HOW TO USE EQA RESULTS WITHIN THE LABORATORY

Dr David James
Chair RCPath Joint Working Group on Quality Assessment

Holiday Inn Leiden | Hote

Joint Working Group on

https://www.rcpath.org/profession/committees/jwgqa.html

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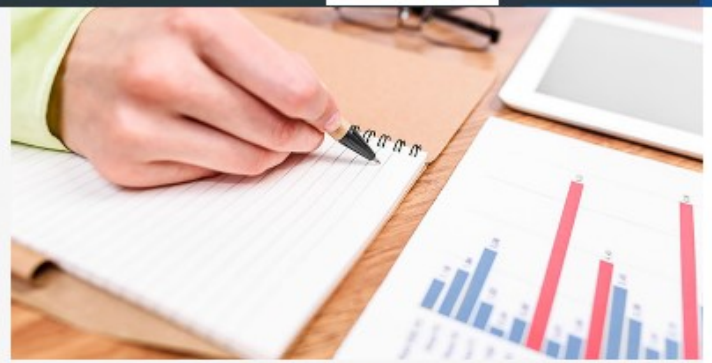

HOMEPAGE > PROFESSION > COMMITTEES > JOINT WORKING GROU...

JOINT WORKING GROUP ON QUALITY ASSESSMENT IN PATHOLOGY

The Joint Working Group for Quality Assessment in Pathology is a multidisciplinary group accountable to the College for the oversight of performance in external quality assessment (EQA) schemes and monitoring of the EQA performance of clinical laboratories in the UK. This is achieved via discipline specific panels which report to the Joint Working Group. In turn, the Joint Working Group will work with failing laboratories but is also bound to report persistent poor performance to the Care Quality Commission.

CHAIR: DR DAVID JAMES

COMMITTEE MEMBERS

- Dr Pat Twomey - (Vice Chair/Chemical Pathology NQAAP Chair)
- Prof Tim Reynolds - (Immediate Past Chair)
- Dr Keith Gomez - (Haematology NQAAP Chair)
- Dr Tony Elston - (Microbiology NQAAP Chair)
- Dr Mark Gompels - (Immunology NQAAP Chair)

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Cellular Pathology NQAAP
Chemical Pathology NQAAP
Genetics NQAAP
Haematology NQAAP
Microbiology NQAAP
Immunology NQAAP
Reproductive Science NQAAP

- Joint Working Group on Quality Assessment Terms of Reference
- Joint Working Group on Quality Assurance June 2014
- Joint working group on quality assurance Nov 2014
- Joint Working Group on Quality Assurance June 2015

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Search the web and Windows

London (PPTP)

06:06
11/11/2016

So where does EQA fit in?

How do we view EQA?

How do we view EQA

- A task that has to be completed?

How do we view EQA

- A task that has to be completed?
- An annoyance?

How do we view EQA

- A task that has to be completed?
- An annoyance?
- Part of that integrated whole?
  - *Likely the view of those here – how much thought do we put into making sure that EQA we perform is appropriate, and are we using it effectively?*

What do we mean by EQA?

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- IFCC definitions*

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  - *Proficiency Testing*
    - Laboratory performance evaluation for regulatory purposes
  - *EQA Scheme*
    - Laboratory performance and method evaluation, Educational
  - *EQA Programme*
    - Interlaboratory comparisons designed and operated to assure one or more of:
      - *Participant performance—analytical, interpretive, clinical advice, Method performance evaluation, in vitro diagnostic device vigilance, Education, Training and help*

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Choosing an EQA provider

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  - *What should we (as lab) be looking for?*
  - *What should EQA providers be looking to deliver?*

Variety of providers

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- In the UK, choice of 5 EQA providers for paracetamol

Variety of providers

- In the UK, choice of 5 EQA providers for paracetamol
- With internet searches, possible to eliminate some choices……such as CAP

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External quality assessment: best practice

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ABSTRACT

There is a requirement for accredited laboratories to participate in external quality assessment (EQA) schemes, but there is wide variation in understanding as to what is required by the laboratories and scheme providers in fulfilling this. This is not helped by a diversity of language used in connection with EQA; Proficiency testing (PT), EQA schemes, and EQA programmes, each of which have different meanings and offerings in the context of improving laboratory quality.

