

Interpretation of Thistle EQA Reports

The purpose of this document is to help labs gain the maximum information from Thistle QA reports

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INTERPRETATION OF NUMERICAL EQA REPORTS

Page 1

The usual identifications such as lab name and Participant Number appear. Beneath that we show you a box with four sections, from the left:

Analyte. The analyte to which the statistical results apply.

Your Result. These are the results we have used to assess your performance. They may not be the actual result you sent in, as any factors you may have used will have been applied (see later).

There are now two sets of information that follows, namely:

Method Performance: These are the stats for your method category, showing the Mean, n (number of results), and the SD of the results in the database, followed by your SDI, your percentage deviation from the mean (%D) and sample performance. Your SDI is calculated as follows: the difference between your result and the mean is calculated and then divided by the SD; giving the number of SDs you are from the mean. The % D is calculated as follows: the difference between your result and the mean is calculated. This figure is then divided by the mean and multiplied by 100, giving the percentage that you result is from the mean. Sample Performance shows your performance for the current sample, and will be expressed by either an A for acceptable or P for Poor. The expression of the performance as Acceptable or Poor does not apply for the HIV, Pregnancy and 5 Part differential programme.

Instrument Performance: This shows the mean, n, the SD of the instruments in your database, followed by your SDI, your %D as for Method Performance, but this time against your actual analyser or analyser group and sample performance. Thus again you have an SDI and a %D, which may be different to the one shown in the previous column for Method Performance.

Exceptions: Some EQAs lack the Method Statistics, e.g. ImmunoAssay and Haematology, as the provision of this information could lead to confusion.

Non-statistical information:

Interpretation Performance Pos & Neg: This will show your result as an interpretation – positive or negative. A mean cannot be given for non-numerical results; instead we will point out the number of negatives, equivocal or positives reported in the space for the Method Mean.

Interpretation Performance < than or > than: For some of the programmes you might have to report a result of < than or > than; depending on the kit / semi-automated instrument that is used. Specific stats cannot be calculated on

a result like this but, we will report the mean of all the numerical results obtained. It is up to the laboratory to interpret their results and compare it to the given mean e.g. Trop T – Your result = <0.40 and the mean for 16 participants are 0.32 – your result is correct because you have reported <0.40 The rest of the stats columns will indicate “Not applicable – N/A”

NB: Results reading zero cannot be submitted, if results are reading below or above the cut off limit they should be submitted as < or > the cut off limit.

Page 2

This shows the methods we THINK you are using in your lab. If this information is wrong, either regarding the principle, the instrument or the reagent manufacturer, please tell us. This information is vital with regard to the stats group you are placed in – if you are in the incorrect group, your report could be misleading. Check the details here very carefully.

To the right of each analyte we show the Acceptable Clinical CV as a percentage. If your result as a %D is within this percentage from the mean result, you will be regarded as “acceptable’ for that result i.e. if your result is less than or equal to the Acceptable CV. These figures come from a variety of sources, such as CLIA’88 (the USA regulation describing satisfactory performance on EQAs) with elements of Biological Variation (BV). From these pieces of information we have taken local advice and created our own South African set of acceptable performance standards.

If you have changed methods or kits or reagents – and told us about it – then a further page or pages will appear now, showing the new methods we have on file for your lab, and the date from which the change will be applied. Once again, you MUST check this vital information and tell us if it is wrong.

In the case of laboratories reporting non-numerical interpretation results, the Acceptable CV will indicate N/A.

Levey-Jennings Section

Two analytes are printed per page, and each follows the same format. The analyte name and unit we use for reporting are shown first. This is followed by two charts:

