

## Electronic Report Interpretation Instructions

### Interpretation:

#### Page 1 of the report

The usual identifications such as lab name and Participant Number appear as usual. 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 and your percentage deviation from the mean (%D). 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.
- **Instrument Performance.** This shows the mean, n, the SD of the instruments in your database, followed by your SDI and your %D as for Method Performance, but this time against your actual analyser or analyser group. Thus again you have an SDI and a %D, which may be different to the one shown in the previous column for Method Performance. Please note that the instrument performance is not applicable for Immunoassay & Coagulation.
- **Sample Performance Summary-** This shows your performance for the current sample, and will be expressed by either an A for acceptable or P for Poor.

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”

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This has not changed and 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. 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 of the report

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:

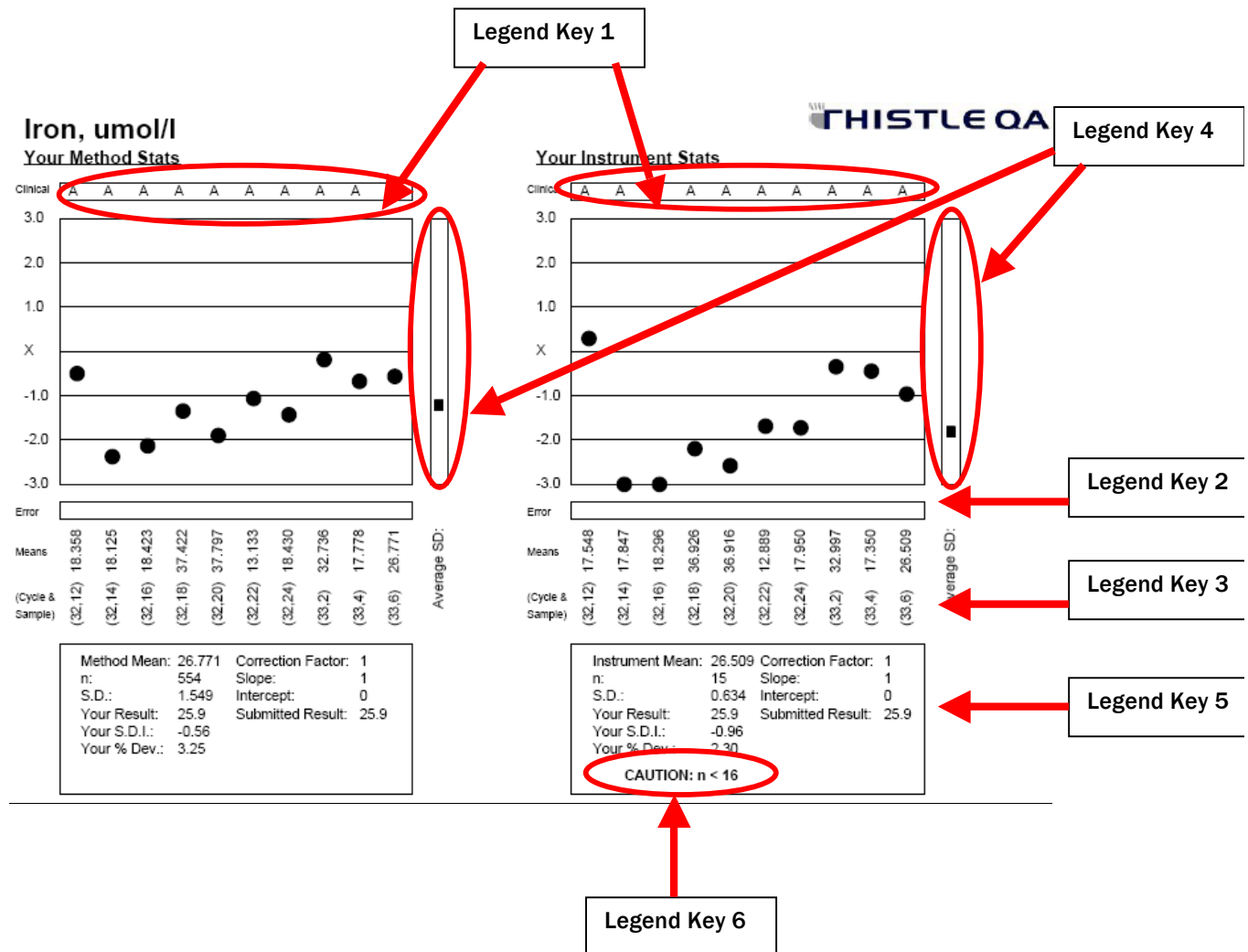
- **Your Method Stats.** This is the traditional Levey-Jennings chart showing your results versus the mean and 2 SD range, and uses the figures and stats from Method Performance on Page 1. This graph shows the performance of your last ten samples, allowing you to see trends and biases. Although there 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. Please note that the instrument performance is not applicable for Immunoassay & Coagulation.

- **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 5).** 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 3 of the report.
- **The Error boxes direct below the Charts (Legend Key 2 – Page 5).** This shows any error for that sample. Blank mean there is no error, and "N" represents a "No Return", and an "L" represents a late return.
- **Directly below the Error Boxes (Legend key 3 – Page 5).** 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 5).** 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 5).** 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 of the Report**

This page contains "Important General Requirements for ISO 17043" information

## **Effective use of the 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.

**Dr. Jim McCulloch**  
**Director**

**Debbie Moosa**  
**General Manager**