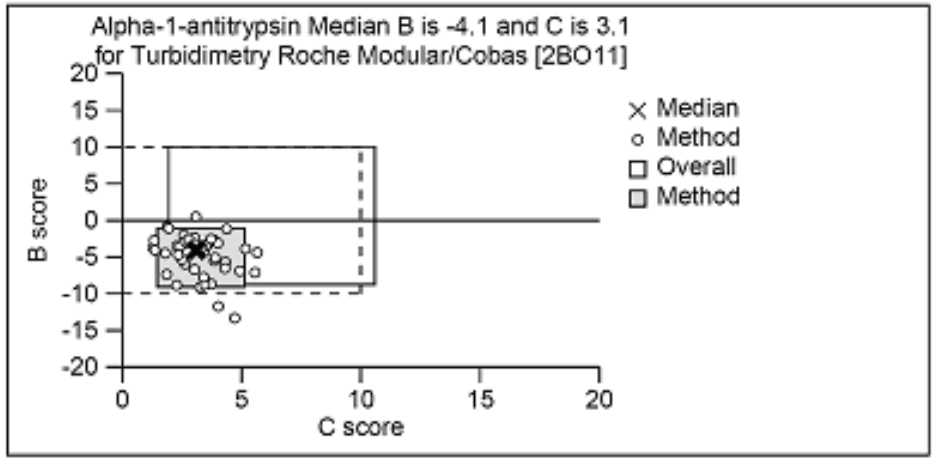


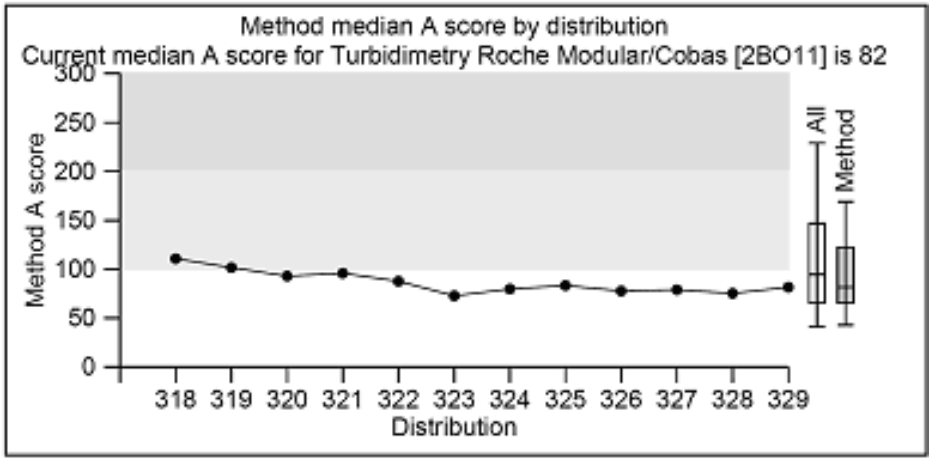


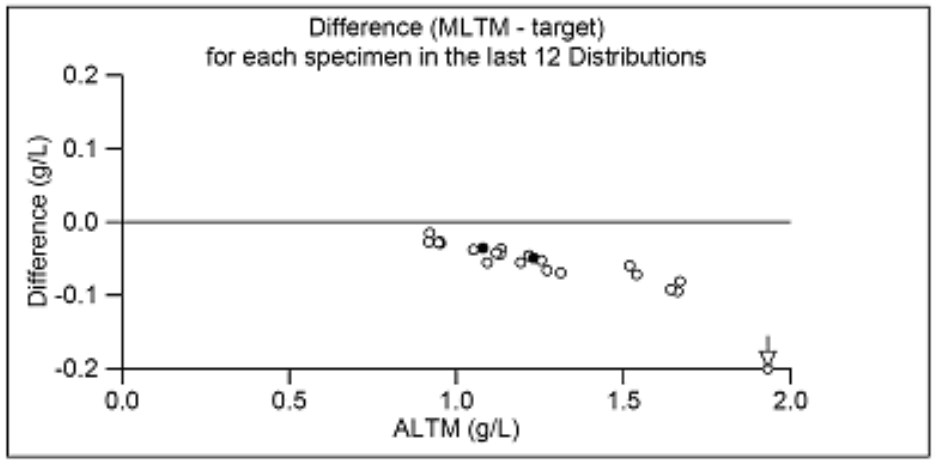


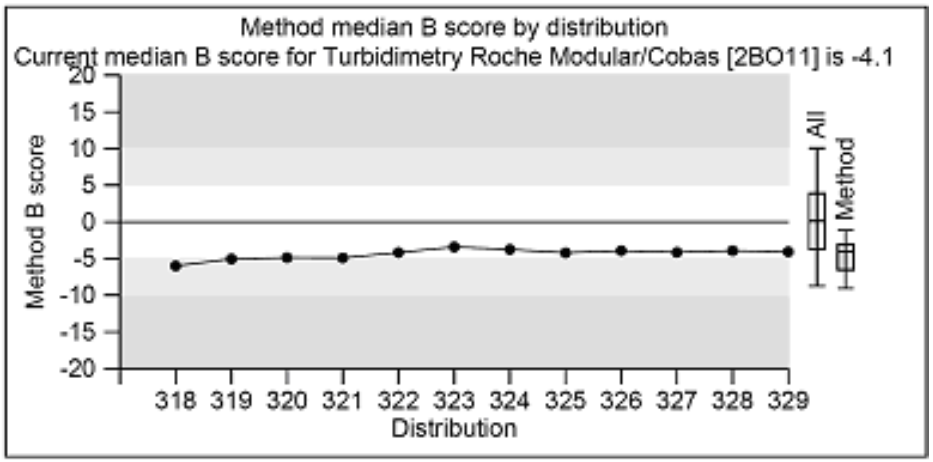
- but: "Assay reformulated and recalibrated" . . .

