

Quality Assessment of Immunology Laboratories by UK NEQAS

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UK NEQAS Organisation- background

UK NEQAS Objectives

- “ Not for profit organisation and INDEPENDENT
- “ **UK NEQAS** has evolved over 40 years and now provides a comprehensive **world-wide service** that enables laboratories to fulfil quality goals and facilitate optimal patient care
- “ To provide laboratories with an assessment of performance both within the laboratory and in relation to that of other laboratories
- “ To monitor and improve the between-laboratory agreement

The primary role of UK NEQAS is education

Confidentiality

Laboratory Code Numbers

All UK NEQAS programmes operate on a confidential basis with participant laboratories identified by a unique code number

Links with Professional Bodies

- “ Schemes have close links with Professional Bodies through Steering Committees and Specialist Advisory

- “ Groups which advise organisers on the scientific content of schemes
 - . The appropriateness of the investigations surveyed
 - . Nature of the specimens distributed
 - . Number and frequency of specimen distributions
 - . Source of target values
 - . Data analysis and performance assessment
 - . Data presentation
 - . Communication with participants
 - . Communication with the diagnostic industry
 - . Research and development for the programme

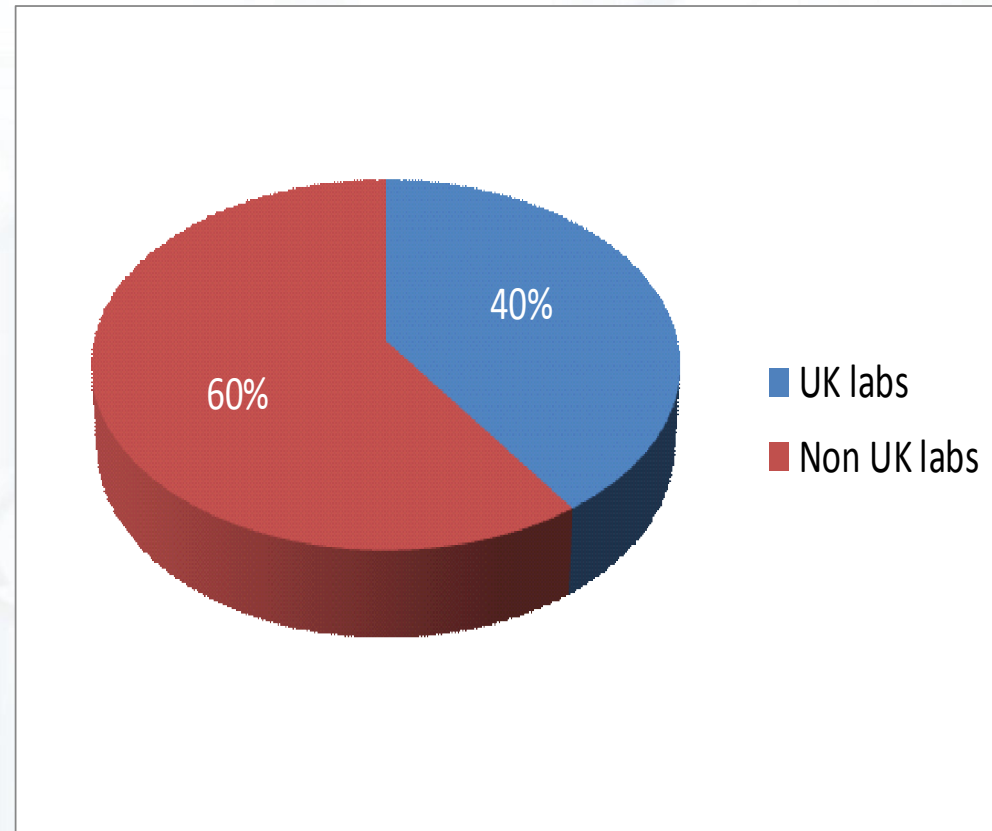
UK NEQAS Immunology, Immunochemistry & Allergy

www.immqas.org.uk

Participant numbers - 2014

“ Currently
approximately
2000 labs
participating
worldwide

“ CSCQ
distributors
within
Switzerland



UK NEQAS Immunology, Immunochemistry & Allergy, Sheffield: ISO 17043 accreditation

AUTOIMMUNITY (some mandatory in Switz.)

