‘A Compendium of Quality’

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Overview

- Range and depth of UK NEQAS services – a Compendium of Quality
- Defining and measuring quality
  - Acceptable performance specifications
- EQA errors and troubleshooting

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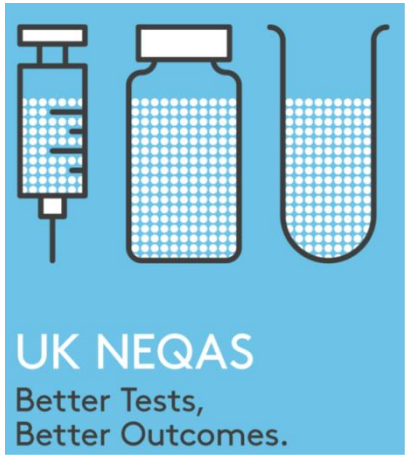
Compendium of quality



6.1.1

PREPQ: Pre-and Post-Analytical Quality Monitoring Service Supporting End to End EQA

6.1.3

Proficiency and Efficiency Testing: Combined technical assessment and clinical interpretation in Histocompatibility and Immunogenetics

Supporting End-to-End EQA

6.1.2

Quality Assurance Masterclasses: Practical learning, real time proficiency

Supporting End-to-End EQA

6.2.2

Harmonising Performance Across Methods: Detection of Antibiotic Resistance

International Collaborative Leadership in Quality Improvement

6.3.1

UK NEQAS: supporting National and International Initiatives on Kidney Function

Supporting Continuous Quality Improvement in Networks and Laboratories

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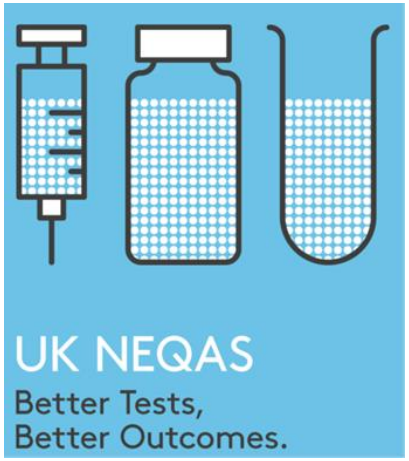
Compendium of quality



7.2

UK NEQAS online competency assessment in Blood Transfusion in a virtual laboratory environment

Innovative Interpretatvie EQA

7.1

Maintaining Relevance – Matching schemes to current pathogens

UK NEQAS for Molecular detection of viruses

8.1

Ensuring the quality of Whole Genome Sequencing as part of the UK '100,000 Genomes' Project

Supporting Personalised Medicine

8.4

UK NEQAS provision for Specialist Centres: International Specialist Molecular testing in haemoglobinopathies

Supporting Personalised Medicine

8.5

Testing breast cancer for selection of HER2-targeted therapy

Supporting Personalised Medicine

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6 ‘Pillars’ of traceability

- Reference materials
- Reference methods
- Reference assay services
- Reference intervals and action points
- Quality assurance
- Uncertainty of measurement

Federica Braga, Mauro Panteghini, Verification of in vitro medical diagnostics (IVD) metrological traceability: Responsibilities and strategies, In Clinica Chimica Acta, Volume 432, 2014, Pages 55-61, ISSN 0009-8981, https://doi.org/10.1016/j.cca.2013.11.022

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6 'Pillars' of traceability

- Reference materials
- Reference methods
- Reference assay services
- Reference intervals and action points
- Quality assurance – IQC and EQA
- Uncertainty of measurement

