A PARTICIPANT INFORMATION BROCHURE

- External Quality Assessments (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 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 organization 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.
- Any changes in a proficiency testing scheme or operation will be communicated to you via email or published in Quality Matters.
- Fees for participation are indicated on the enrolment forms available on the website or on request from Thistle.

Who takes part?

Sixteen countries in Africa are enrolled directly in programmes run by Thistle QA. Our direct database is approaching 4000 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 22000.

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.

What can I join and when?

Lists of all available EQAs and analytes covered are available on the website or on request. The lists are always changing, so call us for an update. Please contact us as well for advice on eligibility criteria for participation if applicable.

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.

Immunoassay	**January & July**
Immunoassay Speciality I & II	
Lipids	
Human Urine	
Blood Gas	
Liquid Cardiac	
Coagulation	
HBA1C	
Maternal Screening	
BNP	
	February & August
HIV Serology	
CSF	
Clinical Chemistry	**March & September**
Haematology	
Therapeutic Drugs	
Human Proteins	
Cardiac	
CTS (Forensics)	
Ammonia & Ethanol	
Clinical Microbiology	**April & October**
Pregnancy	
ESR	
Infectious Disease	**June & December**
Differential Slides	
5-Part Diff	**July & December**

Confidentiality Policy

Thistle QA strives as far as possible to maintain the confidentiality of its participants. All results returned to Thistle QA and reports issued are identified by a unique participant number as required by ISO 17043. The laboratory name will also be used as an identifier for the internal control of the individual laboratory or group unless the lab does not require this. Participants can therefore elect to waive this confidentiality within the PT scheme for purposes of discussion and mutual assistance e.g. to improve performance. Confidentiality can also be waived by the participant for regulatory or recognition purposes.

Thistle QA will not reveal or discuss lab performance with any interested party on any of our EQA's without the written permission of the laboratory concerned. In exceptional circumstances, when a regulatory authority requires PT results to be directly provided to the authority by the PT provider, the participant shall be notified of this action in writing. All staff members have been informed during training which is documented about issues that might compromise their ability to be impartial to all participants on EQA programmes. All Participants confidential information and proprietary rights, including electronic storage and transmission are protected.

How do the EQAs operate?

Provided you have enrolled timeously, your kit will be dispatched approximately 2 weeks before the start date of the new cycle. Bear in mind that samples are imported and there may at times be customs issues which we do not have control over, but we will however endeavour at all times to get the samples out to you on time. Your kit usually has enough samples to cover a six month period. With the kit comes an instruction sheet, method questionnaire, results entry sheet, this EQA Handbook and waiver of confidentiality for you to complete. The results entry sheet already has your own unique QA Number printed on it. Please choose the method of your choice for each analyte listed on the method questionnaire and return together with your results to enable correct registration. Please note that we do not accept submitted results of zero (0) or Less than zero (<0.0). You should instead submit a value of 'Less than the Lower Limit of Detection' (<LLD) for that particular analysis environment, e.g. <0.001. The only exception to this is for the 5 Part Diff program and the normal Differential/Slide program where the possibility of any particular cell type not being present can be accepted.

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. Please note that Thistle QA does not accept any samples back from any lab if problems were experienced since we cannot guarantee the integrity of the samples. Labs are urged to discard those samples accordingly.
- Reconstitution or mixing details
- The important recommendation that you analyse our samples exactly as if they were patient samples
- Storage details
- Factors that could affect the testing if applicable
- Environmental conditions
- Recording and reporting of results
- Contact details for any enquiries
- Return policy of samples when applicable

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 in PDF format 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.

Collusion and/or falsification of results

Labs are informed on all instructions that collusion and/or falsification of EQA results are not good accreditation practice. If this is suspected, Thistle management must be informed and will investigate further and document all relevant information. Once this has been proven, the Quality Manager or HOD of the lab will be informed. The lab will be suspended and all reports will be halted until further notice. The lab management will then need to investigate further and take the necessary action. A follow up meeting with the laboratory management will be arranged. Once Thistle Management is satisfied with the outcome and disciplinary action, the laboratory will be re-instated and allowed to re-join the programme as per current analysis dates.

What type of reports are distributed?

Thistle QA only issues final reports, no prelim or interim reports are issued.
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 with sample 6 and sample 12. Chemistry will receive and additional cumulative report on sample 13.
- Management reports are produced monthly, if required, with a brief summary of overall performance.
- Three of our EQAs carry SMLTSA points for CPD, namely Chemistry, Microbiology and Differential Slides. The relevant information and questions for Microbiology and Differential Slides are distributed with reports monthly. Chemistry legends are posted on the website when available.

Currently, results can be sent to us via fax to email, 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?

We have three sets of statistical approaches when grouping results in a database, namely:

Stats Level 1: All results are grouped in the same method group, when the results are the same regardless of which method is used. This was our historical default group, and has been changed based on new information from suppliers, poor distribution of results (high SDs), bimodal distribution of results, customer comments / criticisms and AdCom recommendations.