Modular AT - November 2012



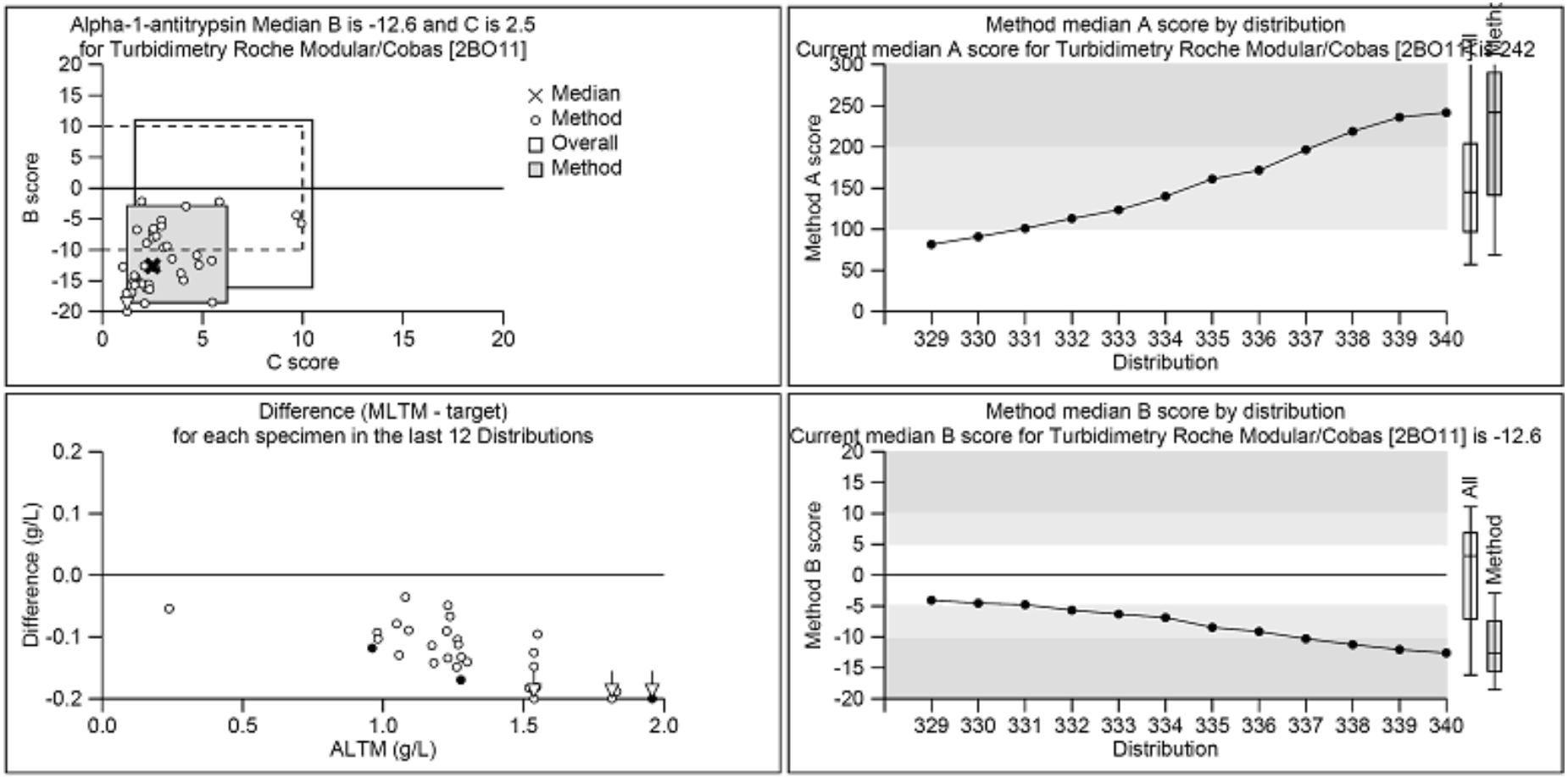






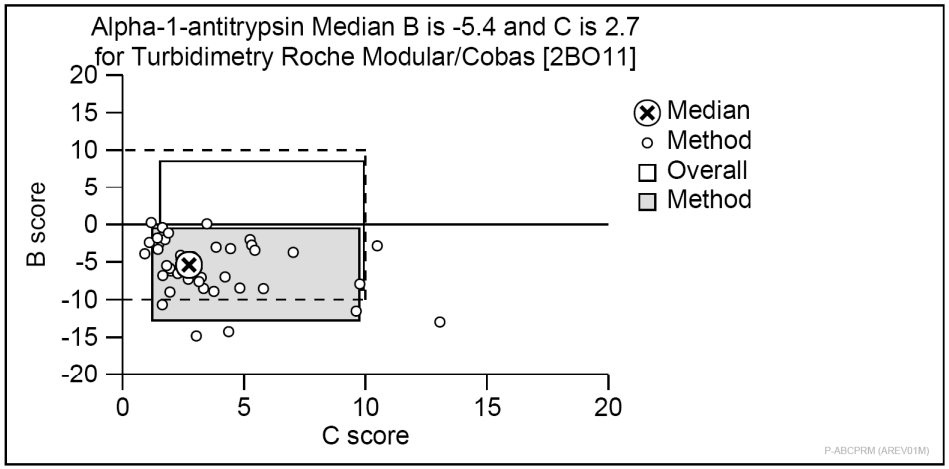
- 4% negative bias - recalibration against CRM

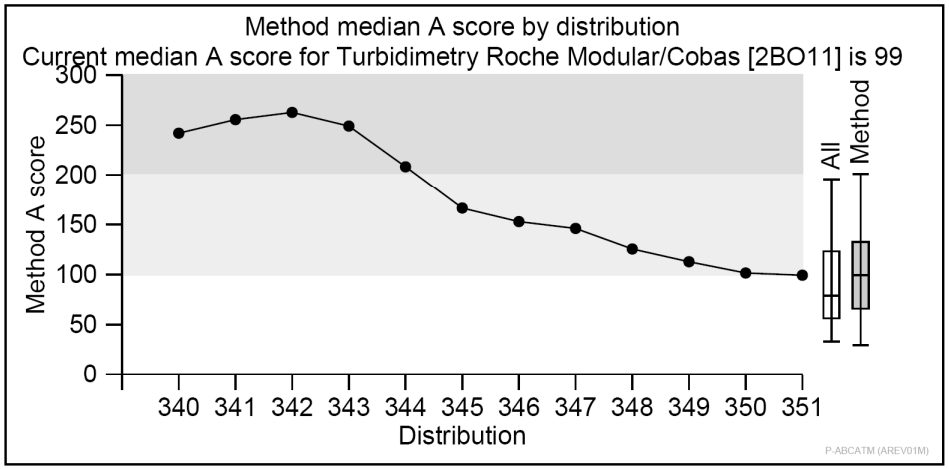
Modular AT - October 2013

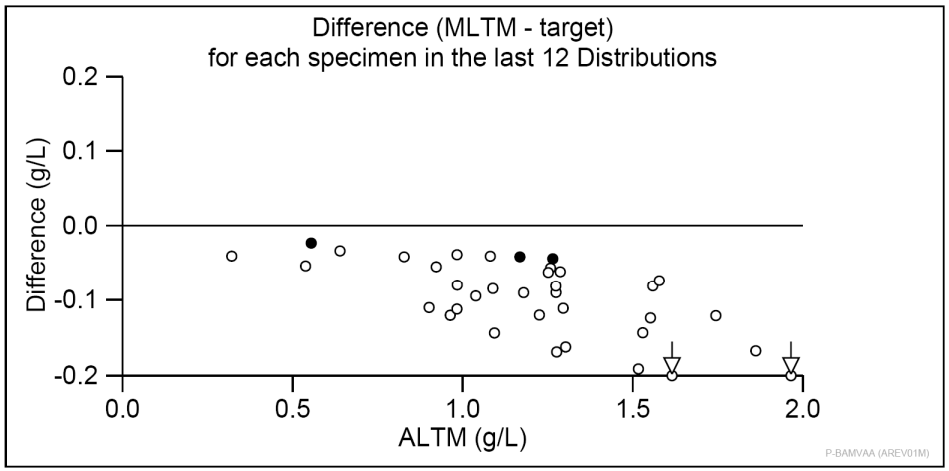


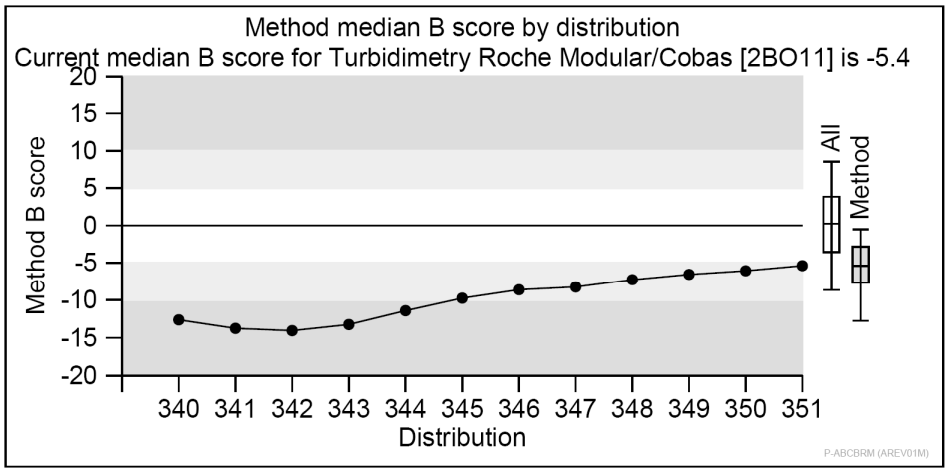
- perhaps there was a problem with the recalibration? . . .