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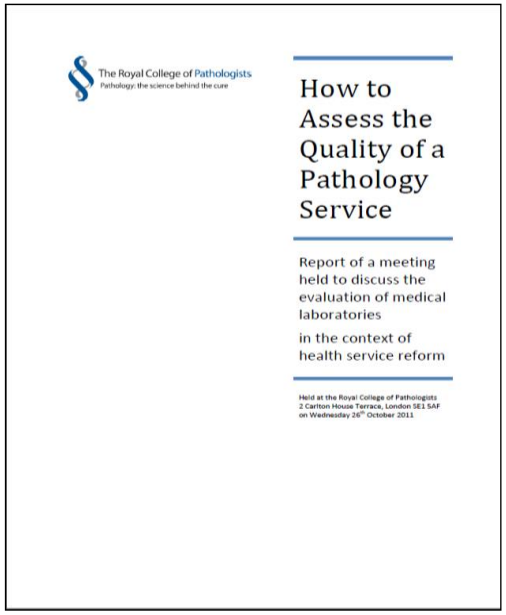
Defining quality



Quality management system
Governance and oversight
Individual competence
End-to-end quality monitoring

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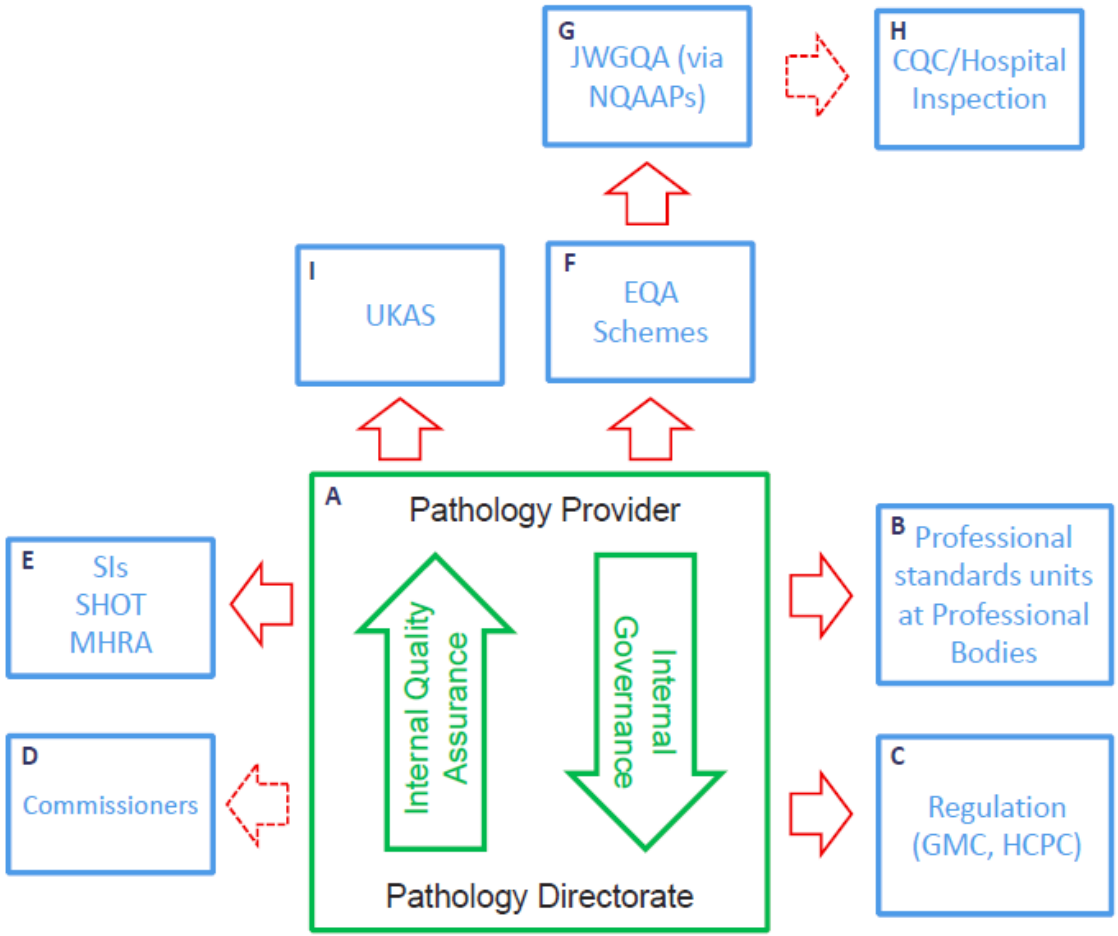
Monitoring Quality