- “ General Autoimmune Serology (846)
- “ Antibodies to Nuclear & Related Antigens (724)
- “ Phospholipid Antibodies (465)
- “ Neutrophil Cytoplasmic & GBM Antibodies (491)
- “ Acetylcholine Receptor Antibodies (85)
- “ Paraneoplastic Antibodies (123)
- “ Bullous Dermatitis (163)
- “ Coeliac Disease (543)
- “ Diabetic Markers (126)
- “ Ganglioside antibodies (59)

IMMUNOCHEMISTRY

- “ C Reactive Protein (579)
- “ Ultrasensitive C Reactive Protein (129)
- “ Beta 2 Microglobulin (140)
- “ CSF Proteins & Biochemistry (384)
- “ CSF Haem Pigments (186)
- “ CSF IgG Oligoclonal Bands (137)
- “ CSF Beta 2 transferrin (42)
- “ Bone Metabolism Assays (112)
- “ Alpha 1 Antitrypsin (43)
- “ Tryptase (159)

ALLERGY / IMMUNODEFICIENCY

- “ IgG Subclasses (140)
- “ Specific Microbial Antibodies (88)
- “ Antibody to Fungal & Avian Antigens (106)
- “ Total IgE (212)
- “ Allergen Specific IgE (361)
- “ C1 Esterase Inhibitor & Functional Complement Assays (138)
- “ Interferon Gamma Release Assays (TB) (160)

ONCOLOGY

- “ Prostate Specific Antigen (311)
 - Total PSA
 - Free PSA
 - Complex PSA
- “ Tumour Markers (226)
 - CA125
 - CA153
 - CA199
 - NSE
- “ Monoclonal Protein Identification (381)

Factors influencing choice of EQA Scheme



- ✓ Accreditation status: ISO 17043
- ✓ Range and number of EQA samples
- ✓ Frequency of distribution
- ✓ Commutable/ Challenging materials
- ✓ Management of poor performance issues
- ✓ Educational value
- ✓ Scheme management and development
- ✓ Post marketing surveillance

Materials used for distribution:

Distributed in liquid format (with preservative) and validated prior to dispatch

Pathological
single donor
human serum

Normal human
serum

International
Reference
Preparations
(IRPs)

Artificial material
produced in
house

Services provided by UK NEQAS IIA

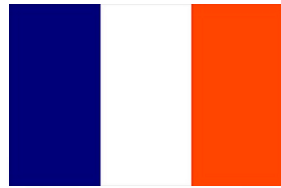
1) Optimal scheme design

- “ Assessment of assay performance across the entire measuring range and clinically relevant concentrations
- “ Appropriate number of EQA samples to assess
 - . Intra laboratory variation
 - . Inter laboratory variation
 - . Calibration issues within assays

2) Continuous education, training and support

- “ Use of EQA incident/root cause analysis forms to initiate troubleshooting**
- “ Educational commentaries associated with more challenging EQA samples**
- “ Meetings to facilitate informative discussions and sharing of good practice**
- “ Interactive training programmes and events**

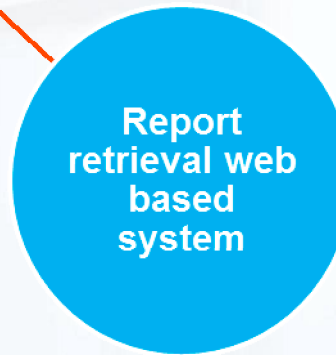
3) Multi-language facilities



Website



Result data entry web based system



Report retrieval web based system

Eligibility for Participation

- “ Participation is open to all diagnostic and research laboratories
- “ Diagnostic kit manufacturers and their agents are encouraged to subscribe to all relevant schemes on either a full participation, or an information only, basis

How are the targets defined?

Designated Response/Targets

“Laboratory returns assessed and a designated response is defined by several methods:

- . Consensus of results submitted
- . Review/comparison of results if sample distributed previously
- . Preselected reference group (panel labs)
- . Use of clinical history of material if available

Selection of a Reference Group

- “ Expert in the field or good reputation
- “ Variety of methods represented
- “ Good record in the EQA programme
- “ Status reviewed and monitored
- “ Includes UK and non-UK laboratories

Performance Monitoring - What is this and how is it done?