Modular AT - September 2014





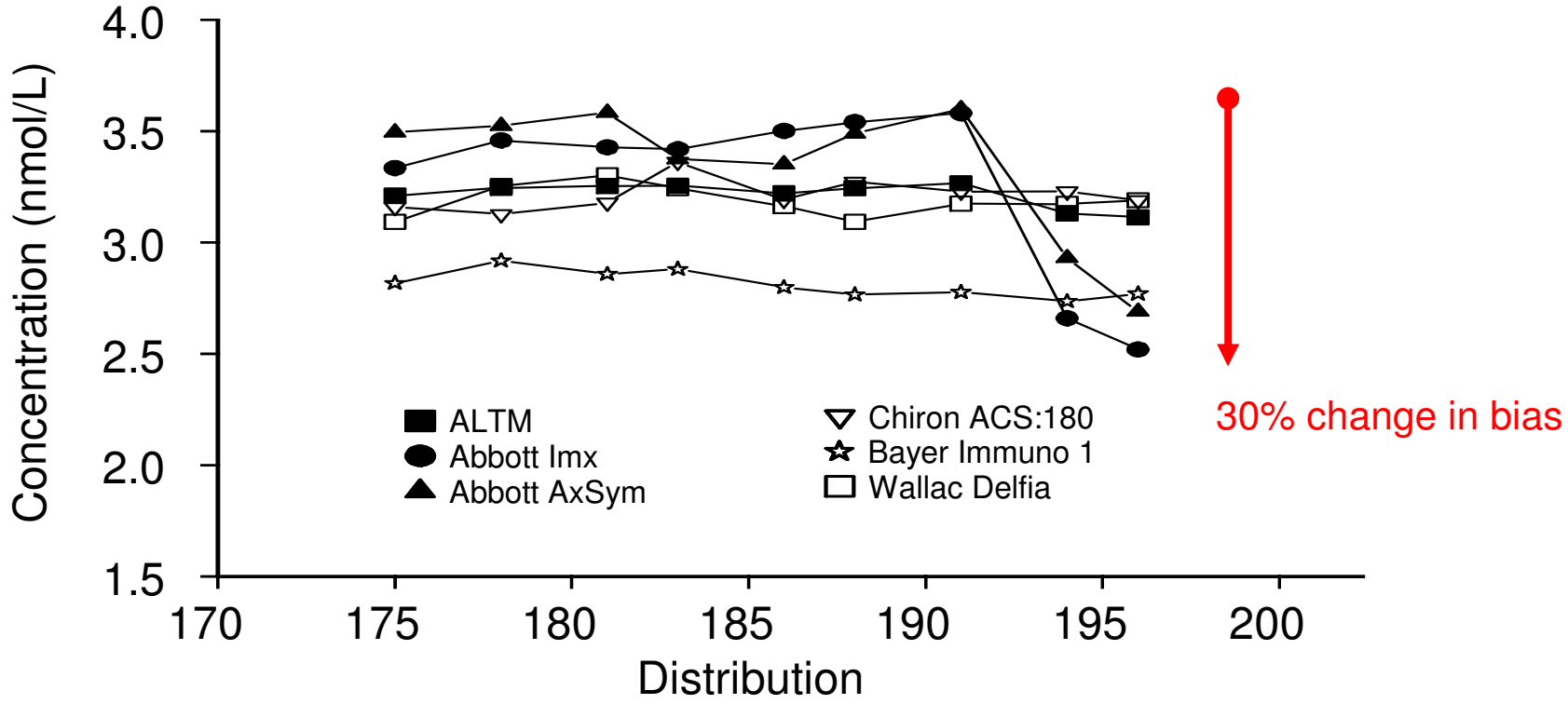




- revised calibrant values issued - back to 5% negative bias

Problems with method means as targets

Repeated distributions of the same material



This is only one of many examples of where being scored against a laboratory's own method mean, rather than the ALTM or method principle target, can mask underlying problems

EQA and manufacturers

Manufacturer issues – the future?

Requirements for an appropriate and effective system

- Recognition that issues may be EQA-specific
  - non-commutability etc
  - EQA should talk to manufacturer first
- Appropriate action, avoiding conflicting communications
  - Scheme Organiser, then NQAAP and/or MHRA
  - one size does not fit all
  - manufacturers require time to resolve issues
    - recognise UK, persuade 'global', investigate, resolve, implement, supply chain . . .
- Information sharing
  - MHRA awareness of what's happening
  - EQA can provide detailed data on request, but only given the context!
- MHRA should 'weight' reports
  - EQA reports
  - NQAAP reports

MHRA

"The responsibility for safety is shared between manufacturers, users and regulators – collaboration and dialogue between these parties is key to getting quality systems working"

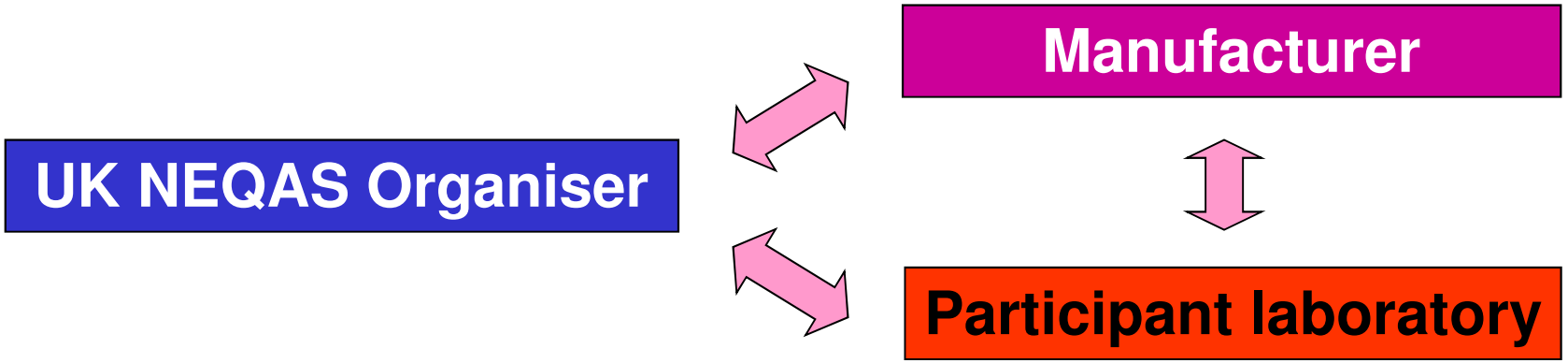
John Wilkinson OBE

MHRA Director of Devices

40 YEARS OF QUALITY 1969 UK NEQAS 2009

EQALM

A partnership !