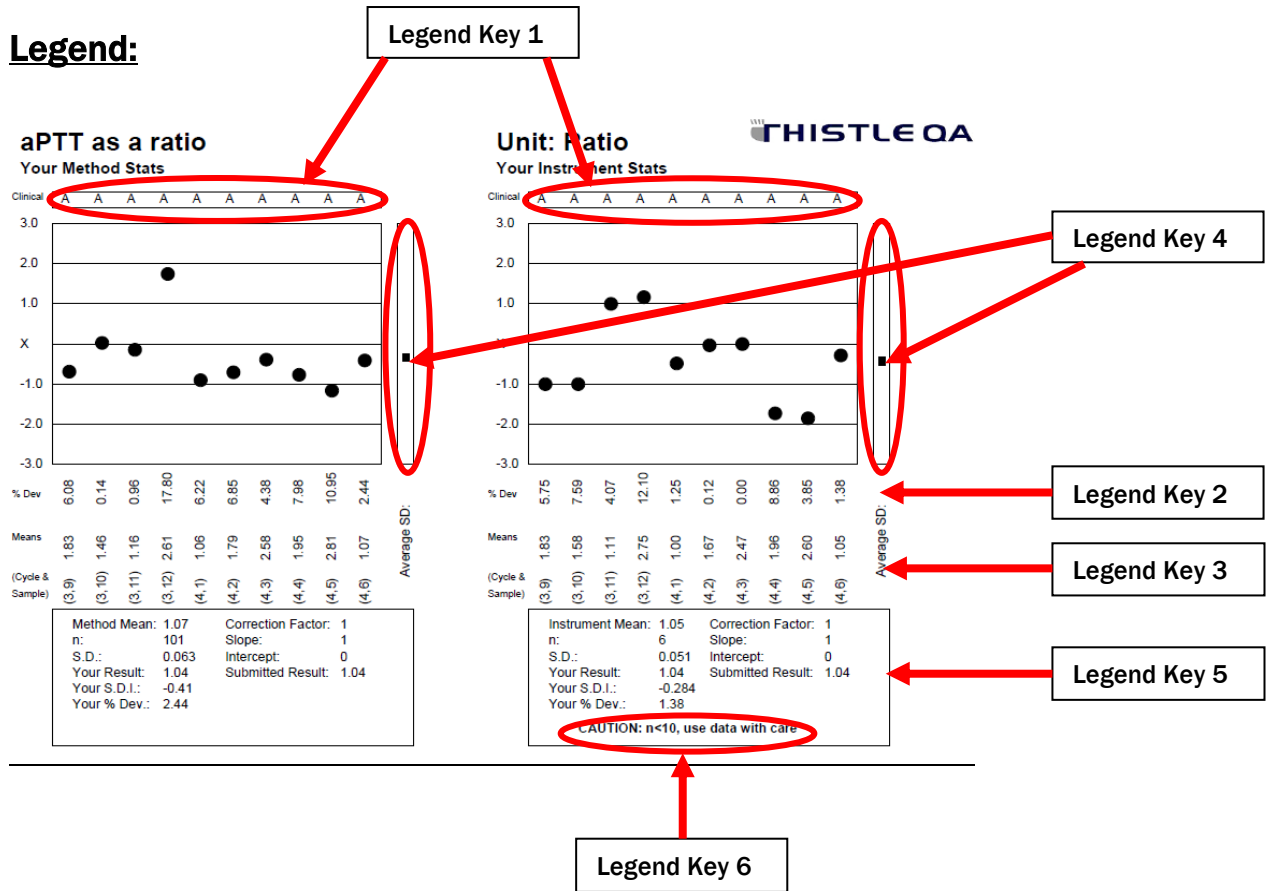
- **Your Method Stats:** This is the traditional Levey-Jennings chart showing your results versus the mean and 2 SD range, and uses the figures and stats from Method Performance on Page 1. This graph shows the performance of your last ten samples, allowing you to see trends and biases. Although there are limitations to using SDs to evaluate performance, if all your results are within the +/- 2 SD range, you generally do not have a QC problem.

- **Your Instrument Stats:** This chart shows your performance against your instrument, using the figures and stats from Instrument Performance on Page 1. Again, the traditional way to interpret is to accept your performance as good if all or most of your results are inside the +/- 2 SD range. However, it must be appreciated that by providing instrument specific stats, the numbers of results used will be less than for Method Performance. We suggest that you use your instrument stats when interpreting your lab performance against your own instrument group. In the case of a low data base e.g. <10 submissions, we suggest you rather use the method stats. We print several stats warnings, when necessary, to alert you of low data base numbers.
- **Interpretation Results:** This will be reported by listing all different kit names under the methods column. After each kit / method an indication is given of how many participants reported Positive, Equivocal or Negative. Laboratories can compare their results to the overall results as well as their specific kit / method results. "Your result" will be shown in a separate box indicating - Your Result: No Return or Positive, Negative, Equivocal.
- **The boxes above the Charts (Legend Key 1 - Page 4):** This shows you the historical clinical performance. An "A" represents acceptable performance, and a "P" represents poor performance. We have used the Clinical CVs for each analyte. These are listed on page 2 of the report. If there is no instrument stats available a U will show here. For Example if nobody submitted for the sample then there will be no stats available.
- **Directly below the Charts (Legend Key 2 - Page 4):** This shows your %D over the last 10 samples.
- **Below the %D (Legend key 3 - Page 4):** This shows the mean value that your results have been compared to, and just underneath that the cycle and samples are listed.
- **The boxes to the right of the Charts (Legend Key 4):** This shows your average SD for the samples shown on the Levey-Jennings chart.
- **The boxes beneath the Charts (Legend Key 5 - Page 4):** This shows the stats relevant to your result for this week against your method and instrument stats respectively. First we show the mean result, the number of data points and the SD of the results in the database, all three in bold. This is followed by your actual result, then the SDI and the %Dev. Following this are the various factors we have on your file, for example, any slopes or intercepts, or correction factors

relating to unit conversion factors. As for your registration details, it is important you check these factors carefully. In general, you should not manipulate results before sending them to us; rather keep us informed of factors in use in your lab and WE will do the appropriate corrections – and show them here, for accreditation inspection purposes.