Stats Level 2: Most methods give results within one modal distribution except for one method, e.g. dry chemistry.

Stats Level 3: Each method is statistically considered separately as none of the methods available for that test can be compared to any other, e.g. HDL on the Chemistry EQA.

a) Participants are permitted to use a method of their choice in analysing PT/ EQA samples. We use the information supplied to us by participants on our Method Questionnaire to allocate method groups to participants on our database, based on the methodology of their chosen method. In addition, we receive information on the instrument used and this allows us to allocate the participant to an instrument group, comprising labs using the same methodology on the same instrument. Labs are thus able to look at both aspects on our reports.
b) This aspect is assessed on an ongoing basis based on continued monitoring of SDs and information supplied by instrument and reagent suppliers.

We use two different, but complementary systems of performance evaluation. 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. All EQA programmes have a system to detect outliers which can be defined as "results that are clearly not part of the general data set". They can be caused by many things, such as:

- The wrong result being entered
- The wrong sample being analysed
- Incorrect reconstitution or mixing of the EQA sample

And of course, there could be something wrong with the testing itself in the lab.

We use robust mean and SD calculations along with Chauvenet's Criterion to exclude outliers followed by a 95% trim. Chauvenet's criterion 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 labelled as out of control.

We have noted that the SDIs have decreased since 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 are still 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.

We have performed preliminary evaluations of iteration (ISO 13528) to reduce our outlier exclusion to one system. This was successful and will be rolled out onto the various EQAs as we re-write our software.

In addition, we classify results as either poor or acceptable based on a percentage range about the mean called 'Clinical CV'. We introduced this concept of "how well we need to do tests for the result to be clinically useful", in other words, Clinical Limits. Each analyte has its own Clinical CV, these are percentage ranges about the consensus mean that are considered acceptable. Due to the wide range of results obtained from positive HIV and Pregnancy samples, we do not apply this criteria to these two programmes. 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.

Esoteric analytes or those with low participant numbers are treated differently. A warning flag will print on the report when the participant number is low. There are many times that you might see low data numbers on your report. Amylase for example has several hundreds of registered methods, quite a few of which have low numbers of users. This could be caused by labs using an old method that most labs have stopped using; or a new instrument method not commonly used as yet.

The question is: what to do when the data numbers are low.

We have three levels of warning printed on our reports:

- CAUTION: n <= 16
- CAUTION: n <= 10, use data with care
- CAUTION: n <= 5, data for information only

There are times when it is possible to work with the data when numbers are low and one yardstick that is useful is to look at the SD. If the SD is less than the SD printed for the method stats, then there is a good chance that the data is acceptable.

Please mail us to discuss this or attend one of our seminars where this is discussed in detail.

Of course when the number of data points is one, it means that you are the only lab using that specific method and instrument combination in which case the information is of no value whatever. Please contact us should you see this on your report and wish to discuss it with us.

How do I use this information?

The following advice applies to all EQAs except Microbiology & Differential Slides.

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.
4. 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.

Differential slide EQAs have no scores, as they are regarded as largely educational in nature. The only statistics calculated reported in this EQA are the mean and the expected upper and lower limits for each cell type. There is no statistical processing for morphology, tests & diagnosis. In each case the number of reported specific morphology observations, further tests and diagnoses is counted and reported by count of submissions. Where appropriate the expected values are reported, but this does not involve any calculations.

How to calculate your stats

Statistical Formulas

$$x = your\ result$$

$\bar{x}$ = mean result

$$n = number\ of\ participants$$

$$\sum = sum\ of$$

$$\text{Mean} = \frac{\sum x_1}{n}$$

$$\text{SD} = \sqrt{\frac{\sum (x-\bar{x})^2}{n-1}}$$

$$\text{CV} = \frac{SD}{\bar{x}} \times 100$$

$$\text{SDI} = \frac{x-\bar{x}}{SD}$$

$$\%\ \text{D} = \frac{x-\bar{x}}{\bar{x}} \times 100$$

Precision of Reported Statistics

You may notice that if you generate your own statistics many tools (e.g. Excel) will return Average, for example, too many more decimal places than you will see on your report. Thistle QA policy, as far as possible, is to display on your reports the average (or mean) to one decimal place higher than the typical precision of results submitted to Thistle QA for that particular analyte. We display the standard deviation to two decimal places higher than the typical precision of submitted results for that analyte. As an example, plasma Sodium is typically reported in whole integer values, e.g. 137, 147 mmol/l, on our reports you will see the average displayed as 134.8 as an example and 0.43 as the Standard Deviation. It should be noted that your reported SDI and %Deviation are calculated using the full precision of the mean and SD, not the rounded values as displayed on the report.

Homogeneity and stability

Homogeneity studies are not performed at Thistle QA since homogenous material is purchased from the suppliers. This data may be requested if available.

Stability

Thistle QA does not perform stability tests and relies on the suppliers to provide appropriate details. Suppliers will be asked to provide details of their stability systems and to provide data of the one pertaining to the material for the cycle about to start. In the unlikely event that stability testing will need to be performed in-house, e.g. due to a supplier being unable to supply adequate details, then this will be done according to MQPT-012 Stability Trials.

