



RANDOX
QUALITY CONTROL

RIQAS explained

The largest global EQA scheme,
serving over 28,000 laboratory participants



External Quality Assessment (EQA) is an essential aspect of any laboratory operation. EQA provides a means of assessing the analytical performance of a laboratory compared to other laboratories utilising the same methods and instruments.

Overall objective of EQA

To develop interlaboratory comparability which allows standardisation of diagnostic testing. EQA measures a laboratory's accuracy using 'blind' samples that are analysed as if they were patient samples. Results are returned to the scheme organiser for statistical analysis. Laboratories receive a report comparing their individual performance against other participants in the programme. EQA has a number of functions:

- Maintaining and improving the analytical quality of laboratory tests
- Improving interlaboratory agreement and raising standards
- Detecting equipment failures, identifying reagent problems, reviewing staff training
- Initiating and evaluating corrective actions
- Comparing different analytical methods

Participation in an EQA scheme will help produce reliable and accurate reporting of patient results. Quality results will reduce time and labour costs, and most importantly provide accurate patient diagnosis and treatment.



RIQAS Programmes

- Ammonia/Ethanol
- Blood Gas
- BNP
- Cardiac
- Clinical Chemistry
- Coagulation
- Glycated Haemoglobin (HbA1c)
- Haematology
- Human Urine
- Immunoassay
- Immunoassay Speciality 1
- Immunoassay Speciality 2
- Lipid
- Liquid Cardiac
- Maternal Screening
- Specific Proteins
- Therapeutic Drugs
- Urinalysis
- Urine Toxicology
- Serology (HIV/ Hepatitis)
- Serology (ToRCH)
- Serology Epstein Barr Virus (EBV)
- Serology (Syphilis)

RIQAS Support

RIQAS support staff are on hand to offer advice and troubleshoot technical queries.

RIQAS is the largest international EQA scheme in the world. It is used by more than 28,000 laboratory participants in 105 countries worldwide. Twenty three programme types are currently available.



Accreditation

RIQAS provides Certificates as proof of EQA participation and performance for laboratory accreditation purposes.

RIQAS is a UKAS accredited Proficiency Testing Provider, No. 0010, and is accredited to ISO/IEC 17043:2010, 'Conformity Assessment- General Requirements for Proficiency Testing', which cancels and replaces ISO/IEC Guide 43 - (1+2) and ILAC GI 3:2007.

Accreditation to ISO/IEC 17043:2010 highlights the superior quality and excellence of RIQAS.

UK Performance Surveillance

- Recognised by the UK National Quality Assurance Advisory Panel (NQAAP) for Clinical Pathology
- Recognised by the Joint Working Group on Quality Assurance (JWG QA)

Independent Advisory Panel

RIQAS participants have access to an independent advisory panel consisting of scientific and clinical experts. This ensures professional and ethical conduct of the scheme and participant confidentiality.

RIQAS Facts

A good EQA scheme should have:

- Sufficient number of participants
- Effective consolidation of programmes
- International recognition through accreditation
- Quality material
- Regular reports with rapid turnaround times
- Independent advisory panel
- Flexible programme choices

RIQAS Features and Benefits

RIQAS samples are custom-manufactured to be both stable and similar to human samples.

- A high level of participation ensures a **large database** of results and analytical methods, therefore increasing statistical validity.
- Programmes accepted by National and International **accreditation** bodies worldwide.
- Human samples **free from interfering preservatives** increase confidence that EQA performance mirrors the performance of patient samples.
- Optimised shipping of samples for each cycle.
- **Wide range** of parameters covering a broad spectrum of laboratory testing.
- Regular reports with **rapid turnaround**, ensuring corrective actions can be taken prior to analysis of subsequent samples.
- User friendly reports, **easy to read** at a glance, saving valuable laboratory time.
- Reduced parameter options for selected programmes offer **greater flexibility**, ensuring suitability for laboratories of all sizes and budgets.
- **Participant certificates** provide evidence of participation in a reputable EQA scheme.
- **Multi-instrument reports** allow assessment of performance of all systems in the laboratory.
- **Interlaboratory group** reports allow comparison of multiple connected laboratories.
- **Reference method** values are provided in the Clinical Chemistry programme for 12 parameters.



RIQAS Reports

RIQAS reports are presented in a user friendly, one page per parameter format. This allows easy interpretation of your analytical performance.

RIQAS Reports

- Statistical breakdown by all methods, your method and, where applicable, your instrument including running means for the last 10 samples.
- Compare your instrument group, method group and all methods using the histogram.
- Identify trends, biases and precision problems using the visual charts.
- The Target Score chart grades your performance in a moving window over the last 20 samples, including the previous cycle.
- At-a-glance summary page for all parameters in the programme.
- Compare your result with statistically robust consensus means.
- Identify acceptable and poor performance using fit-for-purpose performance indicators:
 - SDI
 - % Deviation
 - Target Score



Multi-Instrument Reports

Laboratories can register up to five instruments at no extra cost. Individual reports for each instrument plus a unique multi-instrument report are provided.

The multi-instrument report allows the comparative performance of each instrument. Additional sample packs may be ordered as required.

PDF Reporting

RIQAS reports can now be presented in pdf (portable document format), offering easy review and storage of your laboratory's EQA data.

There are many advantages associated with pdf reporting, increasing the usability and efficiency of data analysis.

Summary CSV files

It is possible to receive an additional summary of your report statistics, acceptable limits and performance indicators as a .csv file for every sample.

A retrospective statistics summary is also available, four weeks after the final date, for parameters where a result has not been submitted on time.

RIQAS Facts

Interlaboratory group reports:

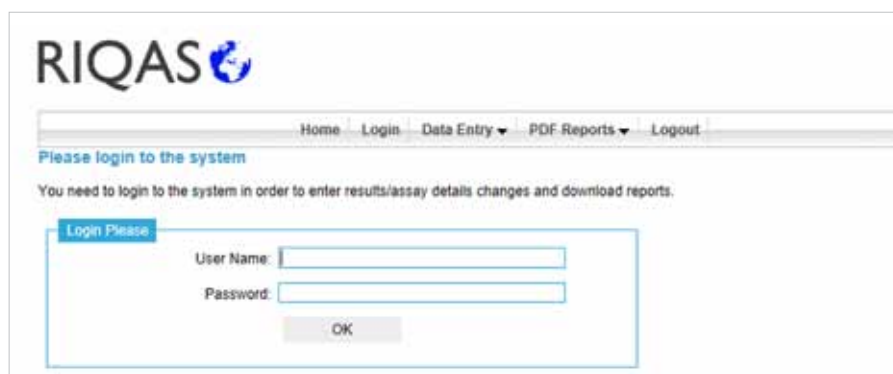
The Group Reporting facility enables laboratory groups to monitor satellite sites. Laboratories can receive individual reports with the group supervisor receiving a report comparing the laboratories within the group. This allows easy assessment of performance of all laboratories within a group.