- “ Each scheme has criteria of satisfactory performance agreed by the appropriate NQAAP and EQA provider
- “ Performance criteria are reviewed on a regular basis to ensure
 - . Criteria are appropriate for assays/technology available
 - . Clinical appropriateness

Performance scoring:

2 methods utilised for performance scoring:

“ Qualitative schemes

- . Misclassification index scoring (MIS)

“ Quantitative schemes

- . Variance index scoring (VIS)

“ Need to be aware of performance criteria that you are being scored against

Misclassification Index

Sample 112-1 was a serum from a donor with SLE.

Sample 112-2 was a serum from a donor with SLE.

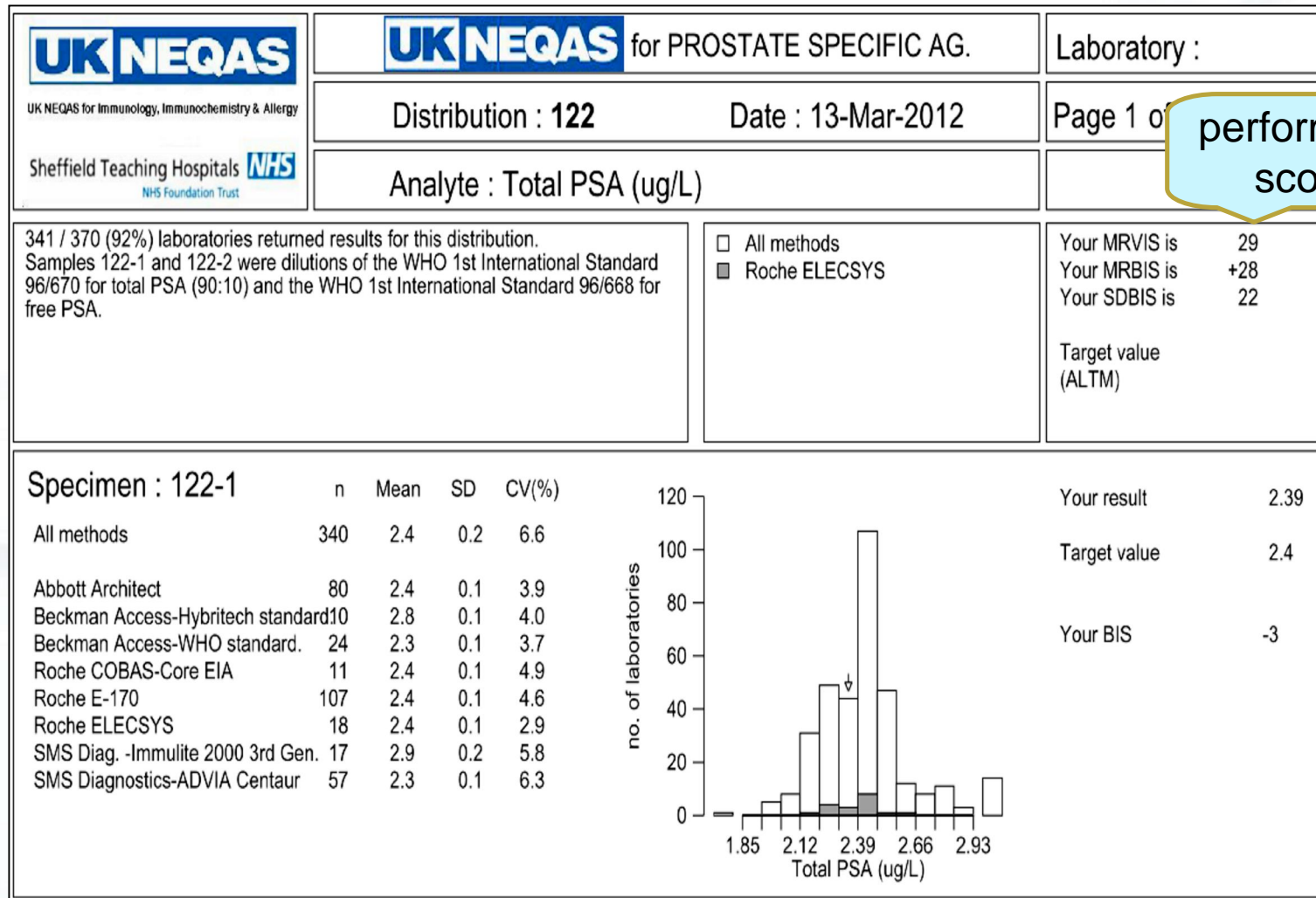
Sample	Analyte	Target Response	Your Response	Score
112-1	ANA	Positive	Positive	0
	dsDNA	Negative	Negative	0
	Centromere(EIA)	Negative	No Response	0
	ENA	Ro/La	Ro/La	0
	ANA Staining	Equivocal	Speckled	0

