See the Complete Picture with

RIQAS

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- Joined Randox in….
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Agenda

- RIQAS Overview
- Why is EQA Important?
- EQA Guidelines
  - Frequency
  - Clinically relevant levels
  - ISO/IEC 17043 accredited
  - Commutability
  - Reports

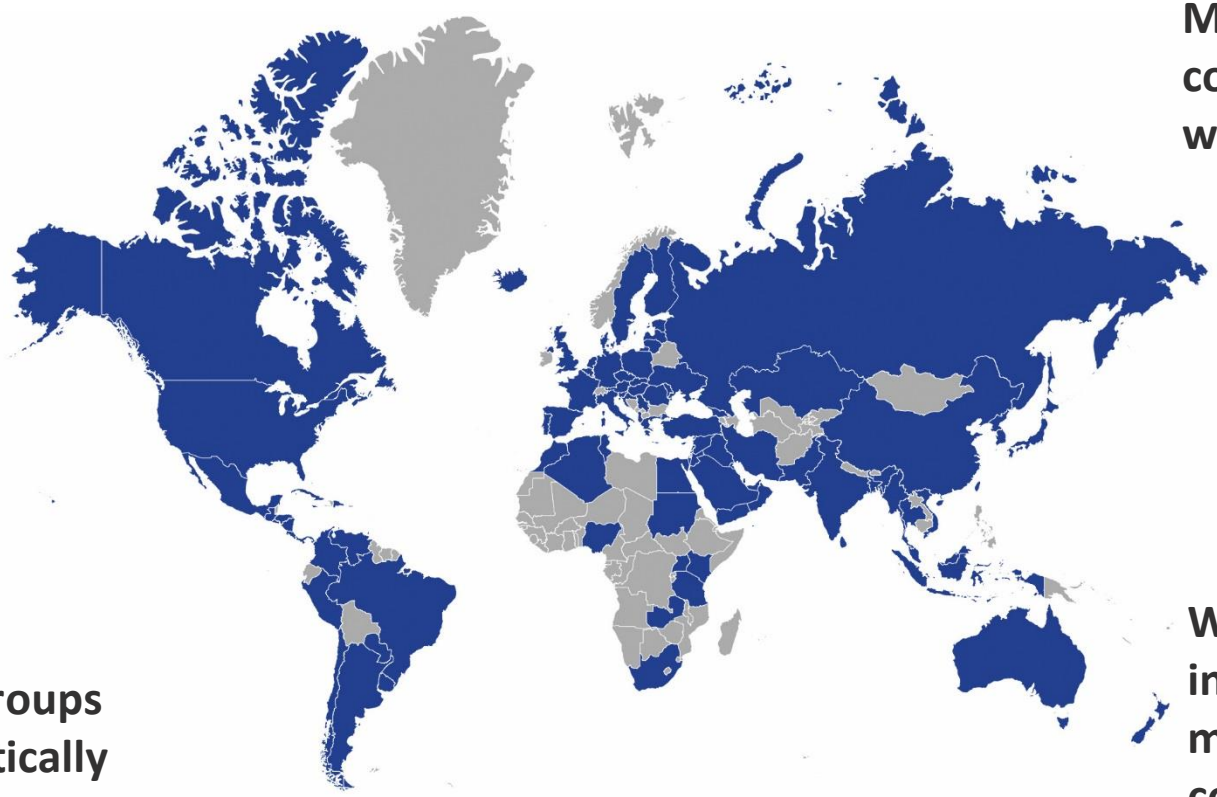
Brain Teasers

- There are 3 houses – one is red, one is blue and one is white. If the red house is to the left of the house in the middle and the blue house to the right of the house then **where is the white house?**
- The maker doesn't need it, the owner doesn't want it and the user doesn't know he's using it – **what is it?**
- A peacock laid an egg on the top of a hill. One side of the hill is rocky, the other side is smooth. **Which way would the egg safely roll to the ground?**