Web-Based Data Transfer

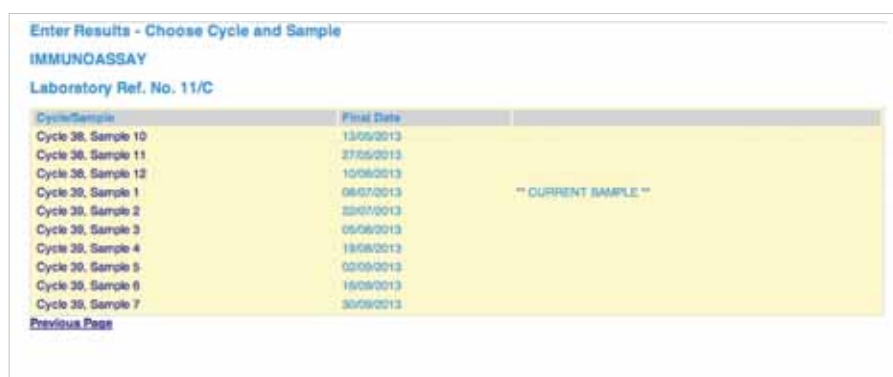
The **RIQASNet** system offers easy direct access for the submission of results and retrieval of reports straight from the **RIQAS** host server.



- Website available in multiple languages.
- Confidentiality and security is maintained through the use of password protected access.
- Submit current, corrected and future results (normal policies apply), directly into RIQAS database. Receipt of results is confirmed by e-mail.



- Multi-lingual registration identifier provides simple identification of multiple registrations.
- Additions and changes to assay details can be made online.
- Requests for new method, instrument and reagent codes can be made online.
- Details of assays or reagent instructions for use can be sent directly to RIQAS for ease of classification.



- Reports are emailed in pdf format as soon as they are prepared.
- Up to two cycles of reports are available to be downloaded from website.
- View, print, store or distribute reports as you wish.
- Update certificate of participation details in multiple languages.



- All that is required is web access, Adobe Reader (for viewing reports) and a valid password to access system. No additional software required.

Participation in RIQAS



Participant registers methods used in their lab by completing enrolment document. Enrolment documents are available from www.riqas.com and should be submitted 3 weeks before the cycle starts. Check RIQAS policies in method questionnaire.



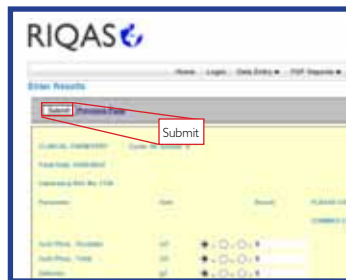
Participant receives a set of numbered samples for the cycle along with a username/ password to access RIQASNet.



Participant analyses the sample on the recommended date, carefully following the instructions for use.



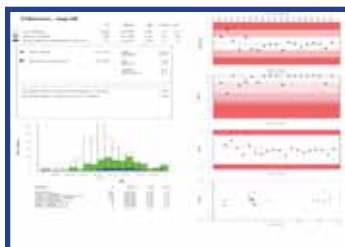
Participant receives report by e-mail or post.



Participant submits the results via RIQASNet, or sends the return sheet by fax or post, before the "final date" deadline.



Participant enters the results on RIQASNet or on the return sheet.



Participant reviews the report to assess performance



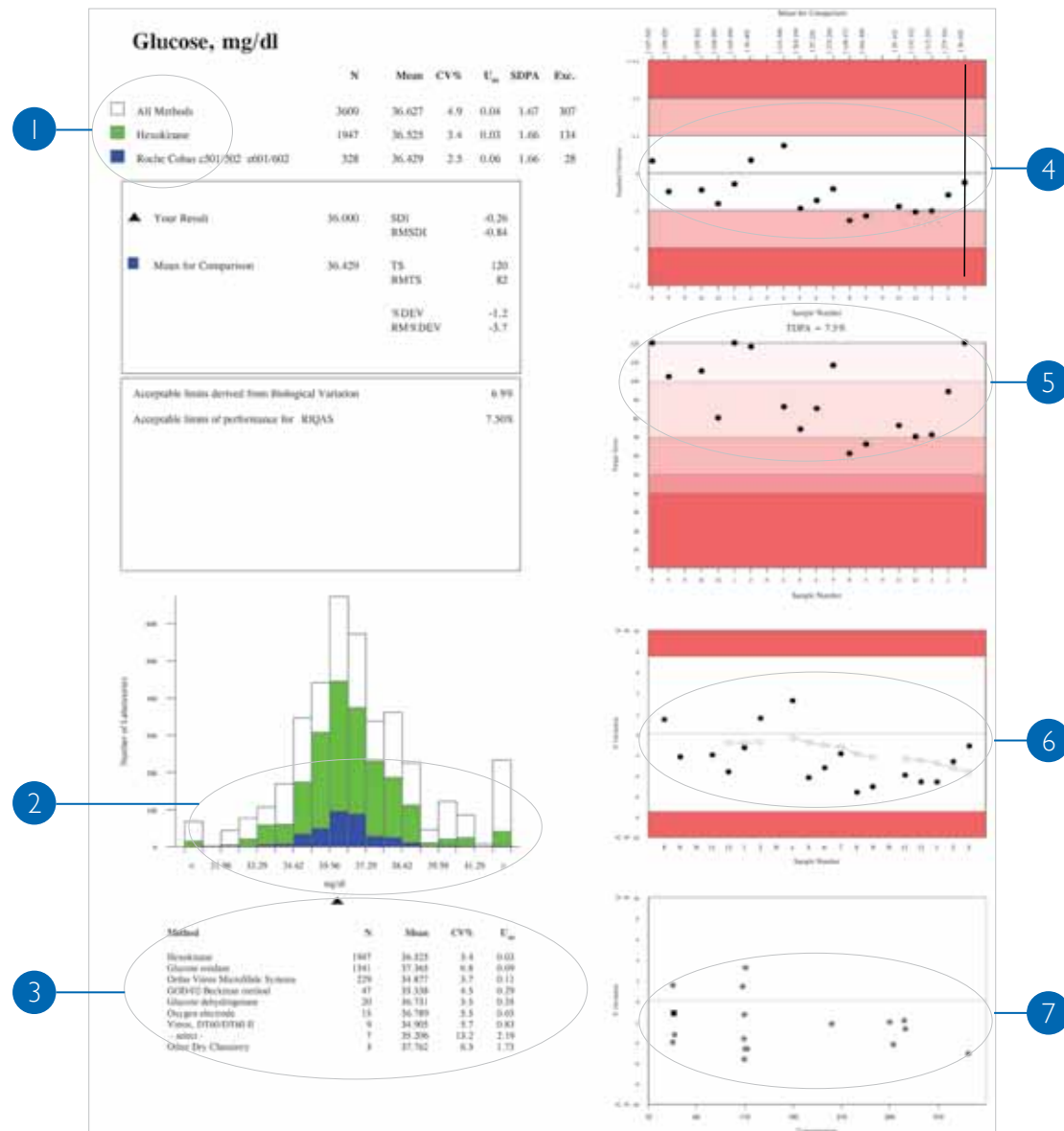
Participant receives an end-of-cycle report, a certificate of acceptable performance and a certificate of participation at the end of the cycle, provided that more than half results are returned.



