

MQP – 014
EDITION 6EQA HANDBOOK**A participant information brochure**

- EQA offers a means of measuring laboratory performance in relation to the general accuracy of tests performed by laboratories across the nation.
- It also increases patient and physician confidence in a particular laboratory. This enhanced confidence reduces overall costs of medical care related to diagnostic testing.
- Typically, a laboratory that performs well on EQA also provides accurate testing results for clinicians.
- There is a well documented educational value for the laboratory from EQA.

From CLIA (USA). www.hcfa.gov/medicaid/clia/pertmeas.htm

What is an EQA?

EQA is:

- An essential part of a quality system for labs
- A regulatory requirement for laboratories seeking accreditation through SANAS
- Designed to help labs identify and resolve analytical problems
- Part of a laboratory's accuracy and precision assessment system

What is special about Thistle QA?

- Thistle QA was the first organisation in South Africa to gain EQA accreditation through SANAS; firstly according to ISO Guide 43 and more recently ISO 17043.
- Many EQAs are international
- Data is stored securely and permanently
- Full participant confidentiality is assured, unless this requirement is waived by the participant.
- We give full in-lab support, with FREE workshops, seminars & bench consultations
- All our teaching carries CPD points.
- We do not subcontract any part of our services.

Who takes part?

Twelve countries in Africa are enrolled directly in programmes run by Thistle QA. Our direct database is approaching 3000 laboratories/ instruments. Both private and state laboratories take part.

Through our data-share facility with Randox (UK) results from 60 countries are included in our database.

The total database available to labs in Africa through Thistle QA is now over 6000.

Thistle QA is truly both local and international.

What material is used?

We buy the best we can find at the best prices.

Only reputable suppliers are used for our material, which is always designed with Africa in mind.

The homogeneity and stability of our material is monitored according to the requirements of ISO 17043.

What can I join and when?

Lists of all available EQAs, and analytes covered are available by fax or e-mail on request. The lists are always changing, so call us for an update.

Despite the official starting dates, we almost always have an excess of material, so you can join any EQA at almost any time. We won't charge you for a portion of an EQA, so ask if any material is available for the EQA of your choice. The official starting dates are as follows.

Immuno Assay
Lipids
Human Urine
Blood Gas
Liquid Cardiac
Coagulation
HBA1C

January & July

Differential Slides
HIV Serology
CSF

February & August

Clinical Chemistry
Haematology
Therapeutic Drugs
Human Proteins
Cardiac
CTS (Forensics)

March & September

Clinical Microbiology
Pregnancy
ESR

April & October

Food Micro

May & November

How do the EQAs operate?

Once you enrol, we send you a kit, usually with enough samples to cover a six month period. With the kit comes an instruction sheet and sheets for you to fill in your results. This results sheet already has your own unique QA Number on it.

In addition, we send you a Participation Certificate.

The instruction sheet has lots of important information and it must be read carefully. For example,

- Dates of analysis, or the final date by which we must receive your results.
- Safety and disposal details for handling the sample
- Reconstitution or mixing details
- The important recommendation that you analyse our samples exactly as if they were patient samples

Turn-around times?

Most of our EQAs work on a 7-10 working day turn-around-time. This means your reports are mailed to you or emailed via PDF within 7 - 10 working days after the final analysis date. Of course, we have little control over postal delays, but with the PDF system reports can be received a lot quicker. Most of our reports are available electronically.

What type of reports is distributed?

There are few limits to what is available. The routine reports have been designed to satisfy most of the needs of a busy routine laboratory - but if they don't suit you, give us a call. We will design and supply what you need. Roughly, the following are available.

- Weekly lab reports, with Levey-Jennings charts, SDIs and Clinical CVs, and a historical evaluation.
- Group reports for those with anything from 2 to 200 labs or instruments, to allow easy scanning for problems.
- Cumulative reports are also printed monthly for those with many sites to control.
- Management reports are produced monthly, if required, with a brief summary of overall performance.
- End of year reports, giving you a peer comparison, as well as comparison to our international data base, when applicable.
- Three of our EQAs carry SMLTSA points for CPD, namely Chemistry, Microbiology and Differential Slides. The relevant information and questions are distributed with reports monthly.

Currently, results can be sent to us via e-mail, from our web site (www.thistle.co.za) or through direct electronic data dump with certain groups of labs.

How are results statistically treated?

Esoteric analytes or those with low participant numbers are treated differently:

- a) A warning flag will print on the report when the participant number is low.
- b) These analytes are monitored at Management Review and will be discontinued after consideration by AdCom within stipulated time frames.

We use two different, but complementary systems of performance evaluation.