Transparency and manufacturer issues

Laboratory performance 'dashboard' proposed

- ? full public access, as well as NHS and regulators
- ? green and red only
  - red = NQAAP referral
  - *amber = Scheme Organiser contact*
- ? aggregate across analytes and/or disciplines
  - mimic CQC 'intelligent monitoring system' for risk
- need to avoid penalising for manufacturer problems

Manufacturers must take responsibility

- complement with an '**IVD performance dashboard**'?
  - red = NQAAP/MHRA referral
  - amber = information shared between EQA and MHRA

Manufacturer divergences

- **The bad news**
  - individual manufacturers' methods do diverge
  - 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

Commutability of materials and methods -

a potential problem?

SPECIMEN SELECTION

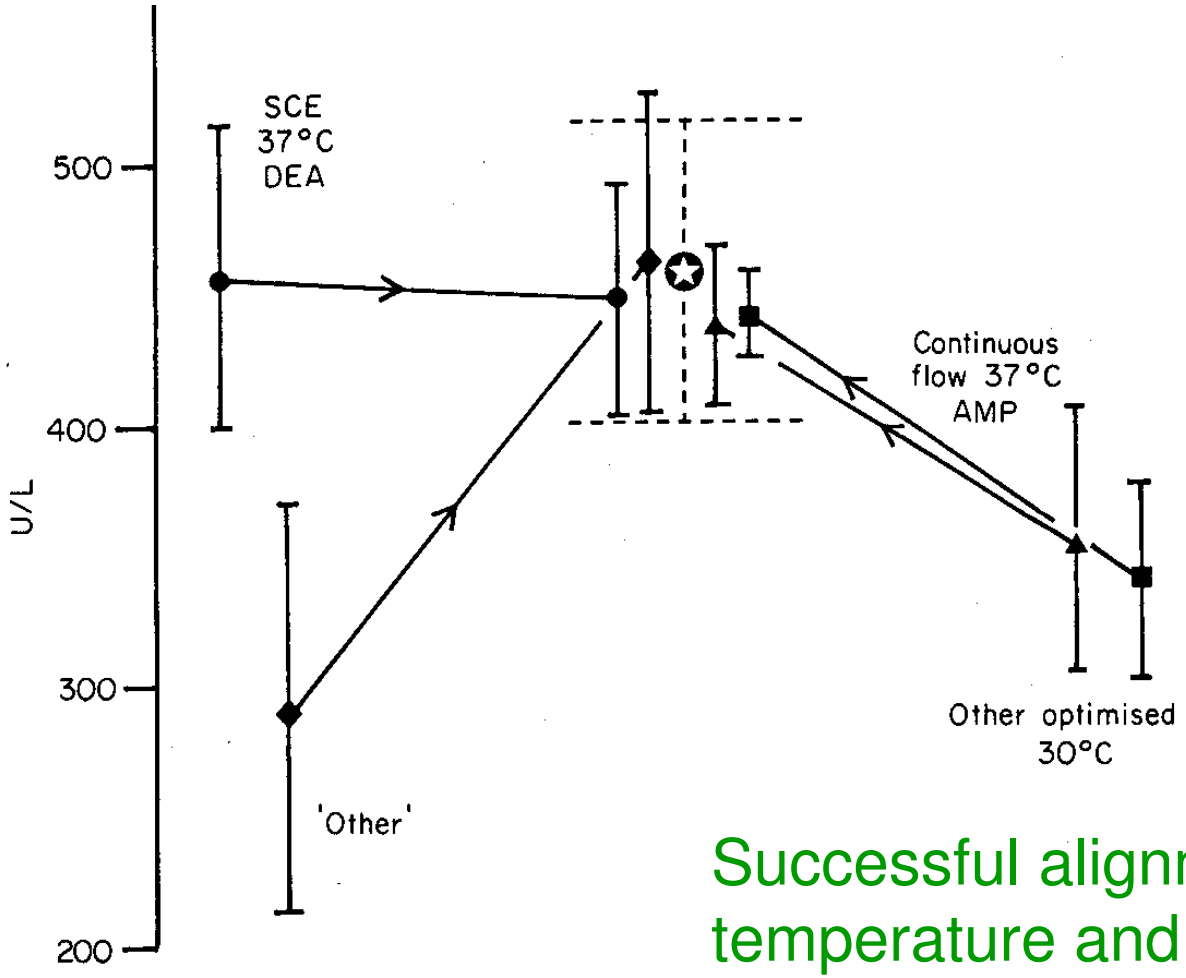
- **Specimens must:**
  - behave as clinical specimens
  - be appropriate for purpose

- **Factors include:**
  - species (human or animal)
  - additives (enzymes)
  - presentation (liquid or lyophilised)
  - imprecision
  - commutability between methods ('matrix effects')

COMMUTABILITY

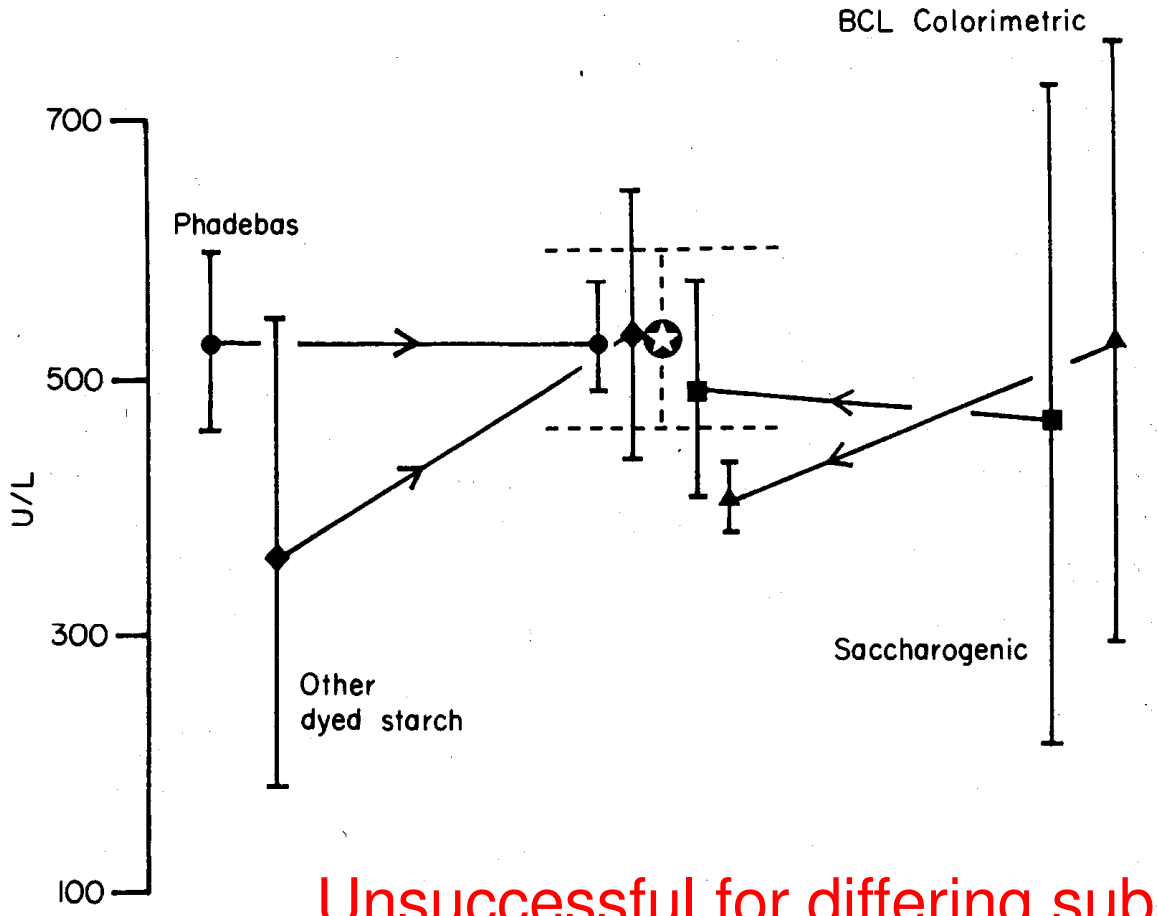
The consistency of the relation between results obtained by different analytical methods for a quality control material and freshly-drawn sera from patients