RIQAS Overview

Over **35,000** laboratory participants

More than **123** countries worldwide

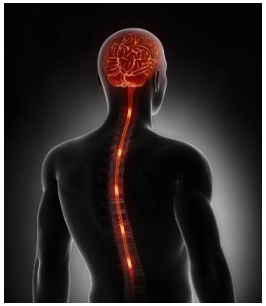


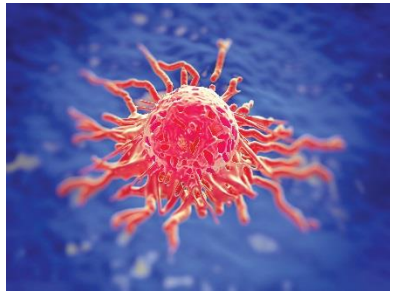
Larger peer groups = more statistically relevant data

Wider range of instruments and methods covered

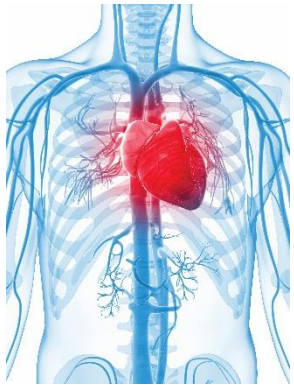
32 Flexible EQA Programmes

- Ammonia/Ethanol
- **Anti-TSH Receptor**
- Blood Gas
- BNP
- Cardiac
- **CSF**
- Coagulation
- **CYFRA 21-1**
- Clinical Chemistry
- ESR
- Haematology
- HbA1c
- Human Urine
- Immunoassay
- Immunoassay Speciality 1
- Immunoassay Speciality 2





- **Immunosuppressants**
- Lipid
- Liquid Cardiac
- Maternal Screening
- Serology EBV
- Serology HIV-Hepatitis
- Serology Syphilis
- Serology ToRCH
- Specific Proteins
- **Sweat Testing**
- Therapeutic Drugs
- **Trace Elements Blood**
- **Trace Elements Serum**
- **Trace Elements Urine**
- Urinalysis
- Urine Toxicology



Why is EQA Important?

ISO 15189: 2012 – Section 5.6.3

ISO 15189

"The lab shall participate in an interlaboratory comparison programme(s) (**such as an external quality assessment programme or proficiency testing programme**) appropriate to the examination and interpretation of examination results. The laboratory shall **monitor the results of the interlaboratory comparison programmes and participate in the implementation of corrective actions** when pre-determined performance criteria are not fulfilled…"

Why is EQA Important?

- The **World Health Organisation** defines EQA as, *"a method that allows for comparison of a laboratory's testing to a source outside the laboratory"*.
- Enables an **objective review** of the quality of the results you produce
- Highlights your dedication to **ensuring laboratory competence** in medical diagnostics
- EQA exposes any unanticipated **areas of underperformance**
- Allows you to **identify any training needs**
- Supports peer group comparison on a **regional, national or international** level

World Health Organization

Benefits of EQA

- Provides management with a **holistic view of test system performance** that IQC alone cannot provide
- Identify **potential equipment or reagent faults**
- **Reduce the cost and time** associated with expensive repeat tests
- **Compare performance** with other analytical methods
- **Initiate corrective action** and evaluate the effectiveness of corrective actions
- Provides an **independent assessment of laboratory accuracy** for added confidence in patient test results

EQA Guidelines - Frequency

There is currently a lot of debate within the industry regarding **how often** a lab should carry out EQA

Poll

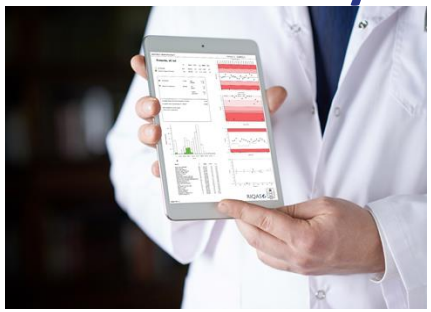
- Raise your hand if…
  - You carry out EQA testing **3 times** per year?
  - **More than 3 times** per year?

