

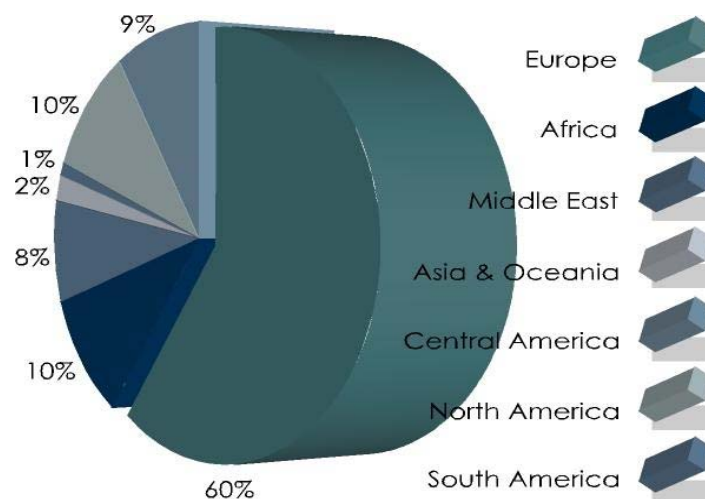
What to do if your EQA results are not good

By Jim McCulloch, of Thistle QA

Foreword

It has often been said that “Oh, well, here comes Jim again. Biased about QC as usual.” Too right! Jim is indeed biased when it comes to producing good quality results for those who depend upon our service – the poor, sick patient. When all labs in South Africa are delivering good quality results to their patients, Jim will stop beating his QC drum. Until then, read on...

And don't forget that Thistle QA is an **international company**. The graph below shows you the distribution of labs whose results are entered onto our database, through cooperation with Randox in the UK.



African labs comprise about 10% of our database, with most results coming from European labs. Based in Johannesburg, but fully international, that's Thistle QA.

Introduction

This article will discuss a Root Cause Analysis (RCA) approach to solving poor performance on an EQA programme. RCA is a way of working backwards once you see you have a problem, to work out what basically – at the “root” – caused it in the first place. It is not an attempt to lay blame anywhere; rather it is a sensible approach to try and identify what went wrong, in the hope that it can be solved. In quality, the aim is always to **solve** a problem – that is, stop it happening again.

If your EQA looks poor, or bad, or unacceptable, the problem lies either with:

- Your lab,
- Your supplier of instrument or reagent,
- Your EQA company, i.e. Thistle QA.

This article will suggest a cooperative approach to deal with the investigation of unsatisfactory performance on an EQA programme.

The final outcome should be a cooperative approach between labs, suppliers and Thistle QA, to prevent problem-dumping, where each of the three blames another. Thistle QA almost always has extra samples available, for both labs and suppliers, **at no cost**, for testing. This should allow labs to double check their performance; and encourage suppliers to check potentially poor performance.

Ideally, a supplier should ask for samples to test an instrument **before** it is launched locally. We don't charge for these samples because this is an ideal opportunity for suppliers to identify potential problems long before clients become concerned by poor EQA reports. Insist that your suppliers use this free service. If someone is asking you to buy or evaluate a new kit or instrument – ask them how it performs with Thistle QA samples.

Have you a problem?

EQA is a vital element of a quality system. It ensures that labs have an independent, external assessment of their testing performance. Good performance on an EQA satisfies the lab itself that it has a robust testing system; it satisfies clients and users that such a system exists; and it allows the lab to demonstrate an acceptable quality system to accreditation assessors.

Routine monitoring of all EQA results allows a lab to identify performance trends and other problems related to performance drift, imprecision and systematic or random errors.

Thistle QA has many ways to help participating labs interpret their reports. Instruction documents, QC courses and telephonic support are available and all clients are encouraged to use them. The QC course in particular should be used, both for its important information, and also for the CPD points it carries. It is available free of charge to anyone, at www.thistle.co.za, under the education section. Four modules are available for self- or group-assessment. Once you finish a module, ask us for the answer sheet.

And remember, all help is given confidentially. We will help anyone asking for assistance. Our mission is to help improve the quality of laboratory testing in Africa.

Understand the basics

Review your EQA report to confirm that the results we show you sent in are correct. If you're not sure – ask us for help. Then, consider the following:

- Have we got your correct method/ instrument code on file?
- Did you receive the material in satisfactory condition?
- Did you test the correct sample?
- Did you prepare the sample according to Thistle QA instructions?
- Have you changed your method/ instrument without telling us?
- Did you follow your established lab procedure?
- Was the instrument operated according to your SOPs?

- Has the maintenance been performed appropriately?
- Was your internal QC acceptable at the time of testing the EQA sample?
- Has this problem occurred previously with EQA samples?
- Did repeat testing on the EQA sample produce similar results?
- Were patient results acceptable at the time of EQA testing?

The above list is the preliminary step towards investigating apparent poor performance. If you follow this, any subsequent complaint or request for help from either your instrument supplier or Thistle QA, will be taken seriously.

Identify root cause

Often, the first cause identified in problem solving is a symptom of a deeper problem. The true or root cause is not always obvious.