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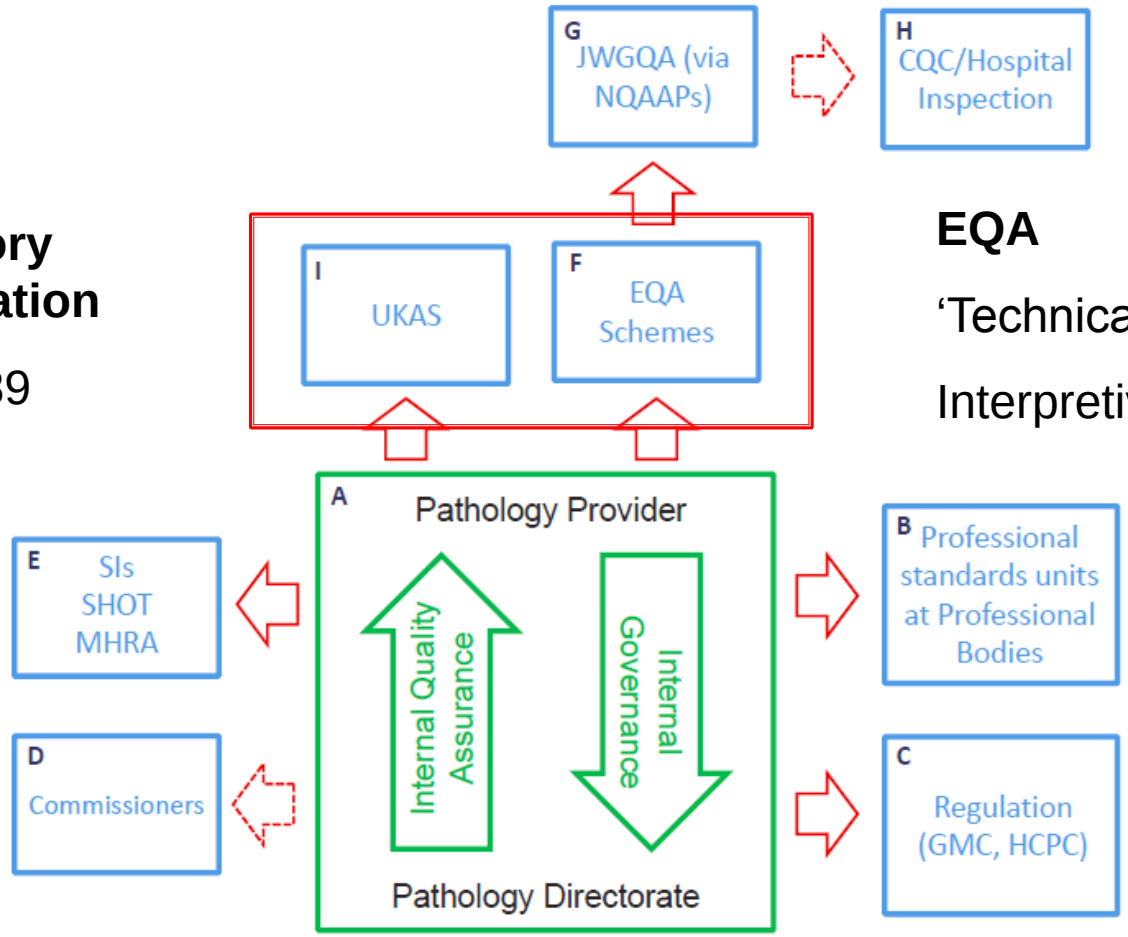
Monitoring Quality

Laboratory accreditation

ISO 15189



EQA

'Technical'

Interpretive (individual)

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Disclosure of EQA performance to UKAS

The Royal College of Pathologists
Pathology: the science behind the cure

3. NQAAP will write to the participant informing them of the outcome of their assessment and any action to be taken. The EQA scheme organisers and now UKAS will be copied in to this letter.

