RANDOX

EDUCATIONAL GUIDE

The Role of EQA in Quality Control

QUALITY CONTROL

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Quality Control (QC) is a vital process for laboratories to monitor the accuracy and precision of patient sample testing. Without QC, laboratory errors could go undetected potentially resulting in misdiagnosis and inappropriate or delayed treatment, all of which could be life threatening for the patient.

Taking An Holistic View

While Internal Quality Control (IQC) does a vital job it is only part of the overall quality management picture. For example, IQC doesn't address calibration issues, instrument systematic errors or wide 'acceptable' limits. Equally, while IQC effectively monitors the reproducibility or precision of laboratory testing, it doesn't enable laboratories to monitor bias or accuracy. Accuracy refers to how close the result generated by the laboratory is to the true value of the sample, in order to effectively monitor accuracy laboratories must participate in a high quality External Quality Assessment (EQA) programme.

External Quality Assessment (EQA), also known as Proficiency Testing (PT) provides:
"a system of objectively checking laboratory results by means of an external agency" (World Health Organisation, 1981).

Participation in an EQA programme is recommended for all laboratories, indeed ISO 15189 states:

'the laboratory shall participate in interlaboratory comparisons such as those organised by external quality assessment schemes'.

It is important that laboratories participate in an ISO 17043 accredited EQA scheme in order to verify the reliability of their results, IQC alone is not sufficient.

Real Life Examples

The following real life example highlights the importance of participating in a reputable EQA scheme in addition to daily IQC, in order to ensure laboratory quality, and prevent the release of incorrect patient results.

This laboratory was running the instrument manufacturers QC for their procalcitonin assay. Figure 1 shows that the lab's results were always within 1SD and showed no apparent bias. According to these results the laboratory has excellent precision and accuracy. However, when the lab participated in an EQA scheme (Fig 2.) they discovered this was not the case.

Fig 1: Graph of Internal Quality Control

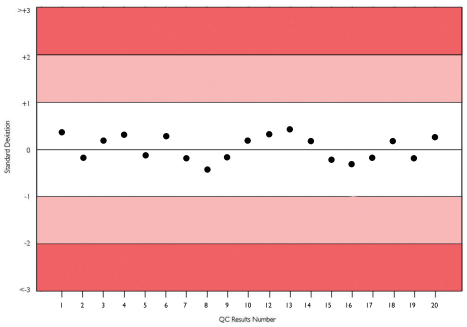


Fig 2: Graph of External Quaility Assessment Results

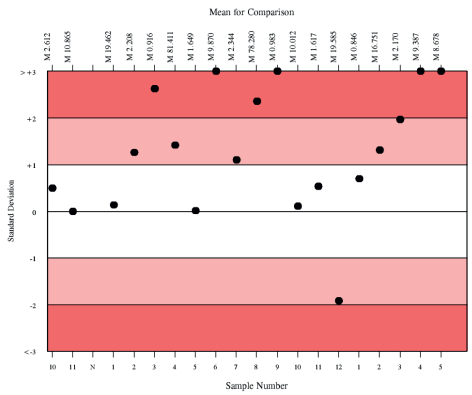


Figure 2 shows the results the lab received from their participation in an EQA scheme. The Levey-Jennings chart on the report clearly shows erractic performance which led to the identification of an instrument fault, that the IQC failed to detect.

How Does EQA Work?

EQA provides a means of periodically assessing laboratory performance in comparison with other laboratories using the same method and instrument. Unlike IQC, EQA provides an effective method of monitoring a laboratory's bias or accuracy through the analysis of samples of unknown concentrations otherwise known as 'blind samples'. It also enables assessment of the complete testing process including pre-analytical, analytical and post analytical phases.

After analysis, results are submitted to the scheme organiser for statistical evaluation. Laboratories will subsequently receive a report comparing their performance to that of other participants in the programme.

Benefits Of EQA

EQA plays an essential role in assuring laboratory quality by supporting daily IQC. It facilitates interlaboratory performance comparison, bringing greater standardisation in diagnostic testing.