Method changes and registration of additional parameters can be submitted via RIQASNet.

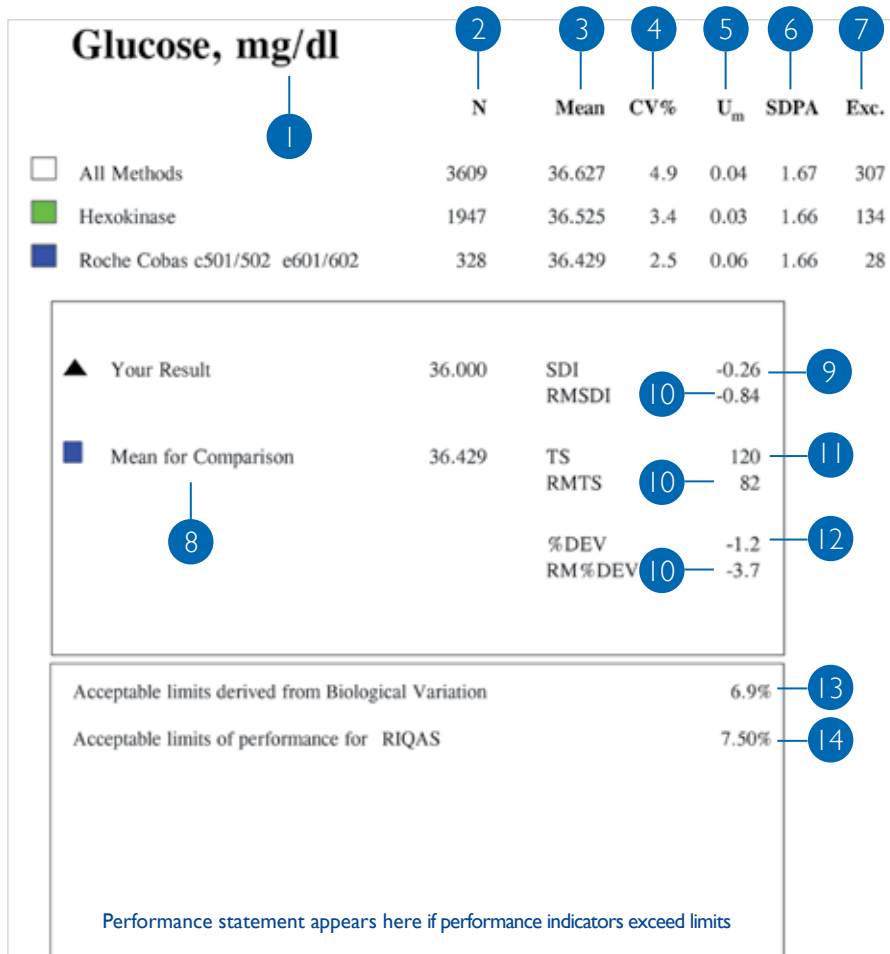
Standard Report

Performance data is presented in a one page format with up to seven sub-reports.



- 1 Text Section: Statistics for all methods, your method and instrument group (programme specific).
- 2 Histogram: Method and instrument comparison.
- 3 Multi-Method Stat Section: Enables assessment of the performance of each method.
- 4 Levey-Jennings Chart: Details features of your laboratory's performance.
- 5 Target Score: This unique chart provides a numerical index of performance, allowing at a glance assessment.
- 6 % Deviation by Sample: Helps to identify trends and shifts in performance.
- 7 % Deviation by Concentration: Rapid assessment of concentration related biases.

Text Section



RIQAS performance indicators include SDI, Target Score and % deviation.

Acceptable performance criteria:
 SDI < 2SDPA
 Target score > 50
 % deviation < defined acceptable limits

- 1 Report is presented in your chosen unit.
- 2 Number of returned results used to generate Mean for Comparison.
- 3 Average value of all laboratories' results.
- 4 Coefficient of Variation.
- 5 Uncertainty associated with the mean for comparison.

$$U_m = \frac{1.25 \times SD}{\sqrt{n}}$$
- 6 SDPA = Standard Deviation for Performance Assessment, calculated from the Target Deviation for Performance Assessment (TDPA) and the mean for comparison.

$$SDPA = \frac{TDPA \times \text{Mean for comparison}}{t\text{-value} \times 100}$$
- 7 After statistical reduction, some results are excluded.
- 8 Ideally this will be your instrument group mean. If N<5 for instrument group, your method group Mean is selected as Mean for Comparison.
- 9 Standard Deviation Index = $\frac{\text{Your result} - \text{Mean for Comparison}}{SDPA_{\text{adjusted}}}$
- 10 Running Mean average of the last 10 performance indicators is used to monitor performance over time and concentration range.
- 11 Target Score - The closer a value is to 120, the better the performance.
- 12 % Deviation from the Mean for Comparison - the closer the value is to zero, the better the performance.
- 13 Biological Variation stated for information purposes only.
- 14 Performance limit set for this parameter.

t-value = factor which represents the % of poor performers reflected in the TDPA (t-value ~ 1.645 when ~10% laboratories achieve poor performance) SDPA is combined with U_m , where appropriate.