The simplest form of RCA is to brain-storm the problem with your technical staff – and to keep asking “why?” until you have found the underlying issues.

The following table breaks the problem areas into three: your lab; your supplier; your EQA company.

Lab issues			Supplier issues	Thistle QA issues	
Clerical	Method	Technical	Instrument/ reagent	Material	Stats
Mislabelled vials	Wrong reference range used	Samples mixed up on bench	Problems with data processing function	Interfering substances	Peer group incorrect
Transcription error between bench and EQA report	Results too close to detection limit	EQA material improperly prepared or stored	Problems in manufacture of reagents/ standards	Non-homogenous material	Incorrect data entry
Incorrect instrument/ method code	Internal controls do not cover the detectable range	Standards/ reagents not properly reconstituted or expired	Carryover from the previous sample	Contamination	Narrow Acceptable range (clinical CV)
Incorrect units or misplaced decimal points	Inappropriate method	Incorrect sample volume used	Block in the instrument tubing/ delivery system	Material transport problems	No participant consensus
Calculations or conversions error	Method lacks sensitivity or specificity	Internal QC material outdated or badly stored	Electrical problems	Material improperly stored	Incorrect method code assigned
		SOPs not followed		Insufficient sample	
		Poor water quality			

A more detailed analysis of this table shows that the major areas of concern are:

The lab can mix up samples, make transcription errors, not prepare reagents or standards correctly, or make calculation/ unit errors.

The instrument supplier can supply you with poor quality reagents, e.g. not FDA approved, or poorly train your staff in instrument operation.

Thistle QA could send you poor quality samples, or group you incorrectly for stats analysis.

Consider all of these potential sources of error when you do RCA!

Action plan

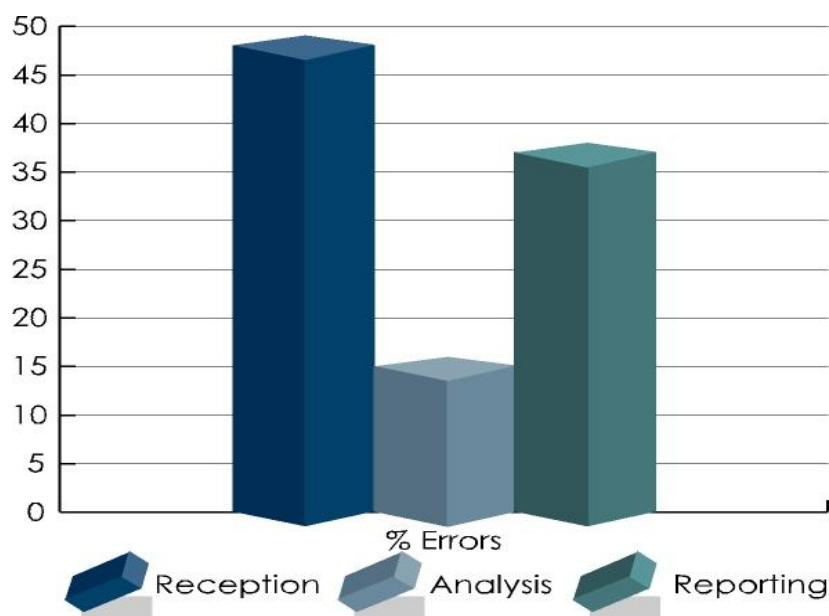
Corrective action to solve an apparent EQA problem needs to be to a degree appropriate to the magnitude of the problem. More simply, you need to assess the size of the problem. And don't panic.

First ask

Ask us for help. We never advise rapid action unless the error is clear-cut and is affecting your patient results. Otherwise, we advise a methodical approach to solving quality problems, involving the following steps.

- Is the error only seen on EQA?
- Have your internal controls changed lately?
- Do you agree with other labs using the same equipment? What does your instrument supply company say about this?
- Have you asked Thistle QA for repeat samples?
- Have you asked Thistle QA for a detailed statistical analysis of the problem?
- Is the difference you see clinically significant?
- Do patient correlations. Do your patient results agree with another lab that shows good quality EQA performance?

Where errors take place



This graph should act as a reminder that errors take place anywhere in a lab – if we need reminded about this! Most errors take place BEFORE the sample even reaches the bench, in the “reception” or pre-analytical area, for a variety of reasons. This could also apply to your EQA sample, so don’t forget to look well beyond the analytical part of your lab.

Final message

Thistle QA is not simply there to identify problems. We are part of the solution.

We would like to work with your instrument or reagent supply company to make sure that we all work together to help solve the problem. It doesn’t help if we all dig trenches and lob grenades at each other.

Samples are available from our stock for you to repeat your testing, to see if it’s a single sampling problem, or repeatable. Also, we encourage all suppliers of reagents and instrument to ask us for samples. They can do this when they are about to introduce a new instrument into the South African market, or when some problems are seen on an EQA. Either way, we want to work with local suppliers to ensure that errors are fixed simply and quickly.

This will cut down hassles to you in the laboratory; and make sure that patients always receive the service they deserve – a good quality result that ensures our referring clinician can practice good medicine.

Patients deserve quality.