performance scores

Sample	Analyte	Target Response	Your Response	Score	Analyte MIS
112-2	ANA	Positive	Positive	0	1
	dsDNA	Positive	Positive	0	1
	Centromere(EIA)	Negative	No Response	0	0
	ENA	Ro/La	Ro/La	0	0
	ANA Staining	Equivocal	Speckled	0	0
				Total MIS	2

The current window of analysis comprises the previous six distributions.

Variance Index Scoring:



Performance criteria:

Individual laboratory performance is classified in terms of MRVIS or MIS scoring system over a time period-usually 12 months

	MRVIS (Quantitative)	MIS (Qualitative)
Ideal	<50	0
Good	50-100	1
Adequate	101-200	2
Poor	>200	>2

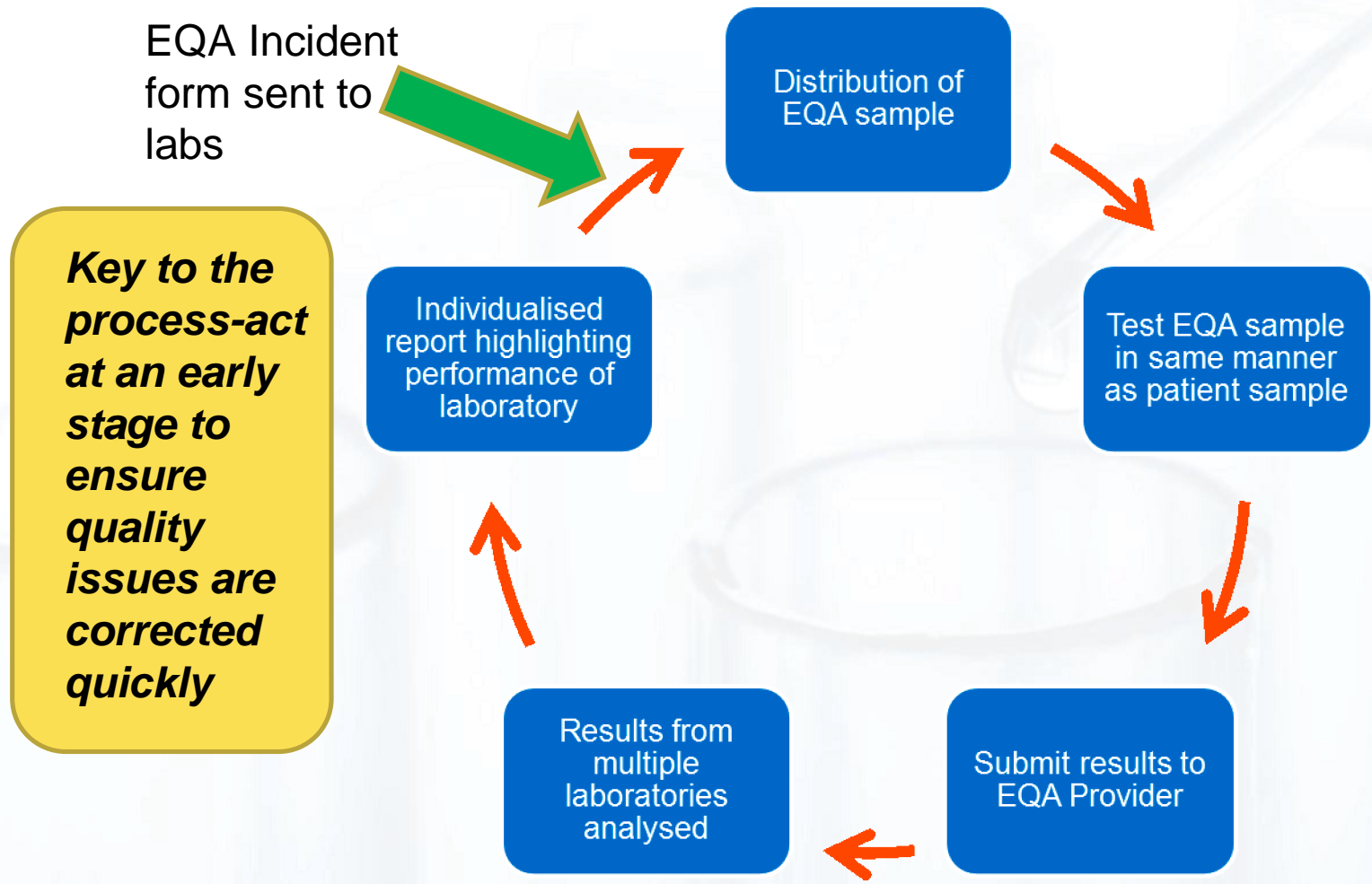
How is laboratory performance monitored?