If $U_m > (0.3 \times SDPA)$ then $SDPA_{\text{adjusted}} = \sqrt{(U_m^2 + SDPA^2)}$ and the reported value is suffixed with "a"

If U_m is less than $(0.3 \times SDPA)$ then $SDPA_{\text{adjusted}} = SDPA$

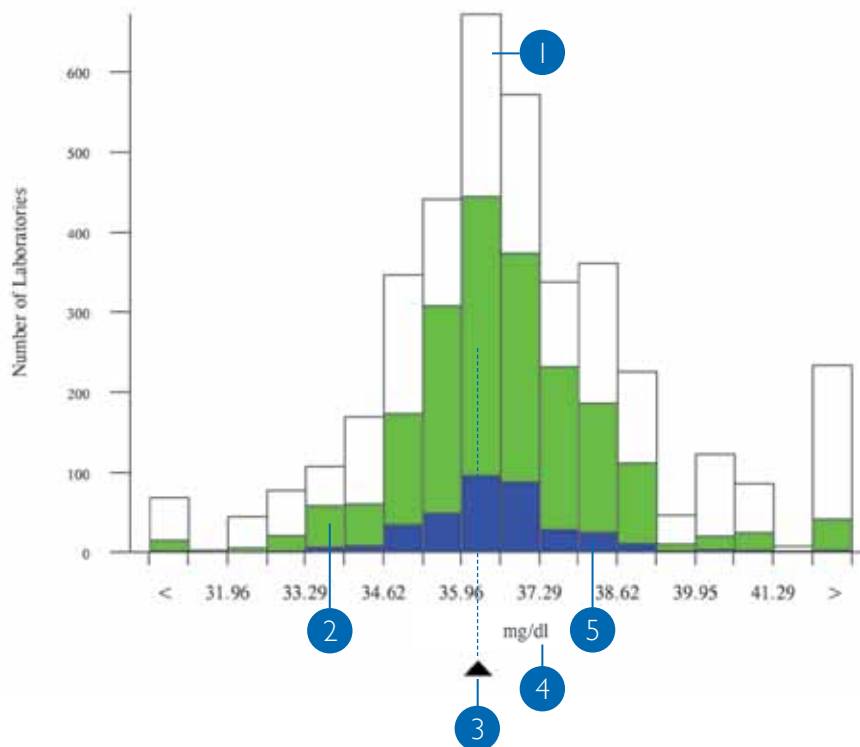
Histogram

The Bar Graph is intended as a quick visualisation of how your lab's result falls into the overall picture of:

□ All methods

■ Your method group

■ Your instrument group (programme specific)



1 Total of 673 laboratories reported values between 35.96 and 36.63.

2 58 laboratories reported values between 33.29 and 33.96 in your method group.

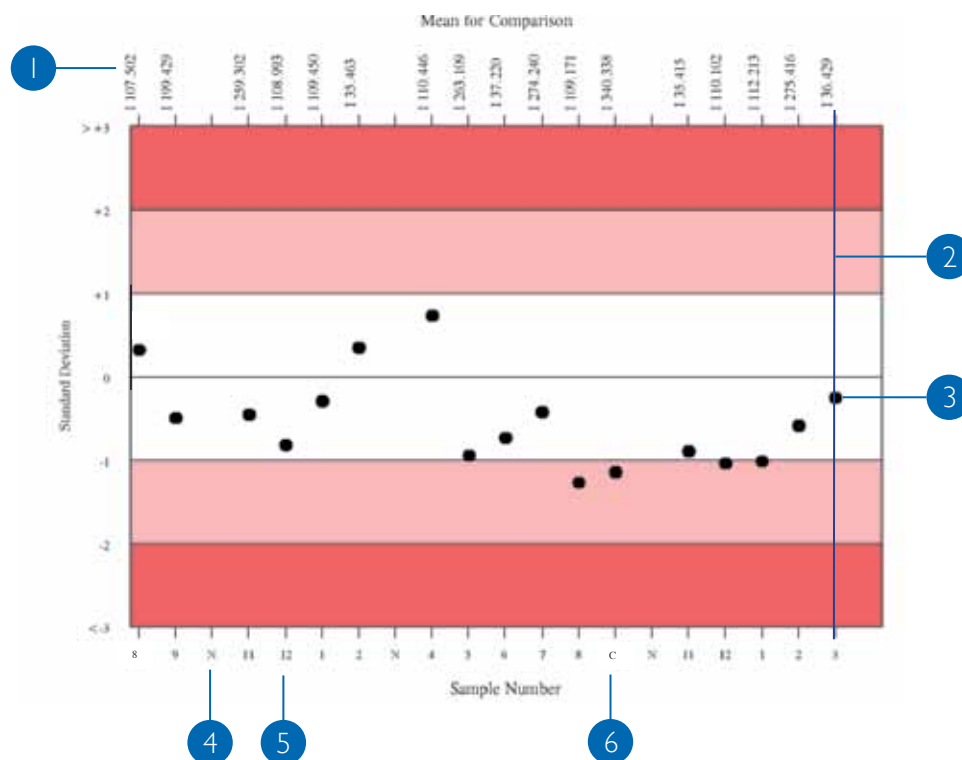
3 Your Result.

4 RIQAS reports show your unit of measurement.

5 25 laboratories reported values between 37.96 and 38.62 in your instrument group.

Levey Jennings Chart

SDIs reflect laboratory performance in relation to fit-for-purpose SDPAs and are useful to monitor performance over time. Acceptable performance is $SDI < 2SDPA$.