Steps 1 and 2 are unchanged from current practice. The only change is the inclusion of UKAS in step 3. This change requires that participants provide details of their UKAS registration solely to enable correct identification of a laboratory. This information will only be used should step 3 become necessary and will not be used for any other purpose.

28th April 2017

Re: Change to the notification process for Persistent Unsatisfactory Performance

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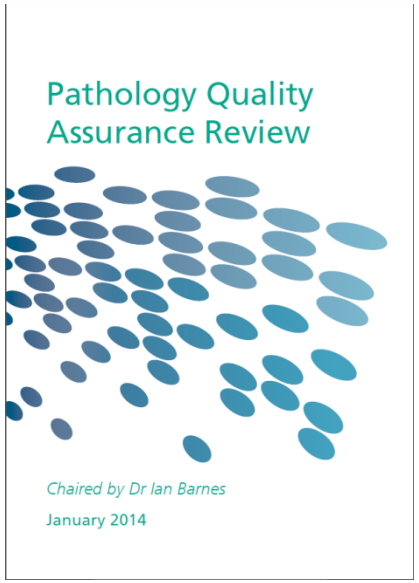
PQA Review 2014

4.29 The JWGQA should harmonise the activities of the different NQAAPs by undertaking work to refresh and set consistent standards for EQA schemes and work with UKAS to enhance their application of ISO17043 for accrediting schemes



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Acceptable performance specifications

Definitions and descriptions

Jones, G., Albarede, S., Kesseler, D., et al. (2017). Analytical performance specifications for external quality assessment – definitions and descriptions. Clinical Chemistry and Laboratory Medicine (CCLM), 55(7), pp. 949-9551

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Models for EQA APS

'Milan models'

- Milan model 1
  - 1a) Outcome based evaluation
  - 1b) Clinical decision applications
- Milan model 2
  - Derived from biological variation
- Milan model 3
  - Derived from the 'state-of-the-art', i.e. the technically achievable analytical performance

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APS: Definitions & Descriptions

- The nature of the EQA material
- The procedure for defining the target value
- The data set to which the APS are applied
- The analytical quality being measured
  - Bias, imprecision, total error
- The rationale for the selection of the APS
  - Passable, satisfactory, favourable, aspirational

UK NEQAS Haematology Performance Scoring

- The Deviation Index

$$DI = \frac{R - M}{HSD}$$

- Analytical Performance Score
  - Calculated from the DI values of the most recent 6 samples
  - DI truncated to a maximum of 3.5
  - Retrospective, long-term measure of performance
  - Action signal = score equal to or greater than 100

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Troubleshooting EQA

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Registration and reporting

- Are you registered in the correct instrument group?
- Have you tested the correct specimens?
- Have you reported your results in time?
- Have your results been entered correctly by the scheme (non-web entry)
- Have you transposed specimens or results?
- Have you reported your results in the correct units?