Stats warnings flags for low database numbers (Legend Key 6 – Page 4): Finally and importantly, we give warning flags when the stats database is less than 16 results, a figure we have arrived at after careful statistical scrutiny. If the warning flag appears, we suggest that you consider the value of the stats in that section very carefully before making any adjustments. If, for example, the stats warning appears and the SD is narrow, the stats are more useful than if the SD had been wide, indicating variation in the results received. This is a complex issue and we will happily discuss it with any lab individually. In addition, if the number of data points is less than 10, a stronger warning appears. Finally, if n is <5 , we advise you to use the data for information only. In our experience, this happens generally with instrument stats and it should be of interest to you that very few people use the same instrument as your lab!

Legend:



The Last Page

This page contains “Important General Requirements for ISO 17043” information.

EFFECTIVE USE OF THISTLE QA STATS INFORMATION

What follows is a brief introduction to this complex issue. Please feel free to contact us for more detailed help. On request we will produce comparative stats reports showing your result versus your method group, or your instrument group; or print your report in our office and call you to discuss any problems you may have; or visit your lab to make sure you are using our information effectively. Again, please follow your own protocols if there is a contradiction with what follows.

The first page gives you a summary, a type of snapshot of performance for that sample, by analyte. Generally speaking if your results are all within 2 SDs, you do not have an analytical problem. Conversely, if you have a result outside 2 SDs, you may have a problem – but it does not mean you must use a new factor on your instrument, or throw an instrument out. Generally, check the simple things first – are you registered correctly,

have you handled the sample according to our instructions, and have you sent us the correct results? If you are consistently outside 2 SDs for your method group stats, but inside 2 SDs for your instrument stats, it means that your instrument is biased against other instruments using the same method principle. This may only be of interest to you, or it may be something that you wish to take up with the instrument supplier. But again, this is better than being outside 2 SDs on both charts. If you are in this category, you do have a problem that needs investigation and resolution. Once you have examined those basics, then you can start to think about other intervention procedures.

Finally - a word on the use of clinical compliance. This evaluation of your results is based on the deviation of your result from the relevant mean, using a percentage figure derived mostly from Biological Variation (BV). BV gives an idealised concept of how well a test should be performed in order to be clinically useful. Often, technology lags behind, meaning that many labs fail this parameter, while being inside 2 SDs. We believe that this comparison provides useful information and produce it here for your interest and will be happy to discuss in detail when required.

INTERPRETATION OF THISTLE STATS

We recommend wherever possible that you use the Instrument Statistics on our report. This gives you the most appropriate set of comparative results for you to assess your own result against. Of course, if the data base is too small or the SDs too wide, even this set of results might not be very useful. And it might be meaningless to compare yourself to the Method Statistics. Give us a call and we'll see if we can help.

If your own organisation has protocols, then please follow them.

What is beneath is a set of guidelines for those unsure how to interpret our reports; or those without clear protocols; or those being hassled by assessors. At all times, though, an EQA result that looks "out of control" in any way, demands action. And that action might be to note it, identify the root cause where possible, fill in an action sheet of some sort, perform an examination of the report's statistics or have a good look at your Internal QC. After this type of scrutiny, you may decide to live with what you see. And as long as your interpretation is appropriate then that's okay.

Sample Ranges around the Cut-off

We are often asked for help with interpreting reports, especially for qualitative analytes when there is no consensus. If we have a sample with 40% of results reported as negative and 60% as positive, what is the "correct" result? It's fairly simple. We could always send out very high positives and totally vacant negatives – and reduce our hassle factor. But obviously we must send out samples with borderline concentrations, hassle or no hassle.

The simple answer to this problem is that if this was a patient then 40% of labs would tell him that he was negative and 60% would tell him he was positive. It may not be a nice concept to accept but it's the stark truth that the analyte and sample don't know there's a cut-off! The mean plus and minus the 2 SD range can straddle the cut-off. So, what is the "correct" result? In this example, chosen because it's extreme, both positive and negative are acceptable results!