VARIABLE LIMITS

Firstly, we produce the usual statistical comparisons of mean and Standard Deviation (SD), sometimes called Standard Deviation Index (SDI). This can only take place after a data clean up procedure. We currently use a system called Chauvenet's Criterion. This is a uni-directional and highly sensitive system that identifies outliers from the mean based on the expected SDI for the number of data points. Consecutive passes are made until the data satisfies the Criterion. At this point, the mean and SD are calculated and all results, including those excluded by Chauvenet's Criterion, are calculated as numbers of SDI away from the mean. Traditionally, this system is used but has the limitation that 5% of labs will always fall outside the +/- 2 SD range, whether more or less labs should have been labeled as out of control. We have noted that the SDIs have tended to fall from the beginning of our EQA service, thus they are lower now than before. This means that overall performance, as measured by SDI, has improved. However, the continued use of SDI means that 5% of labs still are told they are out of control. If the labs who are outside the 2 SD limit improve their performance, the calculation will become tighter - and 5% will still be told they have a problem. The SD or SDI can thus be called a Variable Limit. It changes as performance changes, but always excludes 5%. It is still useful to use this purely statistical assessment. If your result falls outside 2 SDs, you are in the poorest 5% of performers for that test or analyte. This is definitely real and relevant.

FIXED LIMITS

We recently introduced the concept of "how well we need to do tests for the result to be clinically useful", in other words, Clinical Limits. These are percentage ranges about the consensus mean that are considered acceptable. The yardsticks we use for these fixed limits are those published in the USA document CLIA'88 (the Clinical Laboratory Improvement Amendment of 1988), and Biological Variation. In addition a local group of pathologists has evaluated these ranges and given us an African Acceptable Clinical Limits range. If your result is inside these percentage ranges of the consensus mean, it will be called "Acceptable" on your report.

How do I use this information?

The following advice applies to all EQAs except Microbiology, Differential Slides, HbA1C and Serology.

Our reports can show the following situations.

1. Your result is classified as Poor and is outside 2 SDs. This is the worst possible case and means that you are in the worst 5% of performers AND your result is not within the Clinical Limits as specified by CLIA'88. Clearly this needs action, which we discuss later in this Handbook.
2. If you are outside 2 SDs with either an Acceptable or Ideal classification, it means that you are in the worst 5% of performers BUT your result is within the Clinical Limits. You may not like being in the worst 5%. However, although this is still a problem worth noting and monitoring at least, it is obviously less serious than No. 1.
3. If your result is classified as Poor but you are within the 2 SDs, the opposite applies. You are not in the worst 5% of performers BUT you are outside the Clinical Limits. How can this happen? It means that more than 5% of performers fail the Clinical Limit, in other words, you are not alone.

Perhaps your method itself shows a bias or imprecision problem (ask and we'll do a query for you), or that the methodology is not good enough for clinical purposes. This is sometimes the case with certain analytes which are under tight homeostatic control in the human body, such as calcium, and thus clinicians use small serial changes in results to confirm therapeutic efficiency.

As a rule of thumb, category No. 1 is where to apply your attentions, at least to begin with. Thereafter, other problems become important.

Microbiology is simpler in some ways. The scoring system we use is based on CLIA'88. If you score more than 80% overall, you have achieved the required standard. If your score on average is less than 80%, it is fairly easy to see where you have lost points and investigate. Serology is much more difficult. The scoring system is based partly on Target Values and mostly on Consensus Values. It is difficult to say what an acceptable score is, but experience suggests that the 80% score may well apply here too. Neither of our slide EQAs have scores, as they are both regarded as largely educational in nature.

Where do I start investigating problems?

This is never simple. We always suggest, however, checking the simple things first.

1. Have we got the correct registration details for you? Each report shows the categories or instruments for which you are registered. If this is not correct, tell us. Do not change anything unless you have taken this simple step.
2. Have you made a reconstitution or transcription or mixing error? Is it possible that your reconstitution procedure was not followed? Could you have a problem with water quality? Are you sure you sent us the EQA sample results - could there have been a transcription error? Finally, for haematology, did you follow the mixing instructions? Again, check these stages before you make any changes.
3. Is the error you see a once-off? Do not over-react to a single error on EQA. Start your investigations, and certainly monitor your procedures, but do not begin altering calibration factors - not yet!

4. What does your Internal Quality Control (IQC) look like? If you have imprecision on both EQA and IQC, investigate and resolve. If on one only, investigate and resolve. BUT, if your IQC looks fine, without a bias, and you have a bias on your EQA, give us a call. We need to discuss the way in which you integrate your information from your IQC (for monitoring precision) and your EQA (for assessing accuracy).
5. If this information above is not clear, or does not answer your problem, either look on our web page, or give us a call. We are here to help.

What if I need to discuss my quality?

Call us. We offer lots of friendly help and advice, from telephonic discussions, to query reports, showing your specific instrument performance over time. Our database is huge and is there for your support...

**REMEMBER: IF IN ANY DOUBT -
GIVE US A CALL**