RANDOX QUALITY CONTROL

ACUSERA 24.7 LIVE ONLINE

INTERACTIVE DEMO GUIDE

INTERNAL TRAINING DOCUMENT. NOT FOR DISTRIBUTION

Acusera 24.7 Live Online Interactive Demo Guide

Overview

Your Acusera 24.7 Live Online demo account has been populated with data and has been designed for you to use to demonstrate the capabilities of the software to customers.

The reporting features work in the same way as a customer account. However, the account configuration cannot be altered and results cannot be added or deleted.

The demo allows you to:

- Produce charts and reports and showcase their interactive nature
- Highlight errant results on the dashboard

Accessing the demo account

The software will run on Chrome, Firefox, Safari, IE 9/10/11 and Microsoft Edge (earlier versions of Internet Explorer are not suitable).

Visit **randoxqcv2-demo.azurewebsites.net** and enter the log in details provided in your activation email. Note that placing 'www.' in front of the address will prevent access. You will be able to change your password by clicking on your name at the top right hand side of the screen.

Passwords must be at least 6 characters in length and should contain the following:

- At least one uppercase character
- At least one lowercase character
- At least one number
- At least one non-alphanumeric character (e.g. !, ?, @)

On logging in for the first time, you will be presented with the EULA (End User Licence Agreement), which you will need to accept before you can continue.

Account set-up

Your account has been set up with a number of basic chemistry and immunoassay QC tests. Chemistries are run on Roche Cobas 6000 systems and immunoassays on Abbott Architects. The account has been set up with 2 of each instrument type to enable instrument comparisons to be made on the interactive charts.

Details of the account are as follows:

Immunoassay: 2 x Abbott Architect, named Architect 1 & Architect 2

• 6 QC tests set up on each with serum lots 1476EC, 1477EC & 1508EC

Clinical Chemistry: 2 x Roche Cobas 6000, named Cobas 1 & Cobas 2

• 9 QC tests set up on each with serum lots 1039UN & 797UE

QC data included

QC results have been entered using EDI. New results will be regularly uploaded by Randox HQ, ensuring that there is always recent data in the demo account.

Your account has been populated with a mixture of good data and erroneous data. Errors have been included so that you can demonstrate the colour coded alarm flags and show how the interactive charts can be used to help troubleshoot issues.

Erroneous results have been included for the final 2 weeks within the data for the following tests:

Roche Cobas 2:

- Sodium, Potassium & Chloride results are reporting >3SD above and below the mean this is suggestive of a failed ISE module
- CK a decimal place has been omitted; results appear to be x10 or x100 greater
- Urea the user has switched the lots around

Abbott Architect 2:

- Total T4 incorrect units used (values are in ng/ml instead of nmol/l)
- TSH SD is 3 times higher than expected; this could reflect improper sample preparation or a worn out lamp / detector
- Vitamin D the decimal point is in the wrong place

In addition to the above errant results, Randox HQ will enter erroneous data for T4 on Architect 2 on a weekly basis. This ensures that as the EDI uploaded data ages, you will always be able to view information in the Dashboard alerts. It is therefore advisable that you DO NOT show a Levey Jennings chart for T4.

Conducting a customer demo

When demonstrating the 24.7 software to customers, you should concentrate on the features that can significantly aide QC management within the lab – focus on the interactive charts (Levey Jennings charts, Histograms and Performance Summary Charts), the Dashboard and the other available reports.

Dashboard:

- Access the Dashboard from the Utilities menu
- Explain the function of the Dashboard i.e. it will display any alerted or rejected results from the previous 7 days and provides immediate information on any potential issues in the lab

Result History:

- Click on the dropdown beside any analyte and explain that targets, multi-rules etc. that have been configured can be viewed here
- Select an analyte on 'Cobas 1' or 'Architect 1' (all analytes show good QC data) and click 'Next'. Show the raw results and the summary monthly and cumulative statistics in the box at the bottom of the screen

- A comment has been added against the alerted QC result for CRP you can demonstrate this by clicking on the dropdown beside the result highlighted in orange
- Explain the different options for result entry and mention that all results, irrespective of how they were entered, will appear on this screen

Levey Jennings charts:

- Access the LJ chart from the Charts menu on the left hand side
- Select a test run on 'Cobas 1' or 'Architect 1' (which display good data) and click 'Next'
- Click 'Generate' to view your chart(s)
- You will see the charts for each serum lot displayed individually
- Charts will initially display individual data points; click on 'Means' underneath a chart to display mean lines
- Hover your mouse over any point on the chart to display information on that point
- Demonstrate the zoom function
- Demonstrate how the chart can display SDIs or %Dev from target
- Explain that you can look at a user-defined date range
- Explain how to tailor the chart:
 - <u>Combined Lots</u> click on the 'Combine' slider above the charts, followed by 'Generate' and explain the benefits of viewing multiple levels on a single chart – i.e. you can easily identify if biases at one concentration level also exist at other levels
 - Explain the legend & show how you can turn data sets on and off
 - <u>Multiple instruments</u> use the back button to return to the main Charts menu, clear your original data, and select one assay on 2 different instruments pick from the tests showing good performance on both CC or IA instruments. Generate your chart as before (you may find it easier to turn off some of the data sets using the legend, so that you are looking at one lot). Explain why it is of benefit to add multiple instruments on to the chart i.e. if a lab has more than one instrument of the same type and patient samples can be randomly allocated to any instrument, the lab may be required to prove that patient diagnosis / treatment is not going to differ depending on which instrument their sample is loaded on to.
 - <u>Multiple analytes</u> select several analytes in the same way as you did with multiple instruments. Explain why it is of benefit to add multiple analytes on the same chart i.e. if an issue exists with one test, you can see if it is replicated in others; this can help show whether an issue is due to the reagent, QC or instrument. By way of example, look at Sodium on 'Cobas 2' you will clearly see an issue. Now add Potassium and Chloride on the same chart you will see that the same issues exists, demonstrating the failed ISE module. This is further evidenced by the fact that these 3 analytes perform well on 'Cobas 1'