We examine these differences, and identify what factors are important in supporting quality within a clinical laboratory and what should influence the choice of EQA programme. Equally as important is how EQA samples are handled within the laboratory, and how the information provided by the EQA programme is used.

EQA programmes are a key element of a laboratory's quality assurance framework, but laboratories should have an understanding of what their EQA programmes are capable of demonstrating, how they should be used within the laboratory, and how they support quality. EQA providers should be clear as to what type of programme they provide – PT, EQA Scheme or EQA Programme.

Within the UK, the recent Department of Health Review into pathology quality assurance[1] has focussed attention on quality matters, with emphasis on exploring 'the overarching quality and risk management systems in NHS pathology services'.

Clinical Governance should be embedded in all pathology services, and internal quality control (IQC) and external quality assessment (EQA) play an important role in the quality management and improvement processes of clinical laboratory services to ensure high standards of patient care. Focussing on EQA, the purpose of this article is to summarise and define best practice as applicable to participants and providers of EQA, and how EQA performance can influence the quality of service provided by laboratories. It represents the consensus view of the National Quality Assessment Advisory Panel for Chemical Pathology.

This article will largely draw upon examples from clinical chemistry, being the area of expertise of the contributors, but many of the general principles will be applicable across most clinical laboratory disciplines. While concentrating on laboratory-based analytes, we recognise that the issues of maintaining and evidencing quality in point-of-care, or near-patient testing, are much more problematic, and regrettably often ignored, even with clear guidance from the Medicines and Health Regulatory Agency (MHRA)[2] and ready availability of suitable EQA schemes.

EQA OR PROFICIENCY TESTING?

In many parts of the world, the terms EQA and Proficiency Testing (PT) are used almost interchangeably. EQA can mean either 'external quality assessment' or 'external quality assurance'. More precisely, EQA schemes provide an assessment which laboratories use for assurance of quality. By contrast, a widely accepted definition of PT is: 'A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others.'[3] PT is the term commonly used in North America, and also serves a function in terms of regulatory requirements and in licensing and/or accreditation. Additionally in the USA, laboratories must also meet standards defined in the Clinical Laboratory Improvement Act (CLIA).[4] Such linkage to regulation with broad acceptance limits rather than quality improvement programmes based on biologic goals or clinical decision points may inhibit improvement and encourage laboratories to adopt 'special' practices in dealing with PT samples.[5]

A succinct definition of the difference between PT and EQA provided by the International Federation of Clinical Chemistry (IFCC) is summarised in table 1.[6] Essentially, the primary intention of an EQA programme (EQAP) in pathology is to support quality improvements for the benefit of patients.

Clinical laboratories in the UK have a long history of quality assurance through participation in EQA,[7] and although often referred to as EQA, the participation of laboratories fits more with the definition of EQAP.

Although the terms may be used interchangeably, what is key is that laboratory directors should focus on how their PT/EQA provider supports their quality management and improvement processes and where they require additional support/processes. Throughout the rest of this article we will refer to EQA as including PT, and how EQA can impact on laboratory quality and patient safety.

DOES PARTICIPATION IN EQA IMPROVE PATIENT CARE AND SAFETY?

There is not a wealth of evidence that can be drawn upon to support this at present. One issue is that EQA schemes cannot improve analytical quality per se. They can only, at best, identify problems. As such, only changes in the laboratory procedures, processes or methods may improve the quality of laboratory services and the laboratory.

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James D et al, J Clin Path 2014;67:651-655

doi:10.1136/jclinpath-2013-201621

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  - *Accreditation status of provider*
  - *Distribution frequency*
  - *Number of samples/distribution and range of values covered*
  - *Scheme management and development*
  - *Poor performance issues*
  - *Challenging samples*
  - *Educational value*
  - *Post-marketing vigilance of IVDs*
  - *Commutable materials*

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  - *Post-marketing vigilance of IVDs - ? A surrogate for focus of provider*
  - *Commutable materials - non-commutable materials may provide false reassurance of performance*

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Other factors that may impact on decision

- Comparator –
  - *“method mean” - a consensus*
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- Ease of understanding reports – layout and data provided
- Ease of handling of EQA samples – liquid form or require to be reconstituted/special storage etc (may be more important for POCT)

How a lab should perform EQA (I)

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Having made a proactive choice regarding EQA provider – samples arrive!

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- No special measures

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How a lab should perform EQA (I)

Having made a proactive choice regarding EQA provider – samples arrive!