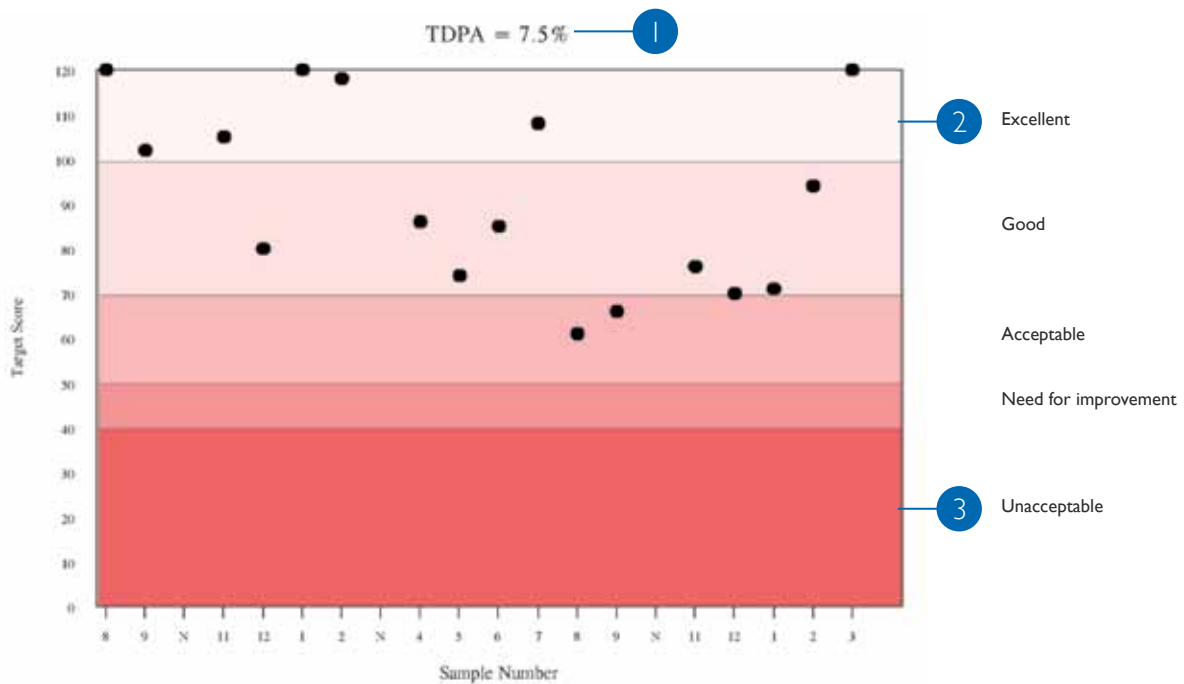


- 1 Where a result has been returned, the Mean for Comparison for each sample is indicated at the top of the chart, allowing easy assessment of concentration related bias:
 I: Instrument mean
 M: Method mean
 A: All method mean
- 2 This line indicates a change in registration details for this parameter.
- 3 Your SDI (Standard Deviation Index).
- 4 N = No result returned from your laboratory. No statistics are shown.
- 5 Sample number.
- 6 C = Corrected results will be accepted for non-analytical errors. Corrected results will be accepted up to 4 weeks after the final date deadline, on application, with evidence of analysis. Late results are only accepted if there has been a Radox error.

 R = Incorrect results can be removed retrospectively on request.

Target Score Chart

The Target Score (TS) allows participants to assess their performance at a glance. The TS relates the % deviation of your result from the Mean to a Target Deviation for Performance Assessment (TDPA). TDPA's are set to encourage participants to achieve and maintain acceptable performance. TDPA's are fit-for-purpose performance criteria which are set taking guidance from ISO/IEC 17043, ISO 13528 and IUPAC. Target Deviations for Performance Assessment are also used to calculate the Standard Deviation for Performance Assessment (SDPA).



1 This is the upper deviation limit of performance for this parameter. TDPA's are reviewed regularly and deemed fit for purpose by the RIQAS Advisory Panel.

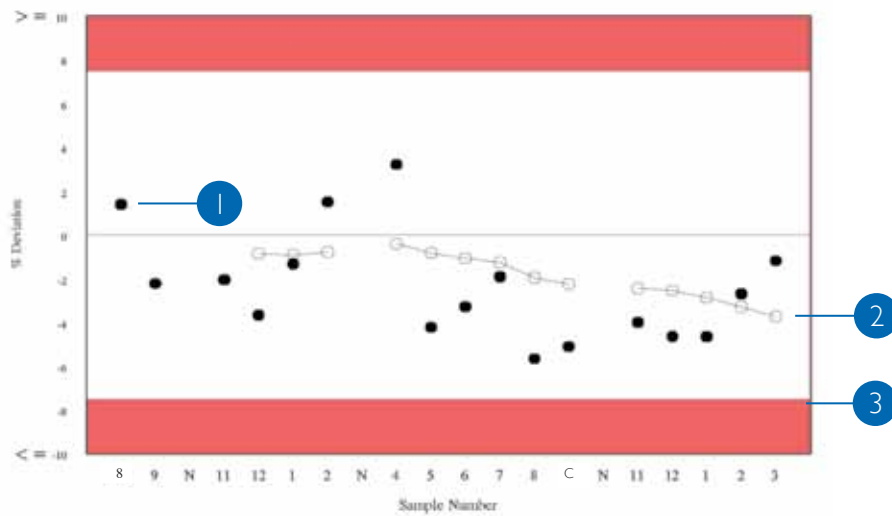
2 High score >50 in the lighter shaded area represents acceptable, good or excellent performance.

3 Heavy shading for values 10 to 50 signifies poor performance.

% Deviation by Sample Chart

This chart helps to identify trends and shifts in performance.

$$\% \text{ Deviation} = \frac{\text{Your result} - \text{Consensus Mean}}{\text{Consensus Mean}} \times 100\%$$



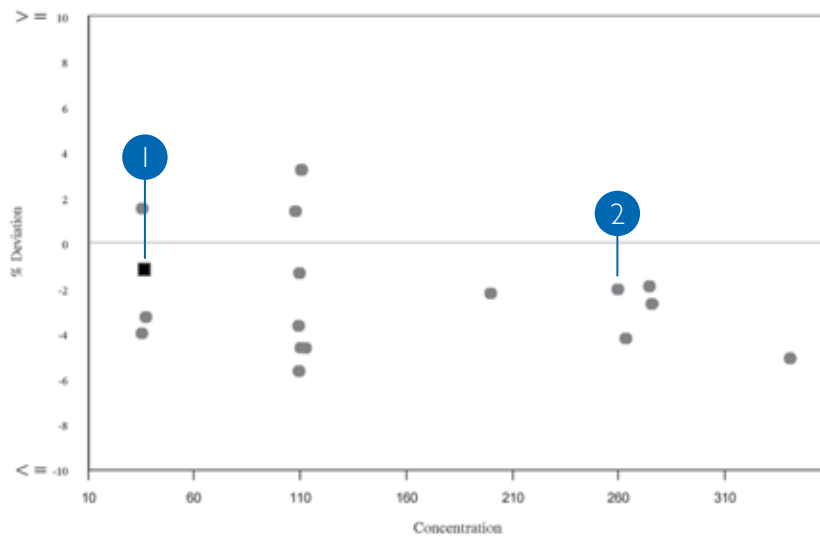
1 % Deviation from Mean for Comparison.

2 Plot of Running Mean % deviations (average of the last 10 % deviations for the sample indicated).

3 Acceptable limits of performance. These are defaulted to RIQAS TDPAs but can be set to e.g. biological variation or regulatory requirement on request.

% Deviation by Concentration Chart

This chart enables rapid assessment of concentration related biases. Biases at low or high concentrations may be easily determined, also whether a particular sample is a random outlier or if a bias is always present at that concentration.



1 Current sample indicated by square.

2 % Deviation at specific concentration.