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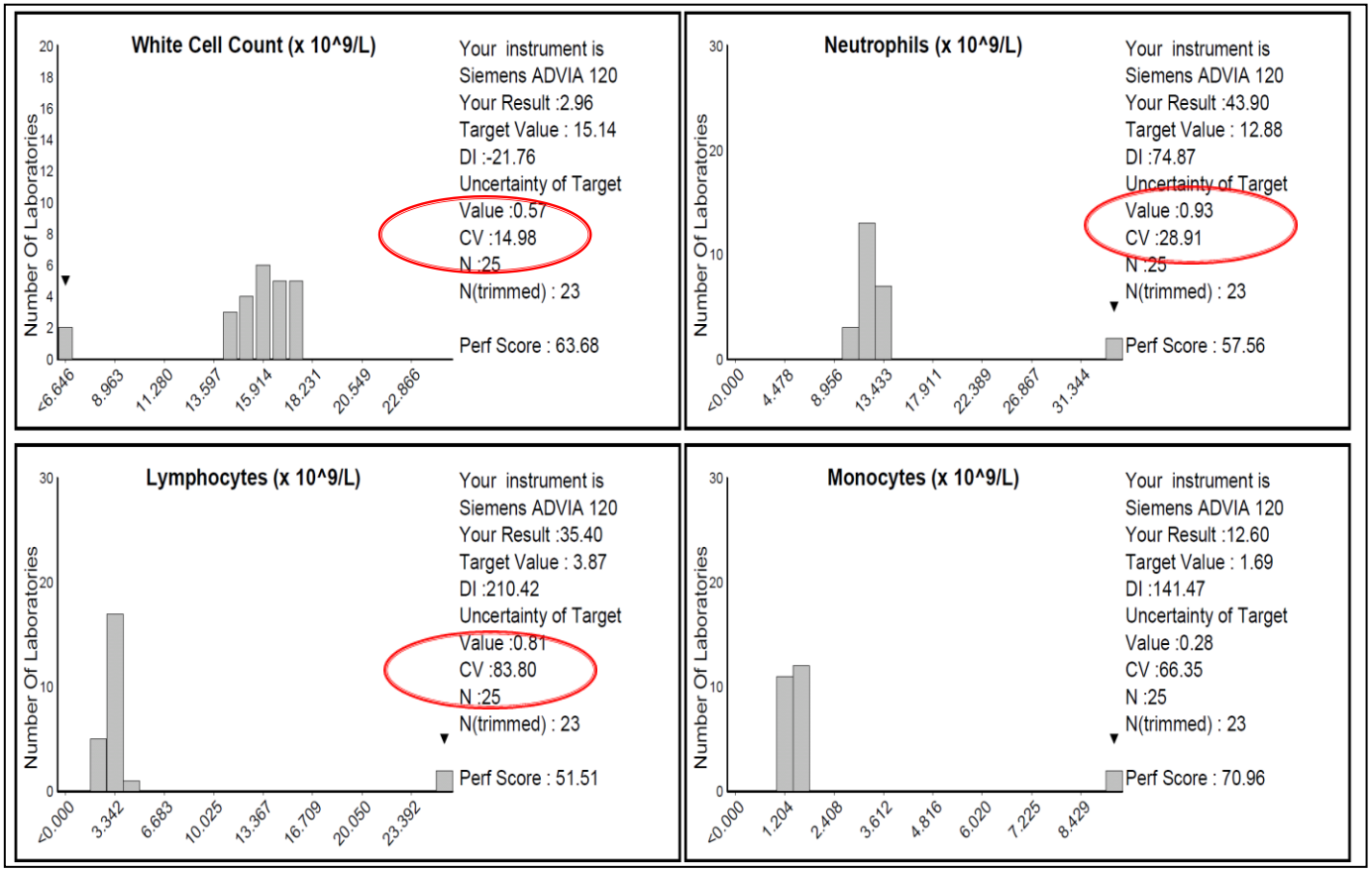
Statistical analysis

- How many instruments are in your peer group?
- What is the composition of your peer group?
- Do you cross-calibrate different analyser models?
- Were there problems in recent surveys that might still be affecting your score?

Examples of error – ADLC



Draft results – not released!!

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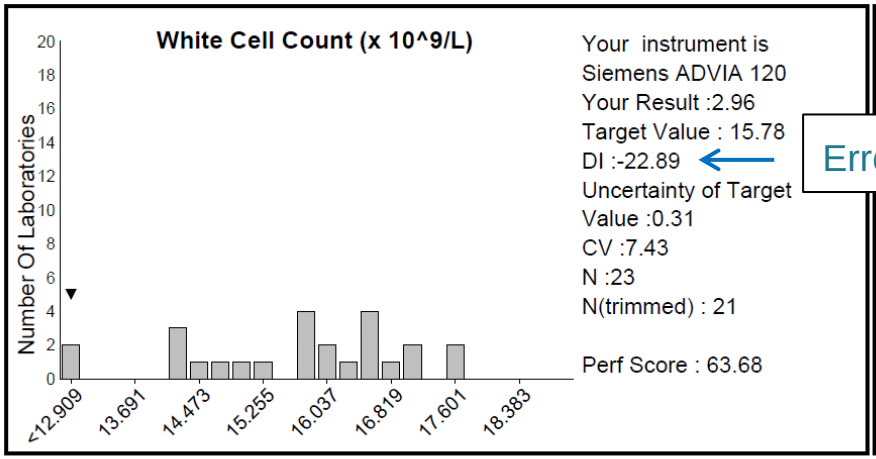