“Samples should be handled as far as is possible in the same manner as patient samples”

- No special measures e.g.
  - *held until IQC is “good”*
  - *Run first thing after calibration*
- Incorporation into routine work flow

How a lab should perform EQA (II)

How many EQA registrations for each test??

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A laboratory has 3 analysers performing FBCs

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a) 1

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How many EQA reports should it receive for each distribution?

a) *1*
b) *3*

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How many EQA registrations for each test??

A laboratory has 3 analysers performing FBCs

How many EQA reports should it receive for each distribution?

a) *1*
b) *3*
c) *4*


29
7
28
12
35
3
26
0
32
15
19
4
21
2
25
17
31
14
20

The multiple analyser question

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The multiple analyser question

- Analysers A, B and C. Only 1 EQA registration
- Analyser A is developing a “fault” – runs OK, but imprecision is increasing
  - *Probability that A receives sample in any month is 33%*
  - *Over a 3 month period, probability of each analyser being used is 22%, more likely that only 2/3 used is 67%*

The multiple analyser question

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  - *Probability that A receives sample in any month is 33%*
  - *Over a 3 month period, probability of each analyser being used is 22%, more likely that only 2/3 used is 67%*
- Role of EQA in evidencing performance

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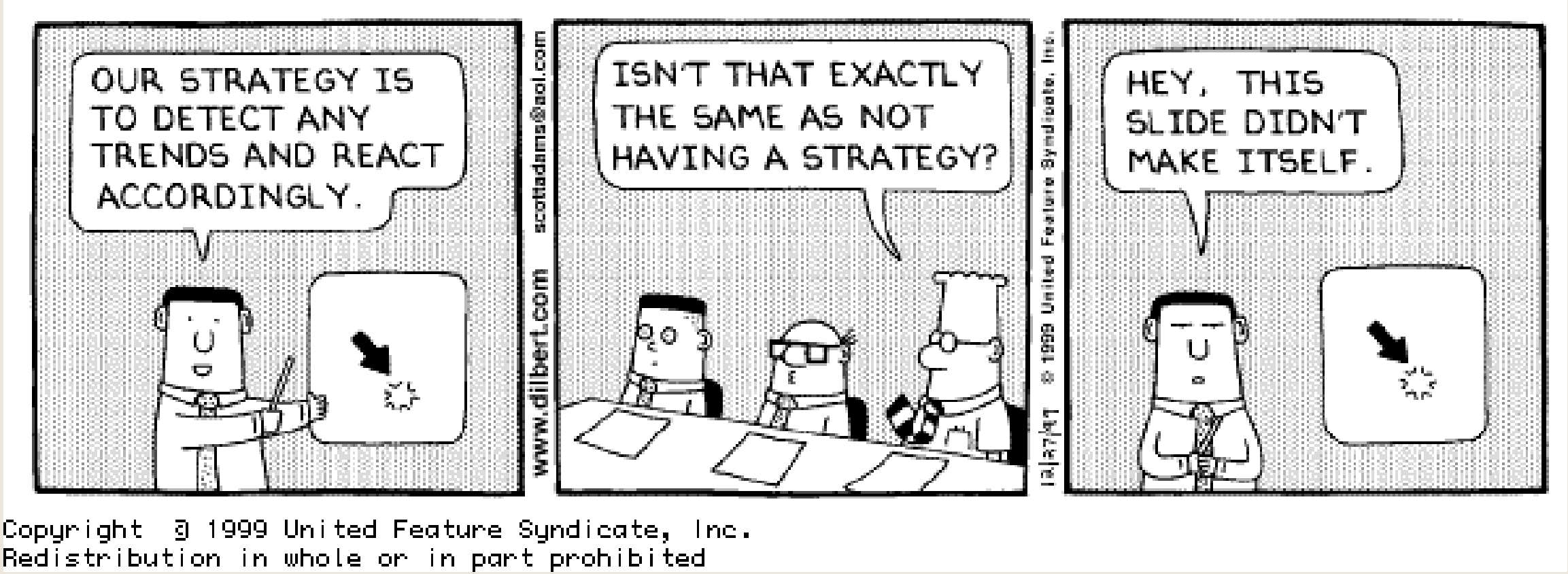
Using the reports



Using the reports

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- Depends on how we view EQA

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- Does report provide us with useful information?