Enzyme calibration studies 1984 - ALP



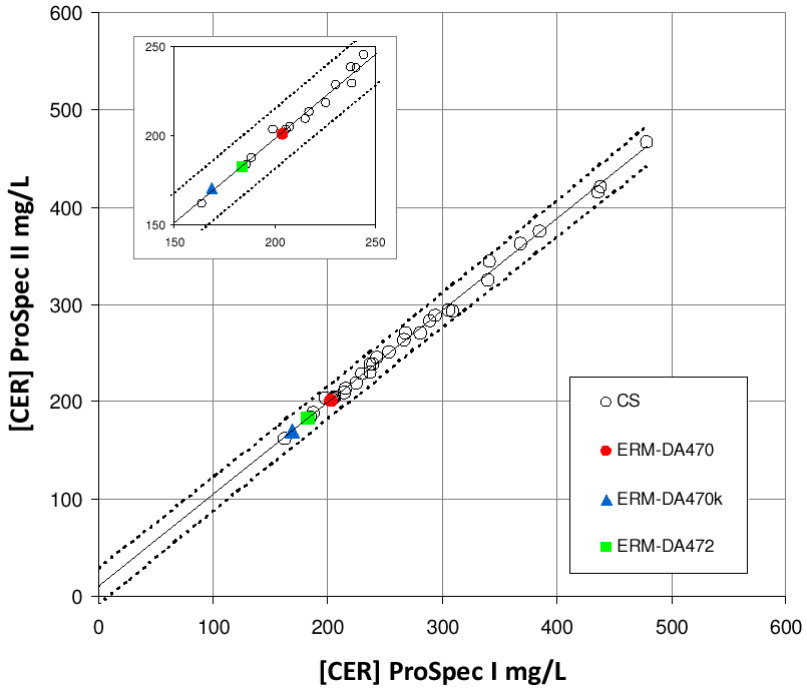
Successful alignment for temperature and buffer

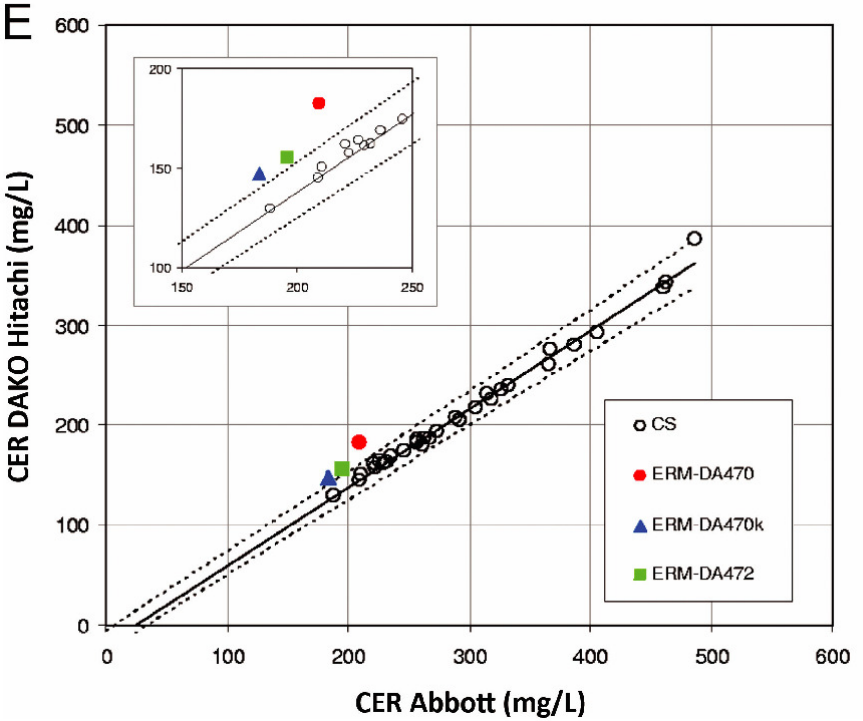
Enzyme calibration studies 1984 - Amylase



Unsuccessful for differing substrate chain lengths

NON-COMMUTABILITY OF REFERENCE MATERIALS
CAERULOPLASMIN IN CRMs





Commutable

Non-commutable

Reproduced from: Zegers *et al* (2013) Clin Chem **59:** 1322-1329

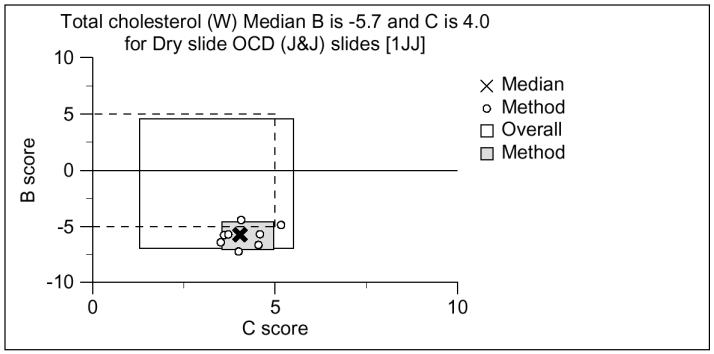
Commutability of materials - an alternative approach

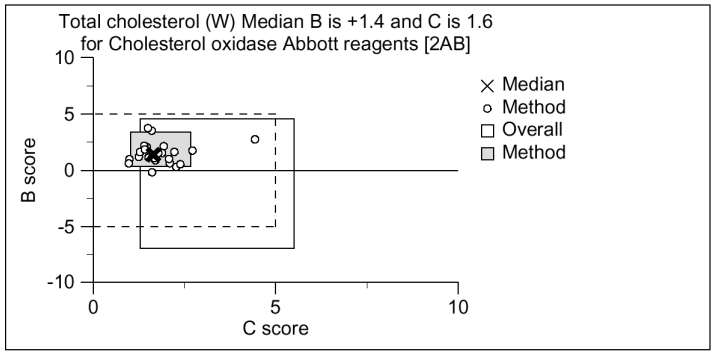
UK NEQAS FOR LIPID INVESTIGATIONS
THE PROBLEM