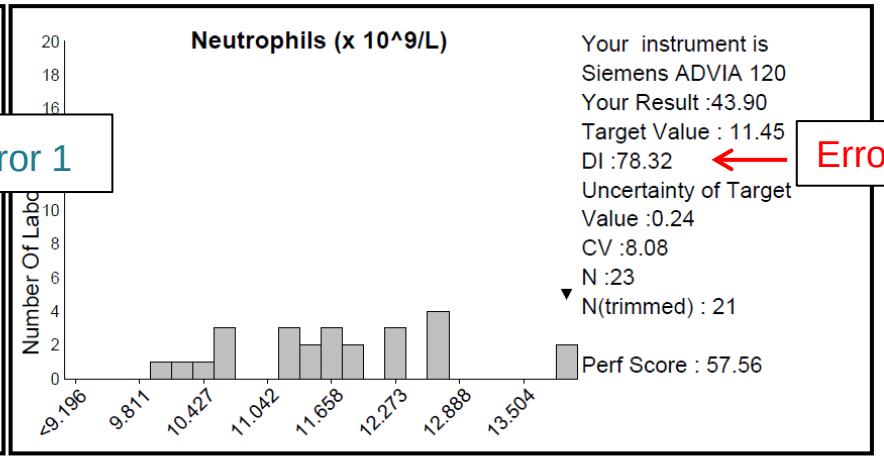

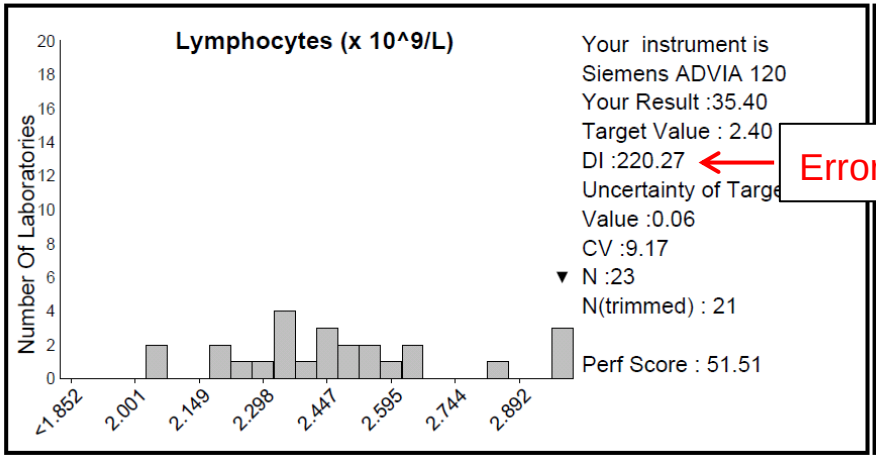

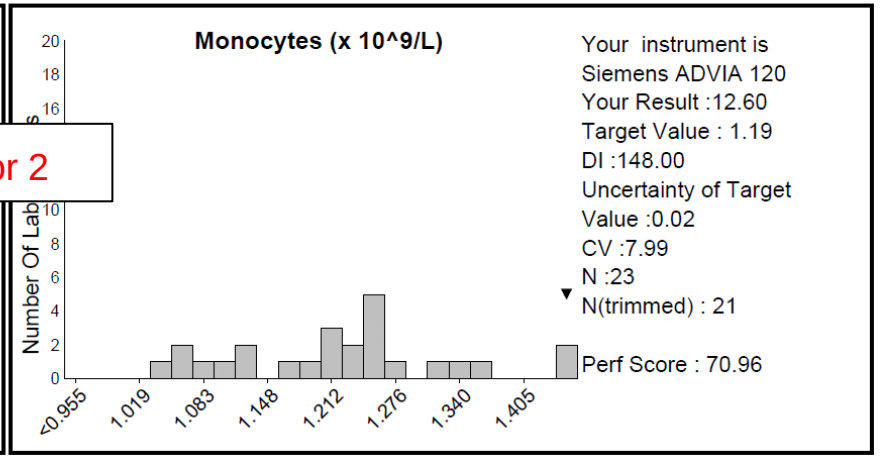

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Specimen analysis

- Are the specimens in date/in good condition?
- Did you store the specimens correctly after receipt?
- Were the specimens mixed / reconstituted / handled correctly prior to analysis?
- Have you tested the specimens in the correct mode or according to the instructions?
- Should you request repeat specimens to exclude specimen quality issues?

Could there be a real problem?

- Are your IQC results satisfactory (*really*)?
- Is maintenance up-to-date?
- Was there a change (personnel, maintenance, reagents, calibration etc.) made that correlates with the change in performance?
- Have you made a calculation error?