Multi Method Stat Section

This section provides an easy way of assessing the performance of the other methods used to analyse the parameter:

| Method | N | Mean | CV% | U _m |
|---------------------------------|------|--------|-----|----------------|
| Hexokinase | 1947 | 36.525 | 3.4 | 0.03 |
| Glucose oxidase | 1341 | 37.365 | 6.8 | 0.09 |
| Ortho Vitros MicroSlide Systems | 229 | 34.877 | 3.7 | 0.11 |
| GOD/02-Beckman method | 47 | 35.538 | 4.5 | 0.29 |
| Glucose dehydrogenase | 20 | 36.731 | 3.5 | 0.35 |
| Oxygen electrode | 15 | 36.789 | 5.5 | 0.65 |

Summary Page

| Analyte | Mean for Comparison | Your Result | SDI | RMSDI | %DEV | RM%DEV | TS | RMTS | Performance |
|----------------------|---------------------|-------------|--------------|---------|--------------|---------|-----------|------|-------------|
| Albumin | 2.120 | 2.230 | 1.00 | 0.37 | 5.2 | 2.0 | 72 | 107 | |
| Alkaline Phosphatase | 17.705 | 19.000 | 0.61 | -0.27 | 7.3 | -2.9 | 93 | 105 | |
| ALT (GPT) | 12.387 | 12.000 | -0.33 | -0.47 | -3.1 | -3.8 | 119 | 103 | |
| Amylase, Total | 20.454 | 22.000 | 0.72 | -0.29 | 7.6 | -2.5 | 86 | 103 | |
| AST (GOT) | 11.976 | 11.000 | -0.86 | -0.03 | -8.2 | -0.4 | 78 | 100 | |
| Bicarbonate | 8.203 | 6.900 | -1.48 | 0.15 | -15.9 | 1.5 | 54 | 98 | |
| Bilirubin, Direct | 0.251 | 0.380 | <u>2.57</u> | 2.64 | <u>51.3</u> | 47.2 | <u>31</u> | 29 | ▲ |
| Bilirubin, Total | 0.701 | 0.640 | -0.91 | -0.29 | -8.8 | -2.9 | 76 | 101 | |
| Calcium | 6.074 | 6.020 | -0.19 | -0.40 | -0.9 | -1.8 | 120 | 92 | |
| Chloride | 76.353 | 77.000 | 0.30 | -0.28 | 0.8 | -0.8 | 120 | 98 | |
| Cholesterol | 112.696 | 110.000 | -0.55 | 0.05 | <u>12.7</u> | 0.2 | 97 | 115 | |
| CK, Total | 111.659 | 111.000 | -0.08 | 0.35 | -0.6 | 2.5 | 120 | 107 | |
| Creatinine | 0.607 | 0.620 | 0.27 | 0.06 | 2.1 | 0.5 | 120 | 117 | |
| Glucose | 36.429 | 36.000 | -0.26 | -0.84 | -1.2 | -3.7 | 120 | 82 | |
| HDL-Cholesterol | 98.836 | 102.000 | 0.21 | -0.04 | 3.2 | -0.4 | 120 | 113 | |
| Iron | 97.374 | 99.000 | 0.28 | 0.01 | 1.7 | 0.1 | 120 | 114 | |
| Lactate (Pilot) | | No Result | | Too Few | | Too Few | N/A | N/A | |
| LD (LDH) | 85.894 | 87.000 | 0.11 | -0.70 | 1.3 | -6.3 | 120 | 89 | |
| Magnesium | 1.313 | 1.390 | 0.79 | -0.07 | 5.8 | -0.5 | 82 | 107 | |
| Phosphate, Inorganic | 1.451 | 1.540 | 1.02 | 0.02 | 6.1 | 0.1 | 71 | 112 | |
| Potassium | 1.770 | 1.840 | 1.10 | -0.25 | 3.9 | -0.7 | 67 | 99 | |
| Protein, Total | 3.850 | 3.830 | -0.11 | 0.07 | -0.5 | 0.3 | 120 | 114 | |
| Sodium | 112.537 | 114.000 | 0.58 | -0.01 | 1.3 | -0.0 | 95 | 104 | |
| TIBC | 133.143 | 133.000 | -0.01 | -0.01 | -0.1 | -0.1 | 120 | 117 | |
| Trig Total | 23.626 | 24.000 | 0.18 | -0.09 | 1.6 | -0.6 | 120 | 114 | |
| Urea | 5.872 | 5.000 | <u>-2.02</u> | -0.57 | <u>-14.9</u> | -4.0 | <u>41</u> | 95 | ▲ |
| Uric Acid (Urate) | 3.135 | 3.100 | -0.20 | -0.44 | -1.1 | -2.4 | 120 | 107 | |

ORMSDI -0.05

5

ORM%DEV 0.8

6

ORMTS 102

7

- 1 RMSDI - is the Running Mean of the 10 previous SDIs (if fewer than 10 results on file, "Too Few" is printed).
- 2 Red triangle appears when all performance indicators (SDI, %DEV and TS) exceed acceptable performance, i.e: when
SDI > 2SDPA
TS < 50
%DEV > acceptable limits set
- 3 RM % DEV - Average of the last 10 %DEV for this parameter.
- 4 RMTS - Average of the last 10 Target Scores for this parameter.
- 5 Overall RMSDI = average RMSDI for this sample distribution.
- 6 Overall RM%DEV = average RM%DEV for this sample distribution.
- 7 Overall RMTS = average RMTS for this sample distribution.

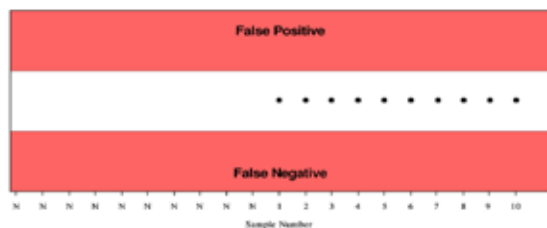
Urine Toxicology Report

SCREENING SECTION

Cannabinoids Group, ng/ml

Your Result Positive

Based on weighed-in value of 125
and your chosen cut-off value of 50
the correct response was Positive



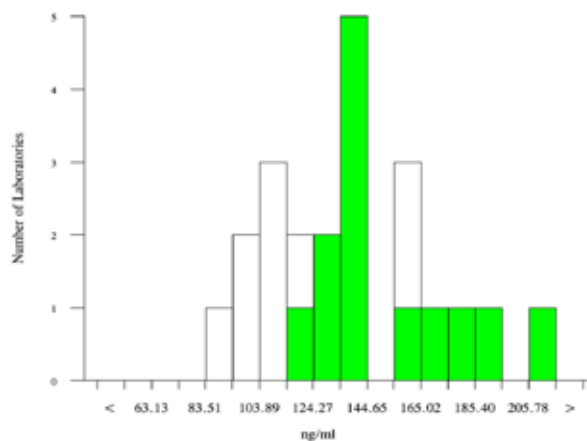
| | | |
|-----------------|------|-------|
| THC | 125 | ng/ml |
| Phenobarbital | 600 | ng/ml |
| Oxazepam | 250 | ng/ml |
| Benzoylcegonine | 500 | ng/ml |
| Ethanol | 20 | ng/ml |
| Free Morphine | 1500 | ng/ml |
| Phencyclidine | 25 | ng/ml |