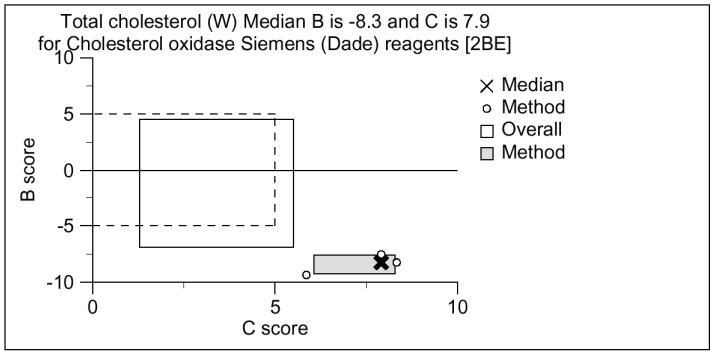
- **Scheme operation**
  - pooling essential for sufficient volume (400 participants)
  - serum donations have been frozen at least once
- **Commutability is adversely affected by:**
  - pooling
  - freeze thaw cycles
- **Outcome**
  - between-method differences
  - ALTM target inappropriate

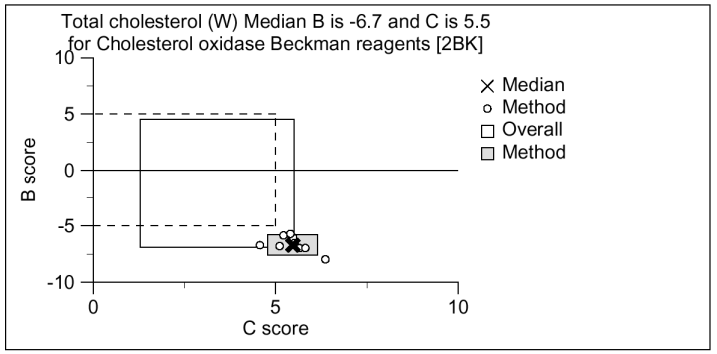
UK NEQAS FOR LIPID INVESTIGATIONS

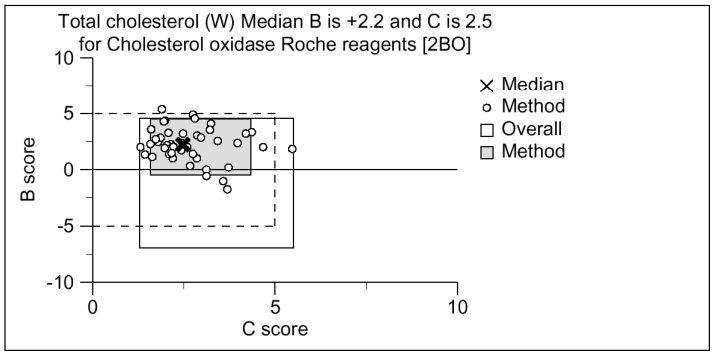
THE PROBLEM

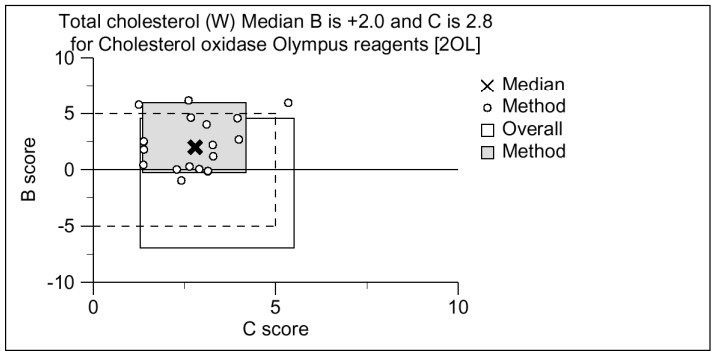












LIP v ALTM target

40 YEARS OF QUALITY
1969 UK NEQAS 2009

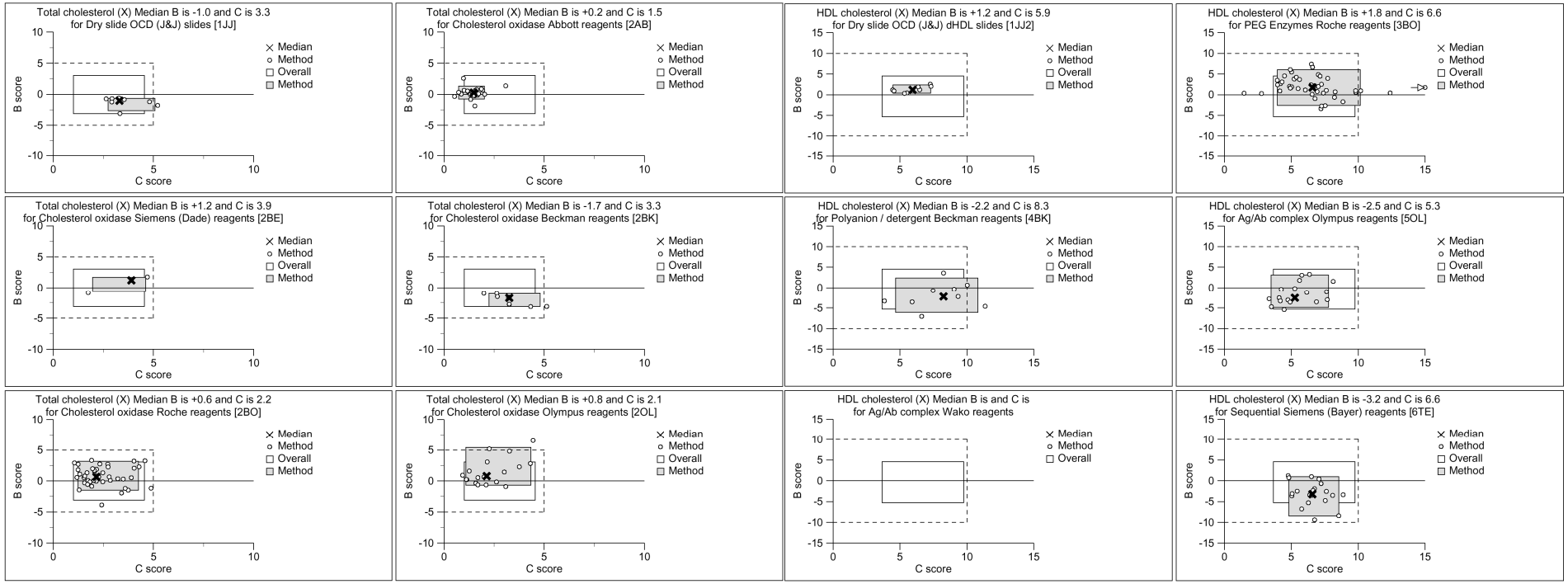
EQALM

UK NEQAS FOR LIPID INVESTIGATIONS
THE SOLUTION

- **Main scheme - LIP**
  - monthly frequency with pooled donations (previously frozen)
  - MLTM targets
  - assesses laboratory performance relative to method
- **Special scheme - LIPX**
  - quarterly frequency
  - participants represent the methods in use in the UK
  - fresh single donations from volunteers, never frozen
  - ALTM target
  - assesses method performance relative to overall consensus
  - **performance data provided to all participants**