- Could patients' results be affected?

Examples of error – Hb

Specimen	DI	Comment
1603FB1	-3.75	
1603FB2	0.14	
1602FB1	-3.63	
1602FB2	-3.09	
1601FB1	27.65	Random error?
1601FB2	-3.74	
1512FB1	Nil return	
1512FB2	Nil return	
1511FB1	-2.58	
1511FB2	-2.3	
1510FB1	-3.27	
1510FB2	28.68	Random error?
1509FB1	-2.08	
1509FB2	0	
1508FB1	-2.96	
1508FB2	-0.84	
1507FB1	-0.13	
1507FB2	-0.61	
1506FB1	-2.01	
1506FB2	-0.97	
1505FB1	Nil return	
1505FB2	Nil return	
1504FB1	95.43	Random error?
1504FB2	0.04	

POCT site

Mixing error: training issue

Maintenance issue: salt build-up on instrument probe

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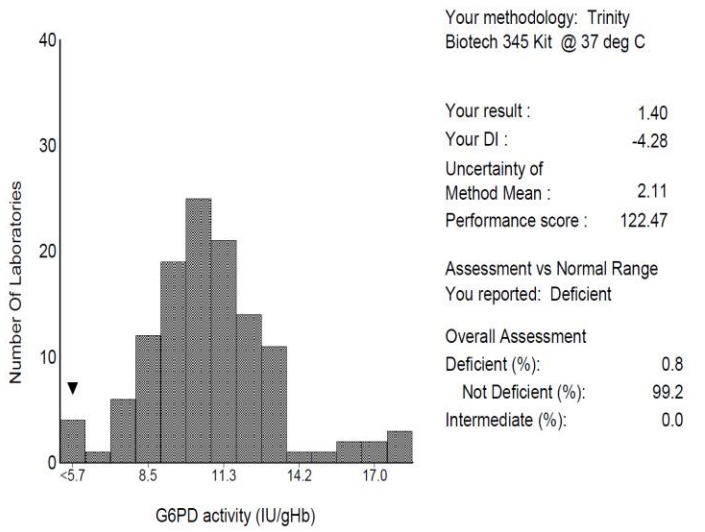
Examples of error – G6PD



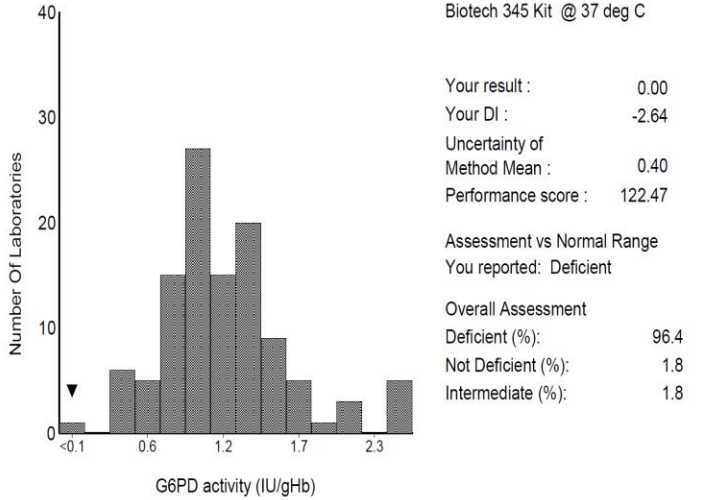
Your methodology: Trinity Biotech 345 Kit @ 37 deg C