Using the reports

- Depends on how we view EQA
- Does report provide us with useful information?
- How do we use that information?

Mr. S. Trenchard
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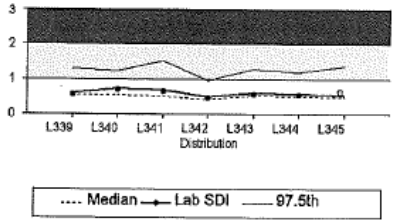
Taunton
Somerset
TA1 2LB

WEQAS
Unit 6, Parc Ty Glas
Llanishen, Cardiff
CF14 5DU
office@weqas.com
Scheme Organiser:
Annette Thomas

Lab: NJ . Scheme: Lipid. Distribution Code: L345.
Distribution Date: 22/08/16. Final. Report Issued: 8/09/16

This Distribution	
Overall Lab SDI:	0.53
Median All Laboratory:	0.49
97.5th centile:	1.37



All SDI Ranges	
< 1	Good
1 - 2	Acceptable
> 2	Poor

Section SDI scores for this distribution

Section	HUB 1	HUB 2	MPH 1	MPH 2	YDH 1	YDH 2
Overall	**0.65**	**0.37**	**0.58**	**0.74**	**0.50**	**0.32**
Cholesterol	0.85	0.26	0.77	0.77	0.37	0.23
Triglyceride	0.44	0.37	0.26	0.53	0.18	0.25
HDL Cholesterol	0.47	0.27	0.47	0.82	1.02	0.47
LDL Cholesterol	0.82	0.59	0.83	0.83	0.44	0.33

SDI Code	Meaning
N/A	Not enrolled for this analyte
?	Analyte enrolled but no results returned
N/S	This analyte not scored
NNR	Non-numerical results
**	SDI score greater than 2

Please note: Method and Instrument Summary reports are available to download via the 'Lab Stats' or 'Section Stats' menu. If you don't currently have interactive access, please contact WEQAS for a registration form on 02920 314750.

A user guide "How to interpret your report" is available to download as a PDF file from the resources area of our website at http://www.weqas.com/resourcelibrary

***** Please note********

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by ? in your SDI scores table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

Scheme: Lipid. Distribution Code: L345.
Distribution Date: 22/08/16. Final. Report Issued: 8/09/16

HDL Cholesterol (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		1.10	1.50	0.90	1.50	
Method Corrected Result		1.100	1.500	0.900	1.500	
Immunoinhibition	Mean	1.077	1.549	0.918	1.512	
	SD	0.037	0.064	0.037	0.064	
	Number	33	33	33	33	
	Uncert.	0.0081	0.0140	0.0081	0.0140	
AU2700/AU5400/AU5800	Mean	1.081	1.561	0.919	1.507	
	SD	0.033	0.060	0.029	0.038	
	Number	19	19	19	19	
	Uncert.	0.0094	0.0172	0.0084	0.0108	
Overall	Mean	1.122	1.571	0.940	1.565	
	SD	0.048	0.071	0.047	0.064	
	Number	193	193	193	193	
	Uncert.	0.0044	0.0064	0.0042	0.0057	
Reference Values CDC		1.077	1.628	0.912	1.557	
Ref. Value Uncertainty		0.0000	0.0200	0.0000	0.0300	
Non-scoring Reference Values						
WeQas SD		0.090	0.126	0.075	0.125	
SDI		0.26	-1.02	-0.16	-0.46	0.47

Sigma Metrics

Critical Level 1: 1.0 mmol/l

Minimum Acceptable score	1.64	Critical Level 1 Sigma score	3.7
MAPS Allowable TE	15.9%		
MAPS Allowable bias %	10%	Lab |bias| %	0.2%
MAPS Allowable CV %	3.6%	Lab CV %	4.3%

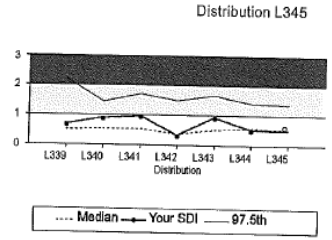
Please note: Linear regression uses CF corrected data.