UK NEQAS FOR LIPID INVESTIGATIONS

THE SOLUTION



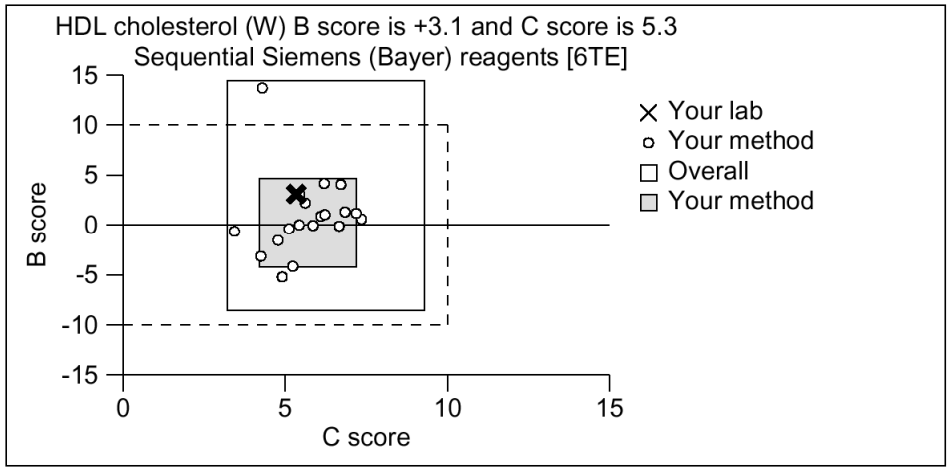
Total cholesterol

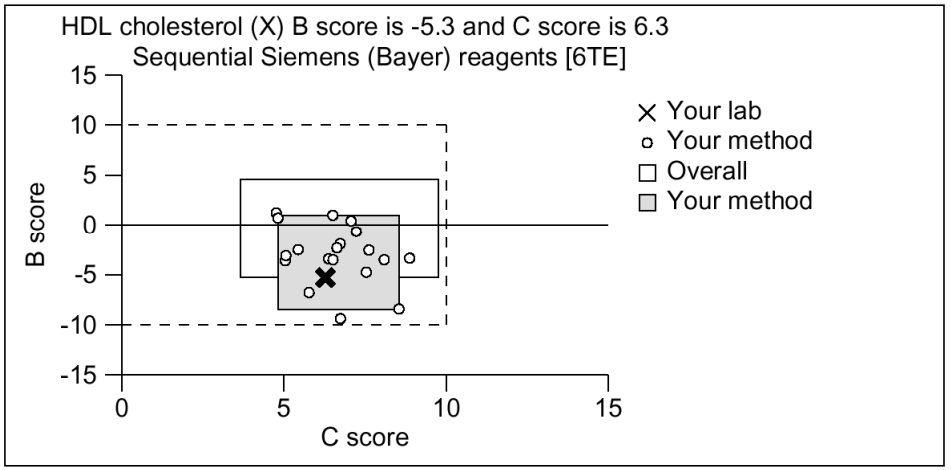
HDL cholesterol

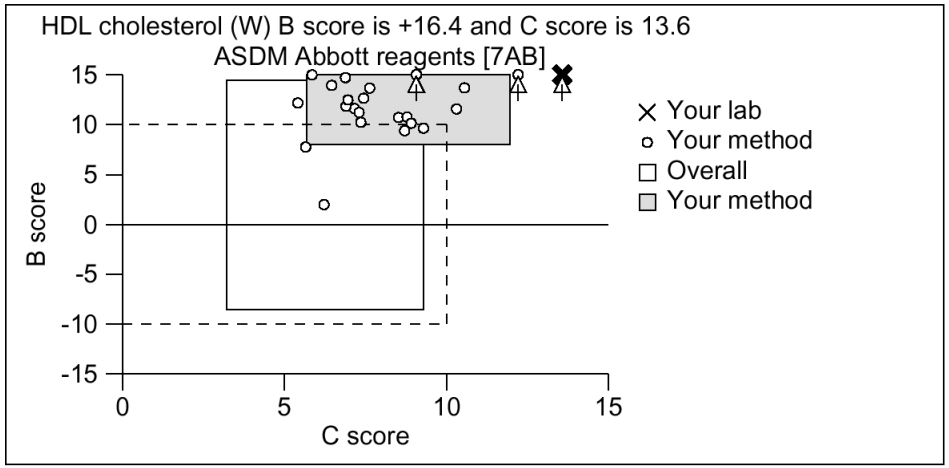
LIPX v ALTM target

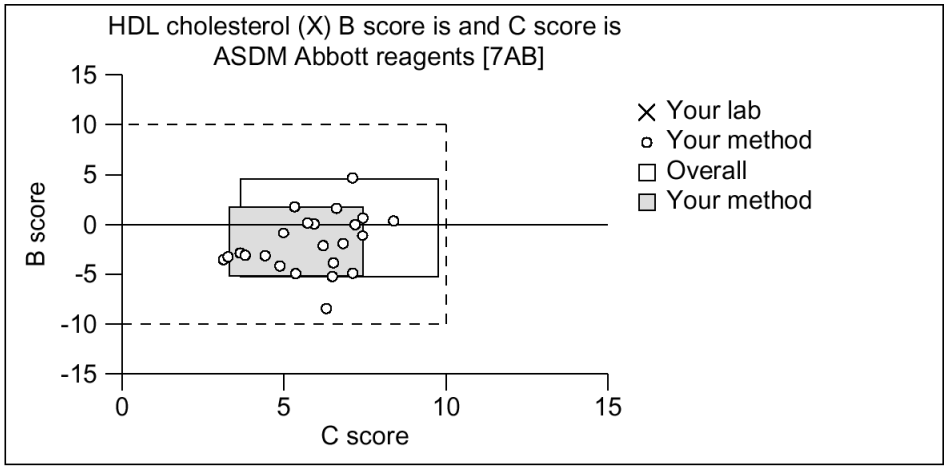
UK NEQAS FOR LIPID INVESTIGATIONS

THE SOLUTION









LIP v ALTM target

LIPX v ALTM target

New IVD Directive

Proposed new regulations

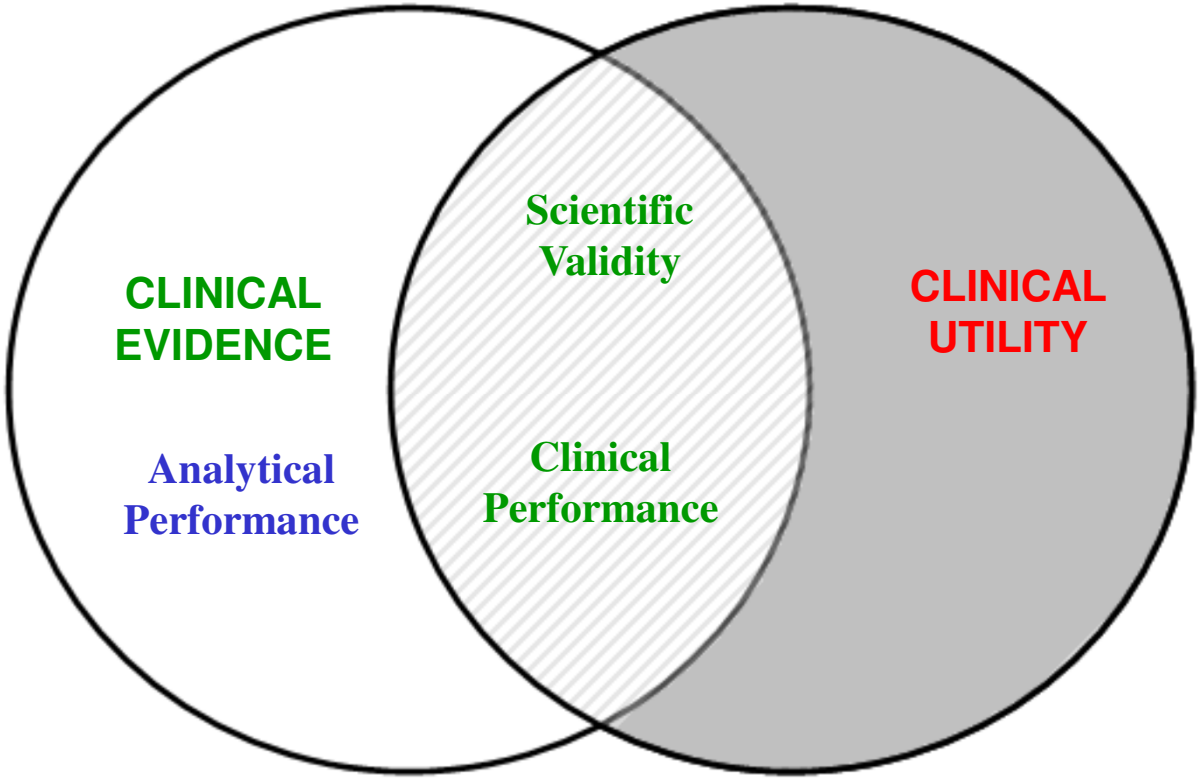
- **Proposals published in September 2012**
  - Implementation 2017 - 2018 ?
- **Common Medical Devices regulation**
- **IVD regulation**
  - Move to risk-based classification rules
  - Clinical evidence & clinical investigation requirements
  - Changes to ‘in-house’ exemption
  - Companion diagnostics
- **Many other aspects aligned across both regulations**
  - Notified Bodies, unique device identifiers, etc

Risk based classification (proposed)

CLAS	RISK LEVEL	POSSIBLE EXAMPLES
A	Low individual risk and Low public health risk	Clinical chemistry analyser Prepared selective culture
B	Moderate individual risk and/or Low public health risk	Vitamin B12 test Pregnancy self testing Anti-nuclear antibody test Urine test strips
C	High individual risk and/or Moderate public health risk	Blood glucose self testing HLA typing PSA screening Rubella test
D	High individual risk and High public health risk	HIV blood donor screening HIV blood diagnostic

[Australian classification]

Clinical evidence



What will it mean for EQA?

- **Unfortunately too early to tell at present, but**
  - there will be changes,
  - and "the devil will be in the detail",
  - but EQA will have a continuing role . . .

UK NEQAS

Compendium of quality

40 YEARS OF QUALITY
1969 UK NEQAS 2009

EQALM

Available as pdf from:

www.ukneqas.org.uk

Improving Patient Safety:
Better screening for Clostridium difficile

What UK NEQAS delivers

We tailored our scheme to determine the sensitivity of kits. EQA specimens positive and negative for toxigenic C. difficile were designed to challenge the clinically important aspects of performance of different technologies/methods used for detection of this pathogen.

Experience and Expertise: Harmonising Performance Across Methods

The Challenge

UK NEQAS data showed that the measurement of the size of red blood cells (mean cell volumes, MCV) varied using different diluents. The UK NEQAS survey material is partially stabilised and does not react in exactly the same way as fresh blood in different instrument/ reagent combinations (non-commutability). This effect could be avoided by comparing similar (grouped) methods. This solution would often be considered if we could not solve the commutability problem. UK NEQAS Directors and Specialist Advisory Groups embedded in daily haematology service provision, knew that a similar, if less marked, difference appeared to be seen with patients' samples in the diagnostic laboratory community and decided to investigate.

The benefits

UK NEQAS works closely with manufacturers to highlight and correct problems of significance to patients as early as possible.

But for the available clinical expertise, it would have been easy to attribute the observed differences to a "matrix" effect (an unusual property of the solution affecting the results) and to regroup the instruments into method groups for the purpose of performance assessment, which would degrade the utility and sensitivity of the scheme.