| | Cut-off | TN | TP | FN | FP | RC | NT | Total |
|--|---------|----|----|----|----|----|----|-------|
| Your Result | 50 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| FPIA | 25 | 0 | 3 | 0 | 0 | 0 | 0 | 3 |
| | 50 | 0 | 11 | 1 | 0 | 0 | 0 | 12 |
| | All | 0 | 14 | 1 | 0 | 0 | 0 | 15 |
| All Methods | 20 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| | 25 | 0 | 3 | 0 | 0 | 0 | 0 | 3 |
| | 30 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 50 | 0 | 54 | 17 | 0 | 2 | 1 | 74 |
| | 65 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 100 | 0 | 3 | 0 | 0 | 0 | 0 | 3 |
| | 145 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| All | 0 | 64 | 17 | 1 | 2 | 1 | 85 | |
| Competitive Antibody Binding | 50 | 0 | 7 | 2 | 0 | 0 | 0 | 9 |
| CEDIA | 50 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| DRI-EIA | 50 | 0 | 4 | 0 | 0 | 0 | 0 | 4 |
| EMIT | 50 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| EMIT II+ | 50 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| KIMS | 50 | 0 | 4 | 0 | 0 | 0 | 0 | 4 |
| Point of Care | 50 | 0 | 22 | 12 | 0 | 2 | 0 | 36 |
| Randox Biochip Array Technology | 50 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| Biosite Triage | 50 | 0 | 0 | 2 | 0 | 0 | 1 | 3 |

QUANTITATIVE SECTION

| | N | Mean | SD | CV% | exc. |
|-------------|----|---------|-------|------|------|
| All Methods | 22 | 134.462 | 27.17 | 20.2 | 1 |
| FPIA | 13 | 145.993 | 22.02 | 15.1 | 1 |

| | | | |
|-----------------------|---------|-------|---------|
| ▲ Your Result | 132.000 | SDI | -0.64 |
| | | RMSDI | Too Few |
| ■ Mean for Comparison | 145.993 | | |



| Method | N | Mean | SD | CV% |
|------------------------------|----|---------|-------|------|
| FPIA | 13 | 145.993 | 22.02 | 15.1 |
| Competitive Antibody Binding | 2 | 136.900 | 35.50 | 25.9 |
| GC/MS | 2 | 119.000 | 7.07 | 5.9 |
| KIMS | 2 | 104.000 | 5.66 | 5.4 |

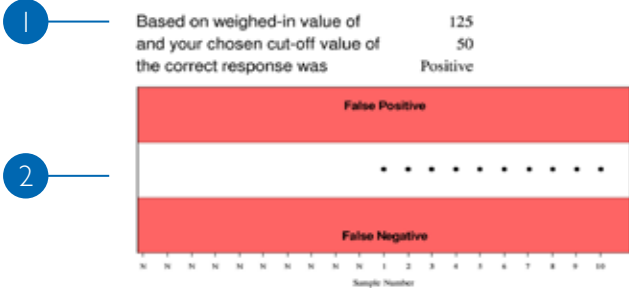
Performance History

| Your Data (Last 10 Samples) | Your Method (This Sample) | Your Method (Last 10 Samples) | All Methods (This Sample) | All Method (Last 10 Samples) |
|-----------------------------|---------------------------|-------------------------------|---------------------------|------------------------------|
| 0 % False Negatives | 7 % False Negatives | 8 % False Negatives | 20 % False Negatives | 22 % False Negatives |
| 0 % False Positives | 0 % False Positives | 12 % False Positives | 1 % False Positives | 6 % False Positives |
| 100 % Correct Responses | 93 % Correct Responses | 81 % Correct Responses | 79 % Correct Responses | 72 % Correct Responses |

Urine Toxicology Report Screening Section

Cannabinoids Group, ng/ml

Your Result Positive



3

| | | |
|-----------------|------|-------|
| THC | 125 | ng/ml |
| Phenobarbital | 600 | ng/ml |
| Oxazepam | 250 | ng/ml |
| Benzoylcegonine | 500 | ng/ml |
| Ethanol | 20 | ng/ml |
| Free Morphine | 1500 | ng/ml |
| Phencyclidine | 25 | ng/ml |

4

| | Cut-off | TN | TP | FN | FP | RC | NT | Total |
|------------------------------|---------|----|----|----|----|----|----|-------|
| Your Result | 50 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| FPIA | 25 | 0 | 3 | 0 | 0 | 0 | 0 | 3 |
| | 50 | 0 | 11 | 1 | 0 | 0 | 0 | 12 |
| | All | 0 | 14 | 1 | 0 | 0 | 0 | 15 |
| All Methods | 20 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| | 25 | 0 | 3 | 0 | 0 | 0 | 0 | 3 |
| | 30 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 50 | 0 | 54 | 17 | 0 | 2 | 1 | 74 |
| | 65 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 100 | 0 | 3 | 0 | 0 | 0 | 0 | 3 |
| | 145 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| All | 0 | 64 | 17 | 1 | 2 | 1 | 85 | |
| Competitive Antibody Binding | 50 | 0 | 7 | 2 | 0 | 0 | 0 | 9 |
| | 50 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| | 50 | 0 | 4 | 0 | 0 | 0 | 0 | 4 |
| | 50 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| | 50 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| | 50 | 0 | 4 | 0 | 0 | 0 | 0 | 4 |
| | 50 | 0 | 22 | 12 | 0 | 2 | 0 | 36 |
| | 50 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| Biosite Triage | 50 | 0 | 0 | 2 | 0 | 0 | 1 | 3 |

Performance History

Your Data (Last 10 Samples)

0 % False Negatives
0 % False Positives
100 % Correct Responses

11

Your Method (This Sample)

7 % False Negatives
0 % False Positives
93 % Correct Responses

12

Your Method (Last 10 Samples)

8 % False Negatives
12 % False Positives
81 % Correct Responses

13

All Methods (This Sample)

20 % False Negatives
1 % False Positives
79 % Correct Responses

14

All Method (Last 10 Samples)