Total Error

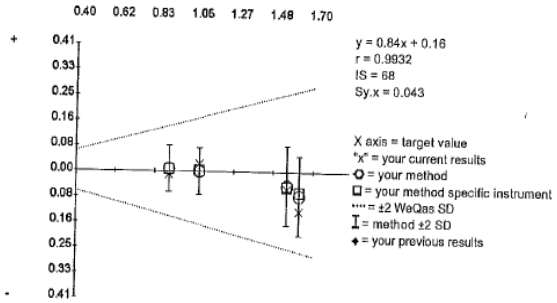
SDI is a measurement of your total error and will include both inaccuracy and imprecision.

This Distribution L345
Your average analyte SDI for the 4 samples is 0.47

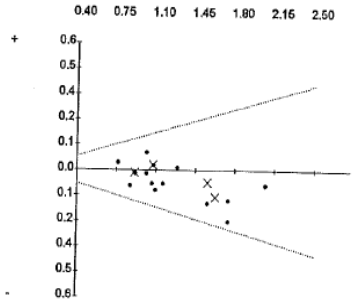
Previous SDI



This Distribution *L345*



Previous Distributions



Precision

This Distribution L345	Previous Distributions	L344	L343	L342	L341	L340	L339
Sy.x = 0.043 mmol/l	Sy.x	0.066	0.033	0.001	0.028	0.074	0.031
IS = 68	IS	54	53	0	43	254	1371

Sy.x is the average deviation from the best fit line and is an index of scatter.

Accuracy

This Distribution L345	Previous Distributions	L344	L343	L342	L341	L340	L339
Systematic proportional error (calibration) -15.58%	Proportional (%)	-7.16	-16.36	-4.74	-27.52	-21.41	-31.06
Systematic constant error (blank) 0.158 mmol/l	Constant (mmol/l)	0.033	0.096	0.072	0.234	0.220	0.277

Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

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  - *Under development*

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- Defining minimum acceptable performance for tests
  - *Is a compromise*
  - *Under development*
  - *All UK chemistry EQA providers able to assess against this*

What do I expect EQA to do in my lab?

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- Clear indication of performance
- Where possible against “correct” value rather than “consensus mean”
- Allow comparison of performance for same test across all labs and analysers (network reports)
- Information on linearity
- Throw a “curve ball”

What do I expect my lab to do about EQA

What do I expect my lab to do about EQA

- Do it

Mr. S. Trenchard
Somerset Pathology Services
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Lisieux Way
Taunton
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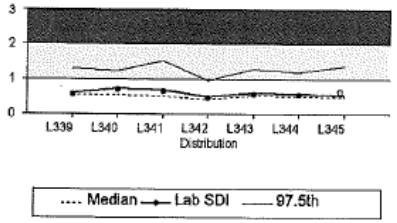
TA1 2LB

WEQAS
Unit 6, Parc Ty Glas
Llanishen, Cardiff
CF14 5DU
office@weqas.com
Scheme Organiser:
Annette Thomas

Lab: NJ . Scheme: Lipid. Distribution Code: L345.
Distribution Date: 22/08/16. Final. Report Issued: 8/09/16

This Distribution	
Overall Lab SDI:	0.53
Median All Laboratory:	0.49
97.5th centile:	1.37



All SDI Ranges	
< 1	Good
1 - 2	Acceptable
> 2	Poor

Section SDI scores for this distribution

Section	HUB 1	HUB 2	MPH 1	MPH 2	YDH 1	YDH 2
Overall	**0.65**	**0.37**	**0.58**	**0.74**	**0.50**	**0.32**
Cholesterol	0.85	0.26	0.77	0.77	0.37	0.23
Triglyceride	0.44	0.37	0.26	0.53	0.18	0.25
HDL Cholesterol	0.47	0.27	0.47	0.82	1.02	0.47
LDL Cholesterol	0.82	0.59	0.83	0.83	0.44	0.33

SDI Code	Meaning
N/A	Not enrolled for this analyte
?	Analyte enrolled but no results returned
N/S	This analyte not scored
NNR	Non-numerical results
**	SDI score greater than 2

Please note: Method and Instrument Summary reports are available to download via the 'Lab Stats' or 'Section Stats' menu. If you don't currently have interactive access, please contact WEQAS for a registration form on 02920 314750.