Ensuring Tests Meet the Needs of Patients and Health Services: MRSA Screening

What UK NEQAS delivers

We design UK NEQAS panels that cover the range of MRSA strains selected from those currently circulating in community and hospital acquired infections, utilising our clinical knowledge and expertise and those of our advisory groups. These continually evolve to meet clinical need.

The benefits

- EQA can help with early detection of non-conformances in culture media related to bacterial strain.
- EQA can help with early detection of non-conformances in culture media due to failure of the media.
- EQA distributions can allow comparison of performance of different commercial products, thus providing evidence to detect and guide investigation and follow-up.
- We provide evidence to monitor compliance of laboratories with UK recommendations for detection of MRSA.
- We enable performance monitoring of commercial and in-house methods.
- UK NEQAS data can support peer assessment and bench marking (UK and internationally) of the recommended testing algorithm.
- UK NEQAS data can provide quality assurance of surveillance data collected as part of mandatory MRSA reporting in the UK.

Personalised Medicine – EQA for Companion Diagnostics

The Challenge

Personalised medicine using targeted drugs in particular individuals has given many patients an effective new treatment choice for some cancers. Accurately detecting specific gene mutations within the tumour is pivotal for best clinical management of these patients. Proper External Quality Assessment (EQA) is essential to reduce variability and ensure the quality of this form of rapidly expanding molecular testing.

UK NEQAS developed an EQA scheme to provide a source of material with an appropriate range of mutations and an educational aspect to help improve the quality of the testing being performed.

What UK NEQAS delivers

Since 2008, four EQA schemes have been developed and delivered to assess the molecular testing in four tumour types:

- KRAS molecular testing in colorectal cancer
- EGFR molecular testing in non-small cell lung cancer
- Molecular testing in gastrointestinal stromal tumours
- BRAF molecular testing in melanoma (pilot).

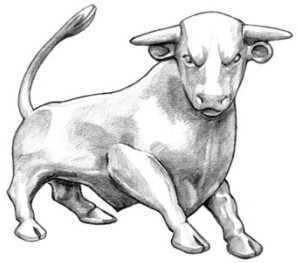
The tumour samples are supplied with appropriate clinical case scenarios and participants are required to submit fully interpretative reports. They are assessed for genotyping accuracy, interpretation of the results and clerical accuracy of the report.

In conclusion . . .

UK NEQAS for Clinical Chemistry

- **Ministry of Health project proposal (1969)**
  - funding for a "**National Quality Control Scheme**"
  - research grant of £500
  - two-year duration
  - *"all the problems will be corrected by then, so we will be able to stop"*

- **Over 40 years on**
  - ongoing EQA is still essential . . .



Birmingham Quality

Birmingham Quality

Previously known as the *Wolfson EQA Laboratory*,
Birmingham Quality provides primarily
UK NEQAS External Quality Assessment
Services in Clinical Chemistry

UK NEQAS

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