And you can tell SANAS I said so!

Acceptable but outside 2 SDs

And how do you interpret the situation where you are beyond the so-called-magical +/- 2 SDs but the clinical CV gives you an A for acceptable?

The clinical CV, or Acceptable Range, was added to the reports some years ago because some of the SDs was becoming seriously tight. Now, that sounds good but it doesn't matter how many results are in a data base, or how close they all are, the fact remains that 5% of labs will be told they are outside +/- 2 SDs – even if the difference between their result and the mean is insignificant. By definition, +/- 2 SDs includes 95% of results!

So, if you get the above situation, look at the actual figures in the report. Work out how far you are from the mean and if it insignificant (and you should know what that means, but if not look at the ranges you use for internal QC and assess it that way) then write that down on your action sheet or wherever your SOPs tell you to log potential problems or non-conformances, and move along.

And in case you doubt this, read ISO 13528. It states that it is acceptable to set "SDs" at a value required for a specific task (Section 6.2.1), or at a value that corresponds to the level of performance that the coordinator and members of the scheme would wish labs to achieve (Section 6.3.1). The example given is an acceptable 10% performance limit for glucose (Section 7.1.2). This sounds remarkably like what we're trying to achieve with our Acceptable Ranges! These Acceptable Ranges are an ISO-acceptable way of setting standards of performance!

And you can tell SANAS I said so!

Inside 2 SDs and A for Acceptable BUT consistently biased

If you find your results always on one side of the mean, but always within 2 SDs and Acceptable, pause and look at the real results. If you are Acceptable, it means you are not

sending out clinically poor results; and being inside 2 SDs means you are NOT in the poorest 5% of results.

This MIGHT be a case for doing nothing. It depends on the size of your bias, the validity of the data base, and which analyte it is.

Summary

Statistics give you valuable information – and very few facts. That information has to be interpreted before you can use it. By all means flag any result “out of control” for investigation, otherwise you are not using your statistical information correctly.

GUIDANCE NOTES FOR THE 5 Part Differential EQA REPORT

- The interpretation of the 5 part Differential is similar to that of numerical results. The only difference is that the “A” representing acceptable performance, the “P” representing poor performance and the Clinical CVs are not displayed on the LJ Graph. The results for the 5 part diff are evaluated based on whether they fall outside or inside two SD and based on the protocol used in the laboratory. If the laboratory normally troubleshoots results outside 2SD, they must follow the same protocol with their 5 Part Diff sample and also look at the factors like, was the sample handled according to our instructions, were the correct results send?

The lab can still use the Acceptable C.V as a guideline as to whether they are sending out clinically poor results or not.

GUIDANCE NOTES FOR THE HIV AND PREGNANCY EQA REPORT

These notes are designed to help participants on this EQA to understand the various sections of the report and thus to get the maximum value out of the EQA.

Page 1

This page identified the report as yours and shows your name and Participant Number, as well as the Cycle and Sample number of the report.

Below that is the section “Performance for this Sample”. Please note that the report might refer to a Qualitative result and/ or a Quantitative result.

Qualitative Result: The report will indicate the consensus result under the MEAN heading, if consensus has been reached. Your own result sent to us is shown on the left hand side and should be compared to the consensus. We require 80% of lab results to agree before we have a consensus result. If the report says “No Consensus” it means that less than 80% of labs did not agree. If the report says “Too few” it means that there were less than 5 results and thus it has not been possible to achieve consensus. The expected results are indicated as positive or negative on the last row of the table on page 1 and at the bottom of page 3.

Quantitative Result: Your numerical result will be shown on the left, followed by the Mean, Number and Standard Deviation (SD) for your instrument. To the right of this is how your result compared to the mean and SD. The SDI (Standard Deviation Index) is basically the number of SDs your result was from the mean. If this is less than 2, the probability is that you do not have a problem. The higher your SDI is over 2, the greater the probability that you have a problem. Please remember that interpreting EQA is never simple and we are always available by telephone or email to offer you some assistance in understanding our reports. The final figure %D (percentage deviation) is the percentage you are from the mean which can be used to keep track of your bias (% deviation) from sample to sample, assisting you with the assessment of consistent trends.

Page 2

This shows the instrument information we have on file for you. Please check this carefully as your report may be meaningless if you are incorrectly registered on our database. If there is any registration changes the following page will indicate the changes made for this Cycle and Sample.

Page 3

This lists the Qualitative results received from all participants on all instruments. Labs can report results as positive, equivocal or negative.

Quantitative results are displayed in Levey-Jennings charts, which show the dispersion of results against the mean for the previous ten results.