A user guide "How to interpret your report" is available to download as a PDF file from the resources area of our website at http://www.weqas.com/resourcelibrary

***** Please note********

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by ? in your SDI scores table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

What do I expect my lab to do about EQA

- Do it
- Treat as a patient sample as far as possible

What do I expect my lab to do about EQA

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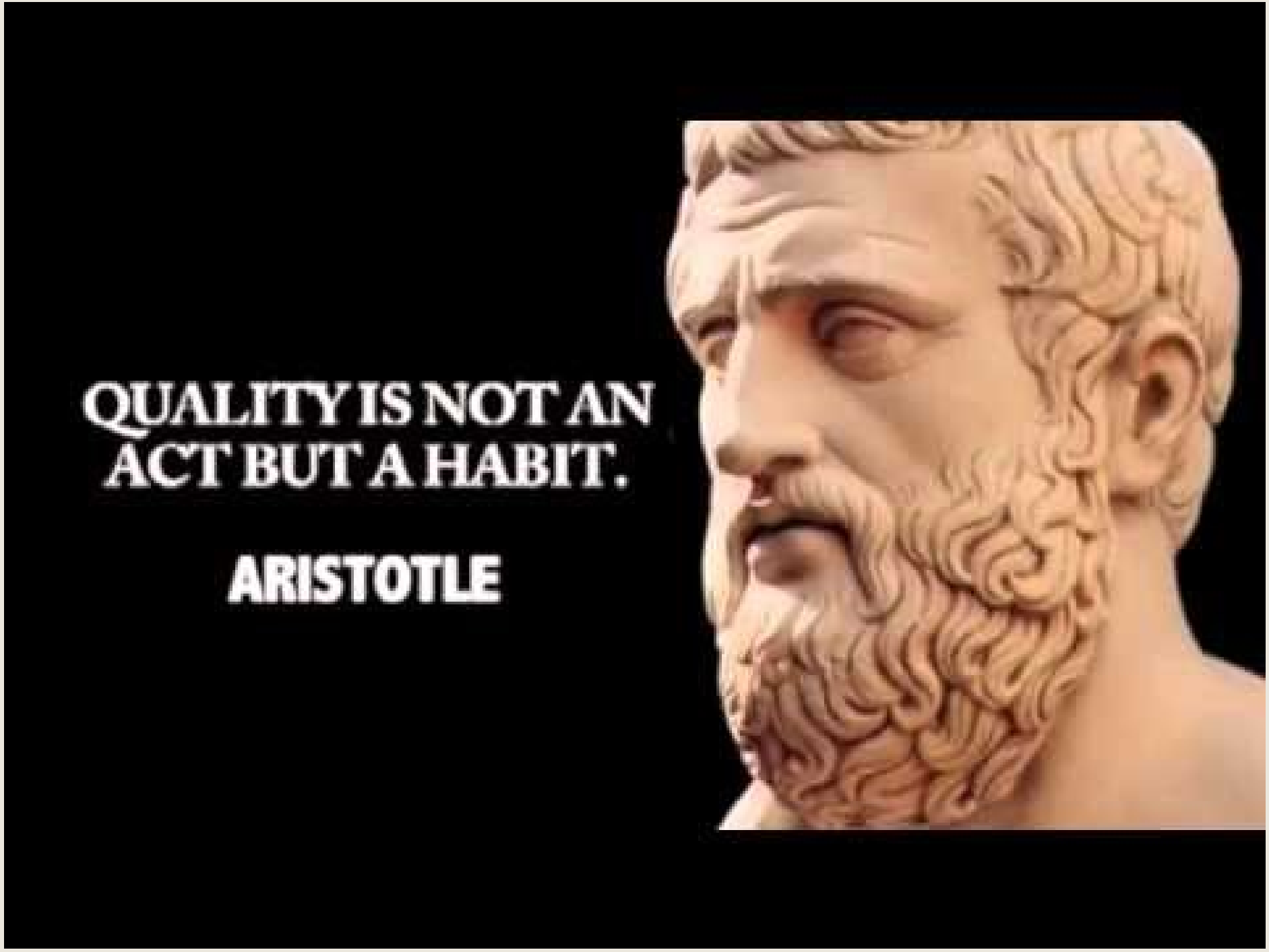
- Treat as a patient sample as far as possible
- Look at the reports

What do I expect my lab to do about EQA

- Do it
- Treat as a patient sample as far as possible
- Look at the reports
- Relate it to other aspects of QMS


PLAN
DO
CHECK
ACT


QUALITY IS NOT AN ACT BUT A HABIT.
ARISTOTLE