



User Guide

Statistical package for retrospectively describing the contribution of each analyser within a network to the overall analytical uncertainty.

The package described here is the result of a project commissioned by the ACB Scientific Committee. The project team is: Pete Ayling, Robert Hill, Nudar Jassam, Anders Kallner and Zahra Khatami.

The project team is grateful to Edward Kearney for helpful comments and early input into project design and also to Alain Rolli and Steve Bunnage for trialling software.

Disclaimer

This package is being distributed as Beta version to allow widespread testing and should not be considered a fully tested product. It is the responsibility of each laboratory to run an acceptance check by ensuring that the package is giving the expected results within the local environment in which it is being used. These instructions should be read in conjunction with the instructions for using the data extraction utility and the statistical notes which explain the statistical procedures behind the data analysis.

What is the main purpose of the statistical package?

It provides a retrospective internal QC report (weekly or monthly) on each analyser within a network. When combined with a record of regular reviews of the reports, it fulfils the requirement of ISO 15189: "to provide evidence for comparability of examination results to the same or different procedures, equipment, sites..." Performance is assessed by measuring analytical uncertainty.

Does this package replace conventional IQC and associated acceptance rules (e.g. Westgard rules) for monitoring IQC

No, this package provides a retrospective analysis of IQC data. A conventional IQC programme is required in addition to the statistical package to make real time decisions on the acceptability of analytical performance.

What is in the package?

The package comprises a data import utility (designed to automatically import data from an instrument data manager export file) and interactive spreadsheets which display analytical performance across a network of analysers by analyte. Instructions for using the data extraction utility are available as a separate document.

A single summary spreadsheet allows the user to review the performance of all analytes on each analyser at a glance. Further information is provided by drilling down to spreadsheets dedicated to a single analyte.

How do I get my IQC data into the statistical package?

Step 1 Export the IQC data from your analysers' data manager to a data or text file.

Step 2 Identify the correct data extraction utility for your data manager then follow the instructions for running the utility.

The data export utility has produced a large number of individual spreadsheets – Do I need to inspect each one?

No. First examine the summary spreadsheet and check for flags indicating potential poor performance of an analyte on one or more analysers. Next find the spreadsheet(s) corresponding to the poorly performing analyte(s) and look at the data in more detail. The correct operation of the summary spreadsheet will depend on setting appropriate performance targets for each analyte. This is the responsibility of senior laboratory management. Note statistical significance or lack of does not necessarily correlate with clinical significance.

What is the significance of the red and blue colours used for the data?

Blue - The blue data is input data. Both the data extracted by the utility and the user configurable settings are regarded as input data

Red – The red data is output data which are calculated parameters used for data analysis

The spreadsheets are very complex – where do I look first?

Start by looking at the raw data in the table that begins with C39 as the cell in the top left hand corner. Orientate yourself with the format. Each column displays replicate measurements of a single IQC material from a single analyser. The red result in each column is the highest observation. The green result is the lowest observation.

Setting Appropriate performance targets

The following cells require input if “Accept” and “Reject” outputs are to be meaningful and for the summary spreadsheet to be a reliable tool for the reporting by exception approach suggested above.

Target values (TVs) may be stored in the 'Evaluation criteria' sheet of the data import utility and will automatically be used to populate the test specific sheets every time the application is run.

For the purposes of explaining the function of spreadsheet the following applies when TVs are set manually;

C22 and Z22 – Enter the TV of the IQC material. This may be based on previous replicate analysis or an assigned value.

C23 and Z23 – Enter the uncertainty of the target value (in terms of sd or %cv). This is informed by performance claims from the instrument manufacturer and information about clinical performance targets based on biological variation. However the figure should be agreed by senior laboratory management and documented in the laboratory's quality management system. Once agreed for that analyte it remains fixed for each subsequent report until formally reviewed. AE29 or AE31 and AF29 or AF31 - Enter the maximum acceptable within instrument uncertainty as defined by the network/laboratory.

Configuring the spreadsheet graphs

The scales of the graphs can be edited to accommodate your data by clicking on "Axes" as you would for any Excel chart. Cell C22 and O22 introduce the target value of the control material into the graph. The confidence interval is limited by the dashed lines taking into account the coverage factor defined in cells L19 and Y19 and the uncertainty entered in cells C23 and Z23. The target value for internal QC material may be determined from values supplied by the manufacturer or derived from historical IQC data. Note that the target value is not calculated from the IQC data displayed in the graph so may need regular review if the dashed blue line is expected to trigger an intervention. However, the target value should remain unchanged during the retrospective IQC cycle. The error bars around the plots of average analyte concentration can be set to Standard deviation (SD), Confidence Interval (CI) or None (N) by choosing an option in the drop down boxes in cells I19 and V19. However the span of the error bars is calculated from the replicate measurements of QC material and taking into account the coverage factor in L19 and Y19.

How do I check whether the performance of one or more of the instruments in the network is unacceptable with respect to analytical trueness (bias)?

Configure the graphs as above and check whether the error bars from any instrument plot project beyond the horizontal dashed lines. By combining this information with the assessment of imprecision (see below) it can be deduced whether any instrument is significantly different with respect to analytical trueness.

How do I check whether the performance of one or more of the instruments in the network is unacceptable with respect to analytical imprecision?

The overall performance of the network is estimated using the ANOVA technique. This is automatically evaluated and reported as 'Significant' or 'Non-significant' in row 36. This statement is based purely on a statistical evaluation. The culprit instrument(s) is not identified by the ANOVA.

What is the difference between statistical and laboratory significance?

Cells AE26 and AF26 indicate whether there is a statistical difference between the performance of the network's analysers for the analyte under consideration. This may give an early warning of deteriorating performance and guide preventative maintenance. However, performance may remain acceptable when judged against the network's performance targets as set in cells AE29 or AE31 and AF29 or AF31.

Cells AE32 and AF32 indicate whether the analytical performance of the analyte is unacceptable at either level of IQC and may therefore require intervention. e.g. masking off one analyser/channel while an investigation/maintenance is undertaken.

What is the purpose of the Levy Jennings plot on the second tab of the workbook?

The Levy Jennings plot provides a conventional IQC graphical plot with a single limit corresponding to the limit of acceptability for uncertainty. The low and high IQC data are plotted separately for each analyte. Results for each analyser are displayed as a colour coded line joining the data points. A suitable period of observation may be chosen by adjusting the X-axis (time axis). The graph can be simplified by choosing only the interesting analyte(s).

What is the purpose of the Youden plot on the third tab of the workbook?

The Youden plot provides an at-a-glance check on whether the results for each instrument are (on average) staying within acceptability limits for uncertainty. If the input fields (blue font) are set up correctly, the plot for each analyser should lie within the box. If not, either the low or high IQC (or both) is indicating an unacceptably high uncertainty. A shift from the average (or median) in the direction of the displayed diagonal indicates a change in trueness. Any deviation in the perpendicular direction indicates deteriorating precision. Both trueness and precision may be affected simultaneously.

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