EQA has a number of functions:

- It compares different analytical methods
- Initiates and evaluates corrective actions
- Provides an objective view of test system performance that IQC alone cannot provide
- It improves interlaboratory agreement and helps raise standards
- It maintains and improves the analytical quality of laboratory tests
- It helps laboratories detect equipment failures, identify reagent problems and review staff competency

In short, participation in an EQA scheme will give labs greater confidence (and evidence) that the patient results they are reporting are reliable and accurate. Quality results will reduce time and labour costs, and most importantly provide accurate patient diagnosis and treatment.

What Should A Laboratory Look For When Choosing An EQA Scheme?

Firstly, make sure the scheme is inspected and accredited to international standards of best practice. It should be accredited to ISO/IEC 17043:2010, which outlines the general requirements for proficiency testing. Accreditation to this level gives scheme participants confidence that the scheme is fit for purpose.

The frequency of programme reporting is also important, the more frequent the better. Some international schemes offer both bi-weekly and monthly reporting enabling identification of errors sooner.

It is vital that EQA is performed regularly. Many EQA schemes operate on a quarterly basis or even less frequently, under these circumstances laboratories are unable to identify errors in their test system until they receive their next EQA report which could be several months away.

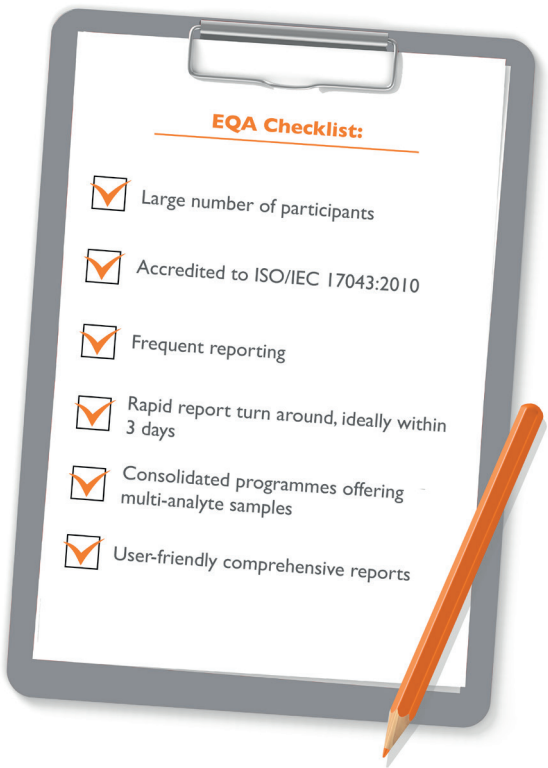
In such instances laboratories are faced with the following questions; when did the error occur and how many patient samples have potentially been affected?

Some schemes can turn around reports within 24-72 hours, this allows corrective action to be implemented immediately with minimal effect on laboratory operations.

> *"External quality assessment programmes should as far as possible, provide clinically relevant challenges that mimic patient samples"* ISO15189

A good EQA scheme will have a large number of international participants – the larger the peer group the better.

This ensures an extensive database of results for many analytical methods and increases statistical validity. By participating in an international scheme (as opposed to a national scheme) laboratories have access to peer data giving a truly global representation of manufacturer's instruments and diagnostic kits.



As part of your EQA scheme you will be provided with 'blind' samples to be analysed as if they were patient samples. Analytes should be provided in a realistic range of concentrations, allowing assessment of normal and abnormal ranges, both analytical and clinical decision levels should be covered. It's important that samples should be stable, but free from interfering preservatives or stabilisers, and offer a matrix consistent with a human sample. Labs should be confident that EQA material mirrors that of patient samples.

EQA programmes should offer flexibility to customise the programme to suit the laboratory's unique requirements. Some schemes offer effective consolidation of programmes through the provision of multi-analyte samples. This allows laboratories to significantly reduce the number of EQA programmes needed to cover their assay range, thereby increasing productivity and efficiency while still meeting their EQA needs.

Perhaps the main value of participating in an EQA scheme lies in the report generated by the scheme provider. Not only should reports be comprehensive covering a wide range of statistics and charts it's also important they are user-friendly and easy to interpret. Look out for reports that provide a means of visually assessing your laboratory's performance over time.