EQA Guidelines – Frequency

- Some competitor programmes only run 3 samples per year! Is this really enough?
- EQA is required to answer the questions IQC cannot
- With fewer testing events errors may not be identified until much later, leaving a period of several months before labs get their next report

Frequency Case Study

- Laboratory A noted when reviewing their **monthly EQA report** tests for Procalcitonin performed poorly
- However, the laboratory's first party IQC results were reporting that the Procalcitonin results **were in acceptable ranges**
- Upon reviewing the kit insert for the IQC it became clear that the Procalcitonin concentrations in level 1 and 3 were **not clinically relevant**
  - Therefore they were **not accurately assessing** the full range of the assay



EQA Guidelines – Clinically Relevant Tests

- **ISO 15189:2012** states "Interlaboratory comparison programmes chosen by the laboratory shall as far as possible provide **clinically relevant challenges** that **mimic patient samples** and have the effect of checking **the entire examination process** including pre-examination procedures and post examination procedures where possible"
- Therefore making use of EQA schemes which test the **full clinical range** of your instrument is essential
- As such you must ensure that the EQA programmes you employ are **fit for use**

Clinically Relevant Levels Example

- When measuring Troponin T the cut off value is **14ng/l**
- Patients who present to the hospital with a concentration **higher** than 14ng/l in their **blood are said to have had a cardiac event**
- Test results **lower** than 14 ng/l would indicate that **the patient is healthy or it is too early** to tell if a cardiac event has occurred

Are you still awake?

A man builds an ordinary house with **4 sides**, except each side has a **Southern exposure**. A **bear** comes to the door and rings the doorbell. **What colour is the bear?**

One more…

What belongs to **you** and yet **is used more by others than by yourself?**

EQA Guidelines – Commutability

- As with IQC material you must ensure the EQA scheme you employ is **fit for use**
- This means that the EQA scheme you select should **effectively assess the performance** of your instruments
- In order to do this the EQA material you employ should be **commutable**, i.e. behave in the same manner as a patient sample

EQA Guidelines – Commutability

- Using EQA material which contains **non-commutable components** will affect the performance of the sample
- As a result the EQA sample will not behave in the same manner as a patient sample – meaning you are **not effectively testing your instrument's performance**

EQA Guidelines – Peer Group

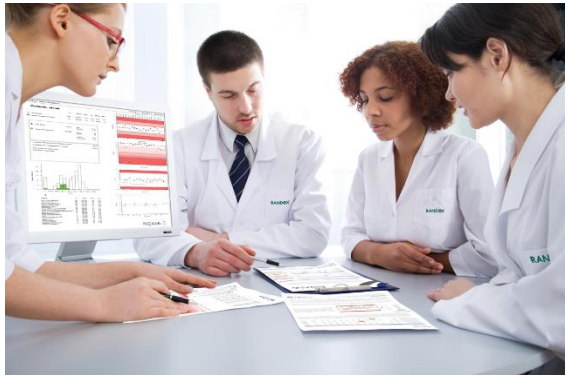
- To further ensure that your medical laboratory **meets quality and competency requirements** the use of an EQA scheme which **includes peer group reporting is beneficial**
- This provides the laboratory with **statistically relevant results for comparison** covering a wide range of instruments and methods
- Thus providing you with **confidence in the results you are releasing**

EQA Guidelines – Peer Group

- Peer Group data for the **instrument and method you use** can be vital to your quality processes
- You can **compare the performance** of your laboratory with other peers using the same programme
- RIQAS currently has **35,000 participants in 123 countries**

EQA Guidelines - Reports

- Every EQA scheme supplies their users with reports **after each testing event**
- It is important that the EQA scheme you select provides **a comprehensive report** which includes the **relevant data** you require to ensure your laboratory is producing **accurate and reliable results**



EQA Guidelines - Reports

- RIQAS Reports are provided within **72 hours** of online sample submission
- They are presented in a **1 page per parameter** format
- Compares results to all **methods, method group and instrument group**
- Up to **7 sub-reports** are displayed, providing a variety of performance indicators and comparisons to allow easy interpretation
- Compare to RIQAS **default limits or user defined limits** e.g. CLIA or Biological variation
- Levey-Jennings charts displaying results for the last **20 samples**

EQA Guidelines - Reports

- Unique target score chart allowing **at-a-glance assessment**
- **% deviation by concentration chart** for rapid assessment of concentration related bias
- Histogram charts **comparing performance to peers, all methods, method group and instrument group** can be viewed on one chart
- Multi-method stat section allows you to assess the **performance of other methods**
- Summary page conveniently **highlighting any poor performing tests** at-a-glance

Summary

- EQA enables an objective overview of the quality of the results your laboratory produces
- There are 5 key areas that you should consider when selecting an EQA scheme
  - **Frequency**
  - **Clinically Relevant Levels**
  - **Commutability**
  - **Peer Group**
  - **Reports**

Thank you for your attention!
Any questions?