Monitoring of Performance

- “ After each distribution performance of all laboratories (UK and non UK) is analysed
- “ Any laboratories that have persistently performed poorly and breached the criteria of poor performance are contacted (incl. NR)
 - “ Does lab realise that they are a PPP
 - “ What steps has the lab taken to rectify the problem
 - “ Is any assistance required from UK NEQAS e.g repeat samples?

The primary role of UK NEQAS is education!

How do we monitor performance?



Key to the process-act at an early stage to ensure quality issues are corrected quickly

Introduction of EQA incident form

What is it?

“An electronic form that needs to be completed by a suitable person within the laboratory

“Enables labs to undertake a root cause analysis following an incident within an EQA scheme

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UNITED KINGDOM

EQA Performance Issues – Incident Form

Following your laboratory's performance issues identified over recent distributions, can you inform us of the actions being taken by your laboratory.

Please complete the form and return to the above address by **Date**. We will then keep the completed form on file as evidence of actions taken to ensure quality performance of testing within your laboratory. This form will be available to you on request at any future date if required.

Laboratory number

Scheme / Distribution

Description of Problem

ROOT CAUSE

Has your laboratory identified the root cause of the recent performance issue(s)?
(e.g. transposition/ transcription/ sample handling/ reagents/ equipment/ staff training etc.)

Please provide details

IMMEDIATE ACTION

Please provide details

CONSEQUENCES/ RISKS

What consequences/ risks does this issue pose to patient care?
(i.e. Is it likely to affect patient results, would it affect clinical utility of test or decision making?
Is it a critical/ non critical incident?).

Please provide details

CORRECTIVE/ PREVENTATIVE ACTION

What procedures have been implemented to prevent reoccurrence of the performance issue(s)?
(e.g. issue corrected results for EQA or patient samples/ training of staff/ dissemination of knowledge/ SOP changes etc.).

Please provide details

FOLLOWUP/ REVIEW

What procedures will be used to review performance to ensure your corrective actions have been successful?

Please provide details

Completed by: _____ Grade: _____ Date: _____

Please provide as much evidence as possible to confirm your actions e.g. extracts from quality meetings. **Please note that if a response has not been received within 2 weeks your laboratory will be referred to NQAAP.**

ROOT CAUSE

“ Has your laboratory identified the root cause of the recent performance issue(s)?

e.g. transposition

transcription

sample handling

reagents

equipment

staff training etc

IMMEDIATE ACTION

CONSEQUENCES/ RISKS

“What consequences/ risks does this issue pose to patient care?”

“Is it likely to affect patient results, would it affect clinical utility of test or decision making? Is it a critical/ non critical incident?”

CORRECTIVE/ PREVENTATIVE ACTION

“ What procedures have been implemented to prevent reoccurrence of the performance issue(s)?

e.g. corrected results issued for EQA or patient samples/
training of staff
dissemination of knowledge
SOP changes etc

FOLLOW UP/ REVIEW

“ What procedures will be used to review performance to ensure your corrective actions have been successful?

e.g audit to review outcome of changes

Benefits to labs

- “ With one document a lab can provide evidence of a satisfactory approach to quality
- “ Undertaken a risk assessment which meets both internal and external governance needs
- “ Individual can demonstrate an educational event by undertaking a root cause analysis Æ CPD opportunities/educational feedback

Persistent poor performance

Persistent poor performance is defined as being in the poor performance category for two or more successive distributions of samples **or** having an unsatisfactory return rate

Swiss laboratories

UK NEQAS and CSCQ have a collaboration agreement. CSCQ can be contacted for any question or problem concerning the EQA-participation, the understanding of the scoring or the monitoring of the performance.

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