Histograms:

- Access the Histogram from the 'Charts' menu
- Generate a chart for a single analyte on 'Cobas 1' or 'Architect 1' in the same way as you did for the LJ chart
- Explain that the Histogram shows the frequency with which each SDI score is attained
- Explain that you expect to see a normal distribution i.e. most results are close to target, and there are decreasing numbers of outliers
- Hover your mouse over part of the chart for added information

- Explain how to tailor the chart (same functionality as Levey Jennings) add multiple analytes, instruments and levels and show the legend. Explain that you can adjust the date range
- Explain that this chart can easily show any analytes that don't fit the normal distribution pattern and that should be investigated. By way of example, add all analytes on Cobas 1 on to a chart you will see that all tests are performing well, but there is a clear issue with CK

Performance Summary Chart:

- Access the Performance Summary Chart from the icon above the Histogram
- Explain that this relates to the second main function of Acusera 24.7 i.e. the peer group comparison
- Show the various levels of peer group available for comparison and the ability to compare against cumulative or monthly data
- Show the lab's data and the peer group data on the RHS of the screen and explain the significance of the SDI and CVI
- Explain that you can view and adjust the level of peer comparison within the Configuration menu

Peer Group Statistics:

- Access the Peer Group Statistics from the 'Reports' menu
- Select one of the lot numbers that have been used to populate the demo account
- Demonstrate how to find peer group statistics for different dates, methods and instruments (note that as you select a more specific peer group, participant numbers will reduce)
- Explain the usefulness of the Peer Group Statistics report i.e. peer group means can be used as fixed means and labs have visibility of performance of methods / systems other than their own (useful if they are planning on changing a method / supplier)

Statistical Analysis Report & Statistical Metrics Report:

- Access these reports from the 'Reports' menu
- Explain that you will see cumulative data and data for a user-defined date range and can see how the information compares to peer data
- On the Metrics report, highlight the TE and the TEa. Show the Sigma scores and highlight how these can be used to show at a glance assays that may need improvement / more stringent QC
- Show how to export the reports to Excel or PDF
- Using the dropdown at the top of the screen, demonstrate how you can order the report by assay or instrument

Uncertainty of Measurement Report:

- Access this report from the 'Reports' menu
- Explain that 24.7 automatically calculates Um from inter-assay precision data derived from the recorded QC results and from intra-assay precision data added by the user
- Highlight that the QC means are included, so that you can easily see the concentrations you are reporting uncertainties at
- Use this opportunity to discuss with your customer how they currently calculate Um many will be doing it very manually, using spreadsheets

Exception Report:

- Access this report from the 'Reports' menu
- Explain that this report provides the % of results that lie within 2SDs, between 2-3 SDS and outside 3 SDs from target

Data Review Report:

- Access this report from 'Utilities'
- Discuss how this report will display any rule violations and / or results with comments attached for a user-defined time period. This report can be very useful for an audit.

Acusera Advisor:

- Access this function from the 'Utilities' menu
- Explain the function of Advisor it is an add-on that will recommend and allow the automatic application of performance rules based on the lab's performance and will also recommend QC frequency
- Select an analyte and show the rule recommendations. Explain that you have the option whether or not to apply these rules

Assay Details:

- Access the registered details from the 'Configuration' menu
- It is not necessary during a customer demo to show the full functionality of account configuration, but it is useful to mention this section because it is possible to construct a report containing all the registered details; this may be useful if e.g. an auditor wants to see detail of all the methodologies / suppliers run in the lab
- Use the waffle to show how you can view all the reagents supplied by a particular manufacturer and demonstrate how this information can be exported

Other functions:

It is probably not necessary to demonstrate the remainder of the functions of the software, but you may wish to mention the following:

- Options for data entry Connect / EDI / manual. Explain that EDI is a simple, semiautomated means of importing data without full LIMS connectivity; when the EDI has been configured and an external data file saved, importing the data is as simple as attaching a file to an e-mail
- Multi-rules explain that you can select from 10 commonly used multi-rules, but that you can also tailor your own multi-rules
- Users mention that a customised level of access can be set up for each individual lab staff member
- Development of a single platform for the lab's full QC needs:
 - o RIQAS Net site being redesigned and due to be incorporated at the end of 2017
 - Verify data reduction software functional now
 - RQC tab this will tie in with QC value assignment and will allow a 24.7 user to automatically populate fixed means from Randox QC pack inserts and also to formulate customised pack inserts for their analytes / instruments / method