Stability studies are not conducted for diff slides. Participants are requested to comment on the quality of each slide received. These results are then available on the reports and actioned if needed.

Traceability

Most EQAs use consensus to establish the target value or mean and thus traceability is not required. Where the company supplying the material has target values or supplies CRMs as is the case with the Food Micro programme, certificates will be available on request. Other than in this instance, no target values, consensus means or assigned values are disclosed to any participant thereby ensuring that no participant gains an unfair advantage from early disclosure.

Uncertainty of the mean

Measurement Uncertainty of the calculated means displayed on the report is the calculated standard deviations displayed on the report (www2.southeastern.edu). Stats are not calculated according to assigned values, but consensus mean for all PT's except manual PT's like Differentials and Microbiology.

Use of Consensus vs. Reference as Assigned Value

As stated in IUPAC, Pure and Applied Chemistry 78, 145-196, 2006, "There are several possible approaches that the proficiency testing provide can employ to determine the assigned value and its uncertainty. All have strengths and weaknesses". It is suggested that the appropriate method for assignment will ultimately depend on the purposes of the scheme and the robustness of the statistics available. When considering a method for assignment, it is suggested that the following should be considered:

- Costs to the organiser and participants
- Legal requirements
- Need for independent assigned values
- Specific requirement for traceability

Using a reference laboratory or a certified reference material can be considered advantageous as the material is "tailored to the scheme requirements". However, "the principal disadvantage is that it may require disproportionate effort and cost if, for example, substantial investigations are required to validate the methodology for the material in question". In addition, reference values are available for very few parameters offered by Thistle QA. It is for these reasons that Thistle QA chooses the consensus of participant values as the method for assignment. The use of a consensus value is currently the most widely used method for determining the assigned value due to the low inherent cost and lack of additional work requirement. It has been stated that "long experience has shown that consensus values are usually very close, in practice, to reliable reference values provided by formulation, expert laboratory consensus, and reference values"
(IUPAC, Pure and Applied Chemistry 78, p160, 2006).

The principal disadvantage of participant consensus values is that their uncertainty may be too large where the number of laboratories used to derive the consensus value is small. Despite this disadvantage, there is a "large body of experience demonstrating that proficiency tests operate well using the consensus, so long as organisers are alive to the possibility of occasional difficulties and apply appropriate methods of calculation" (IUPAC, Pure and Applied Chemistry 78, p160, 2006).

Performance evaluations

We offer several documents on our website under Report Interpretation to give advice on the proper interpretation of our reports. In addition, seminars and workshops are regularly performed on request. Please contact us should you wish to have the Report Interpretation documents emailed to you, or to arrange a seminar.

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?

If you are not happy with our evaluation of your performance, you can appeal against this by contacting us either telephonically or via email. We offer lots of friendly help and advice, from telephonic discussions, to query reports, showing your specific instrument performance over time or variation between methods or procedures. Our database is huge and is there for your support. All calls are logged and will be resolved within 2 days unless otherwise specified.

REMEMBER: IF IN ANY DOUBT –

GIVE US A CALL

Revision History

Edition	Issue Date	Description of change	Requested By	Page no.
10	27/06/14	• Collusion or falsification of results • Reasonable precautions to prevent collusion between participants or falsification of results • for Microbiology and Differential Slides • All EQA programmes have a system to detect outliers which can be defined as "results that • There are many times that you might see low data numbers on your report…. • Homogeneity and stability • Homogeneity studies are not performed at Thistle QA • Target, means… • Uncertainty of the mean… • or variation between methods or procedures	D. Moosa	5 - 6 6 7 - 8 8 10 11 12
11	13/03/15	• Confidentiality Policy • Thistle QA strives as far as possible to maintain the confidentiality of its participants... • Please note that we do not accept submitted results of zero (0) or Less than zero (<0.0). • Please note that Thistle QA does not accept any samples back from…. • Thistle QA only issues final reports, no prelim or interim reports are issued. • Use of Consensus vs. Reference as Assigned value… • you can appeal against this by	D. Moosa	4 5 5 6 10 - 11 12
12	25/06/15	• Homogeneity studies are not performed at Thistle QA since homogenous material is purchased from the suppliers. This data may	D. Moosa	8

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13	15/04/16	• Deleted reference to Epicor	D. Moosa	9
14	16/09/16	• Deleted Food Micro **May & November** • printed with sample 6 and sample 12. Chemistry will receive and additional cumulative report on sample 13. Removed Fax as submission mode	R. Otto	2 4
15		**Precision of Reported Statistics** • You may notice that if you generate your own statistics many tools (e.g. Excel) will return Average, for example, to many more decimal places than you will see on your report. Thistle QA policy, as far as possible, is to display on your reports the average (or mean) to one decimal place higher than the typical precision of results submitted to Thistle QA for that particular analyte……	F. Motsai	8
16	29/10/18	**Changed the dates for Diff slides and 5 Part Diff**	F.Motsai	2