Supplementary EQA Schemes

If your existing EQA scheme does not fully meet your laboratory needs you could benefit from supplementing your existing scheme with individual programmes from another international quality assessment scheme. Completely changing EQA providers can be a tricky proposition for some laboratories, particularly if you are part of a lab chain.

By supplementing your existing scheme with individual programmes from another EQA scheme you could benefit in a number of ways, for example greater programme frequency, access to less routine programmes and multianalyte programmes.

Conclusion

By looking further than your EQA scheme, you may be able to fulfill your complete EQA needs by covering your full assay range, increasing productivity and ultimately saving your laboratory time and money.

If you would like further information please contact:

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ACUSERA True third party quality controls

As a world leading manufacturer of multi-analyte true third party controls, thousands of laboratories rely on Randox to accurately assess test system performance and ultimately empower them with the confidence required to release patient test results. With more than 390 analytes available, the number of individual controls required to cover your test menu is significantly reduced while simultaneously reducing costs, time and storage space. A choice of formats is available, including liquid or lyophilised, which ensures flexibility and suitability for laboratories of all sizes and budgets. Many features of the Acusera range can help you to meet ISO 15189:2012 requirements:

- Designed to react to the test system in the same manner as a patient sample, helping to reduce inconvenient shifts in QC results when reagent batch is changed and ultimately providing a true indication of laboratory performance.
- The presence of analytes at key decision levels ensures accurate instrument performance and eliminates the need for additional low/high controls at extra expense.
- Manufactured independently from any instrument, the Acusera range delivers unbiased performance assessment with any instrument or method, while eliminating the need for multiple instrument specific controls.

Product Portfolio

Antioxidants | Blood Gas | Cardiac Markers | Routine Chemistry | Coagulation | Haematology | Diabetes Immunoassay | Immunology | Lipids | POCT | Therapeutic Drugs | Toxicology | Urine Chemistry

Uniquely combining more than 100 analytes conveniently in a single control, laboratories can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.

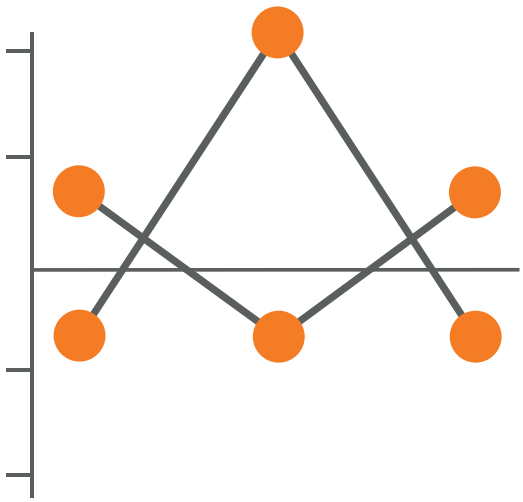
ACUSERA 24•7 Interlaboratory Data Management

Designed for use with the Acusera range of third party controls, the Acusera 24•7 software helps laboratories monitor and interpret their QC data. Access to an impressive range of features, including interactive charts, the automatic calculation of Measurement Uncertainty & Sigma Metrics and live peer group data generated from our extensive database of laboratory participants, ensures Acusera 24•7 is the most comprehensive package available.

- Advanced statistical analysis with automatic calculation of performance metrics including; Sigma, UM, TE & %Bias.
- Instantly discover how you compare to your peers with peer group statistics updated live in real-time reducing time and money spent troubleshooting.
- Interactive charts allowing you to add events and multiple data sets for quick and easy performance monitoring.
- Automated data import with bi-directional connection to LIMS (eliminating manual data entry).

Software Features

Dashboard | Result History | Interactive Levey-Jennings Charts | Interactive Histogram Charts
Performance Summary Charts | Statistical Analysis Report | Statistical Metrics Report
Uncertainty of Measurement Report | Exception Report | Peer Group Statistics | Acusera Advisor
Audit Trail Report



'The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality controls rules are violated and indicate that examination results are likely to contain significant errors the results shall be rejected… Quality Control data shall be reviewed at regular intervals to detect trends in examination performance'.

ISO 15189:2012

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