Generally labs should find their average results, shown to the right of the Levey-Jennings chart to be close to the mean, i.e. close to the mean line. Beneath the chart are the results and stats box, showing the method mean and The SD as well as various other stats information. To the right of the chart is a list of other quantitative results received.

Page 4

This is the last page of your report containing scheme related information.

GUIDANCE NOTES FOR THE MICRO EQA REPORT

Page 1

As well as all the usual identifiers, we show the expected organism in the particular sample. The sample only contains one organism.

The scoring for the organism ID is done manually because considerable checking takes place. For example, an organism name may have changed and some labs may still use the old name. In addition, if a lab follows its protocols and identifies the organism as far as it would go routinely and indicates that it would then send the sample to a reference lab for checking and further ID to be performed, we mark them out of 3 and not 5 as for a full ID. So if you make a correct ID, you will receive 5 out of 5; if you make a partial ID and then would send to a reference lab, and the partial ID is correct, you will receive 3 out of 3. Lower scores are given for IDs that are close but not totally correct.

We may sometimes alter the name of the organism you send us, as various reporting systems would mean many similar but not identical names will appear on Page 2. If we do this, you will always be told that a change has been made.

So, let us know if you feel that following your lab SOPs may adversely affect your score. And should you disagree with the score we give you, please let us know. If we do not agree, we can always send your request to our Advisory Committee for a decision to be made on re-scoring, if necessary. This is done confidentially; of course, no names are mentioned to AdCom.

At the lower end of Page 1 we show your Historical Performance, over this sample and the previous five samples, six in all. There are few guidelines but a score of greater than 80% is suggested as acceptable by some authorities.

Scores are shown for both Organism ID and Antibiotic Analysis (out of 2 points per antibiotic for which there was CONSENSUS – see later, under **Page 3**).

Page 2

This page shows the various organisms reported to us for this sample, for each Expected Organism, i.e. each pathogen.

Page 3 and 4

Antibiotic Analysis is on this **two pages** including EVERY antibiotic for which we received a report. This list will allow you to compare your antibiotic profile for this sample and organism with the profile in use generally. The column to the right shows you whether we reached consensus or not, defined as (a) at least five results, and (b) 80% of labs agreeing on the result.

If consensus is reached, each antibiotic is scored out of 2, so you will be allocated 2 points if you agree with the consensus finding.

There are two sets of antibiotic results, sensitivity results observed by the lab displayed on page 3 and sensitivity results reported to the doctor as per lab protocol displayed on page 4. Only results for antibiotic observed in the labs will be scored. Antibiotics reported to the doctor are not scored. Results for this antibiotics are included in the report as this encourages the laboratories to be aware of the importance of what they release to the clinicians as this could be the source of the increasing resistant.

GUIDANCE NOTES FOR THE DIFF EQA REPORT

Page 1

The usual identifications such as Lab Name, Participant Number, Sample and Cycle Numbers as well as the Sample date appear. Beneath that we show you the Performance For This Sample which has 6 sections, from the left:

- Cell type
- Expected result. As confirmed by AdCom.
- Seen By. The number of labs reporting this cell type.
- Mean.
- 2 SD Range.
- Your Result. These are the results we have used to assess your performance.

Page 2

Once again the usual identifiers appear in a box, beneath that we show you the Morphology Results which has 4 sections, from the left:

- Morphology. This is a comprehensive list of possible morphological features.
- Target. This is the expected morphological features that you should be able to see as verified by AdCom.
- Yours. This is the result that you have submitted.

- Number of labs. These are the number of labs reporting this feature.

Page 3

The identification box appears again, beneath that we show you the Haematology Blood Films – Diagnosis Results with 4 sections, from the left:

- Diagnosis. This is a list of all the submitted diagnosis as well as the expected diagnosis.
- Target.
- Yours. This is the result that you submitted.
- Number of labs. These are the number of labs reporting this result.

Page 4

The identification box once again appears, beneath that we show you the Haematology Blood Films – Further Test Results with 4 sections, from the left:

- Test Description. This is a list of any further tests suggested that can be done to confirm your diagnosis.
- Target. This is the Target suggested tests as verified by AdCom.
- Yours. This is the further testing that you suggested.
- Number of labs. These are the number of labs also suggested these further test.

This is followed by a Slide Quality box where labs comment on the quality of the blood smear received. This has 2 parts:

- Slide Quality: Poor, Acceptable or Good labs - comments on the quality of the blood smear.
- No. of labs. These are the number of labs commenting on the quality of the blood smear.

The Last Page

This page contains “Important General Requirements for ISO 17043” information