Your result :	1.40
Your DI :	-4.28
Uncertainty of Method Mean :	2.11
Performance score :	122.47

Assessment vs Normal Range
You reported: Deficient

Overall Assessment

Deficient (%):	0.8
Not Deficient (%):	99.2
Intermediate (%):	0.0



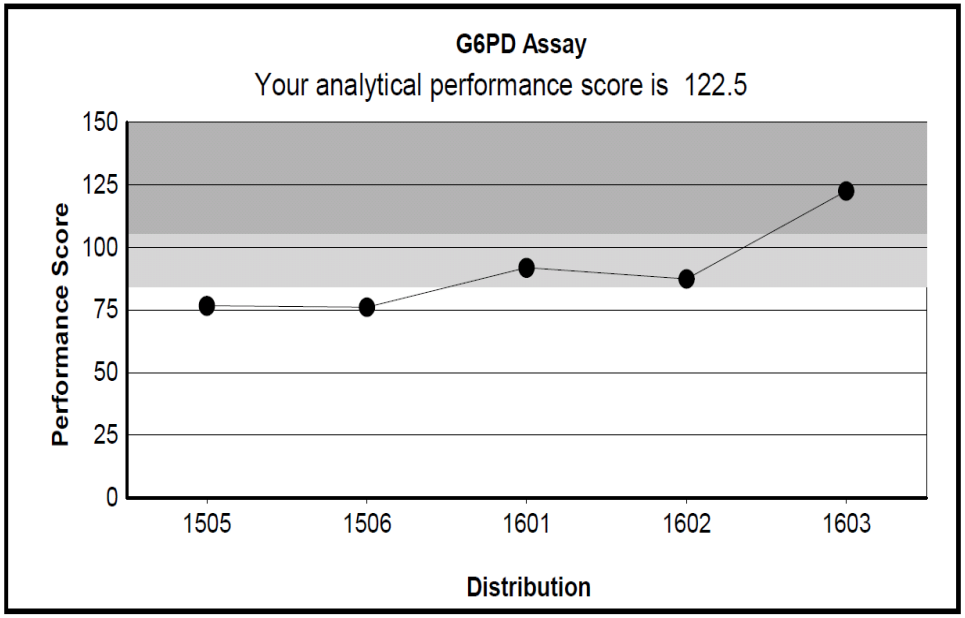
Your methodology: Trinity Biotech 345 Kit @ 37 deg C

Your result :	0.00
Your DI :	-2.64
Uncertainty of Method Mean :	0.40
Performance score :	122.47

Assessment vs Normal Range
You reported: Deficient

Overall Assessment

Deficient (%):	96.4
Not Deficient (%):	1.8
Intermediate (%):	1.8



- Error in Hb units -> results 10x too low
- 62 patients affected
- 43 incorrectly diagnosed as G6PD deficient

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Could there be a real problem?

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- Have you made a calculation error?
- Could patients' results be affected?

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Unsatisfactory sample quality

We may withdraw specimens from analysis or scoring on occasion:

- A problem with the survey material batch was detected after distribution (stability, preparation, labelling, contamination)
- A problem for a specific group of participants occurred (technology, method, region)
- Uncertainty of the target value too great
- Lack of consensus in results
- Statistical analysis – CV% too great, changes in numbers of instruments etc.

Summary

- EQA services continue to expand in terms of geography, technology and concepts
- Assessing performance assumes
  - Quality can be defined and quantified
  - Standards reflect the quality of service
- Performance standards must not lead to the lowest common denominator
- Acceptable performance standards allow effective comparison of performance
- Understand errors to investigate out-of-consensus EQA result

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