22 % False Negatives
6 % False Positives
72 % Correct Responses

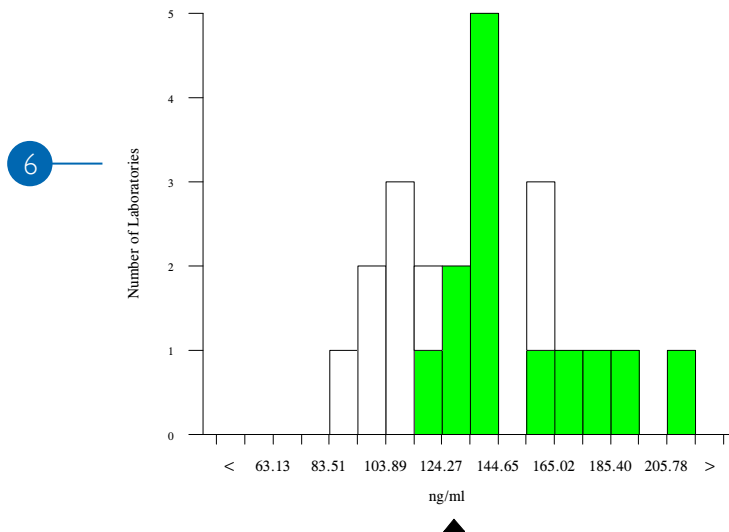
15

- 1 Screening Text Section.
- 2 Screening Results: This chart is a quick visualisation of your performance over the last 20 samples. A result in the white section indicates a correct response. A result in the upper red section indicates a False Positive response, and a result in the lower red section indicates a False Negative response.
- 3 Comment section for RIQAS to provide your laboratory with additional relevant information regarding this sample, such as spiked metabolite concentration.
- 4 Screening result response categories. All abbreviations indicated at the bottom of the report page.
KEY
TN - true negative TP - true positive FN - false negative
FP - false positive RC - sent for confirmation NT - not tested
- 5 Screening Summary: Your screening result shown in the appropriate response category and your cut off for this sample.
- 6 Screening results for all cut-offs returned for this sample within your method group.
- 7 Total screening results over all your cut-offs for your laboratory's method.
- 8 Screening results for all cut-offs returned for this sample over all methods.
- 9 Total screening results over all cut-offs for all methods.
- 10 Screening results for other methods using same cut-off as your laboratory.
- 11 Performance history for this parameter; based on previous 10 samples.
- 12 Performance of your method over all cut-offs for this sample.
- 13 Performance history of your method over all cut-offs, based on the previous 10 samples.
- 14 Performance of all methods over all cut-offs for this sample.
- 15 Performance history of all methods over all cut-offs, based on the previous 10 samples.

Urine Toxicology Report Quantitative Section

| | N | Mean | SD | CV% | exc. |
|---------------|----|---------|-------|------|------|
| □ All Methods | 22 | 134.462 | 27.17 | 20.2 | 1 |
| ■ FPIA | 13 | 145.993 | 22.02 | 15.1 | 1 |

| | | | |
|-----------------------|---------|-------|---------|
| ▲ Your Result | 132.000 | SDI | -0.64 |
| | | RMSDI | Too Few |
| ■ Mean for Comparison | 145.993 | | |



| Method | N | Mean | SD | CV% |
|------------------------------|----|---------|-------|------|
| FPIA | 13 | 145.993 | 22.02 | 15.1 |
| Competitive Antibody Binding | 2 | 136.900 | 35.50 | 25.9 |
| GC/MS | 2 | 119.000 | 7.07 | 5.9 |
| KIMS | 2 | 104.000 | 5.66 | 5.4 |

1 Quantitative Text Section: Comparison statistics. Caution is needed when the N value is too small to support statistical significance.

2 Your Result.

3 Your Mean for Comparison.

4 Standard Deviation Index = $\frac{\text{Your Result} - \text{Mean for Comparison}}{\text{SD of Mean for comparison}}$

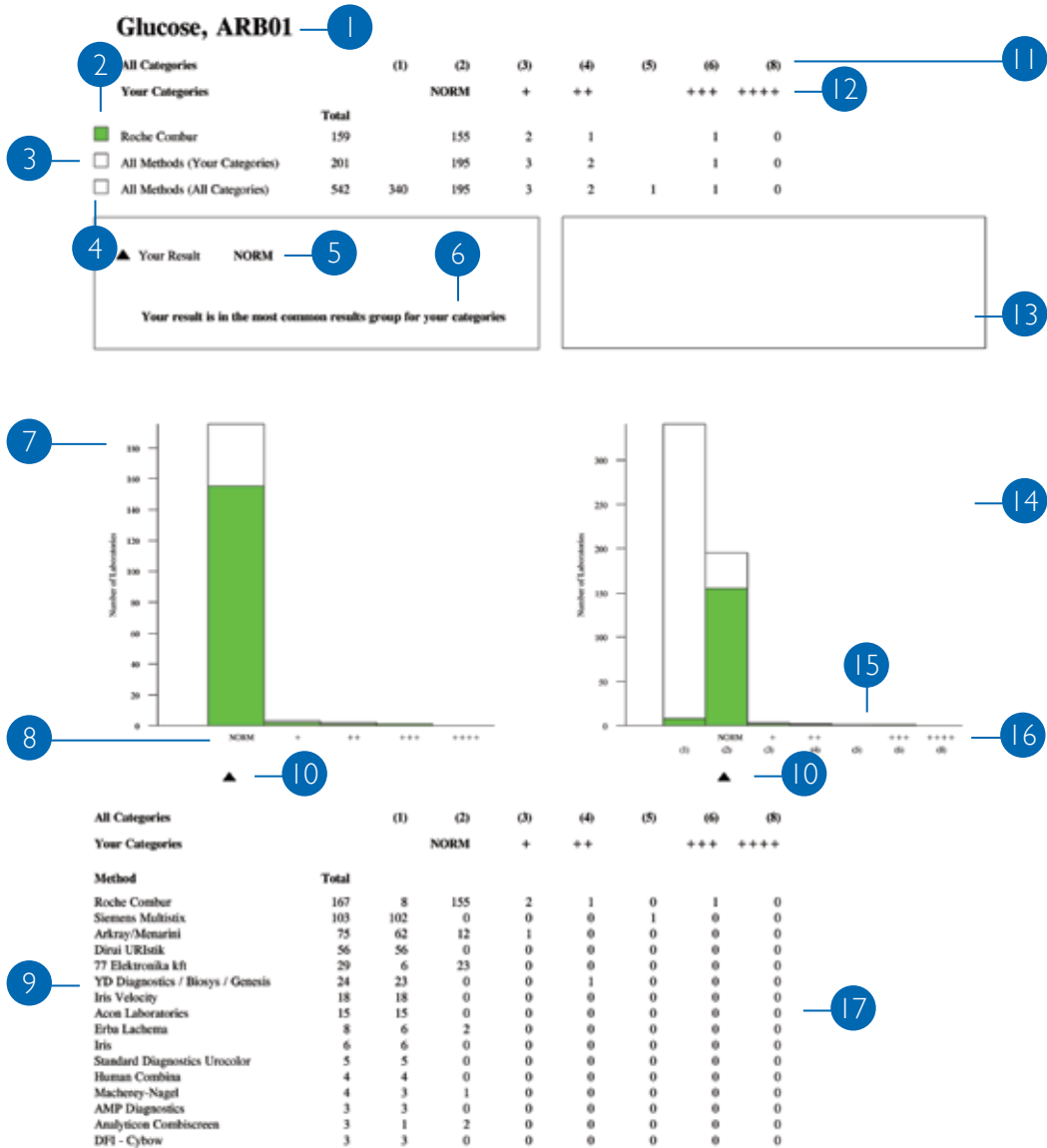
5 Running mean SDI = average of last 10 SDIs for this parameter (If fewer than 10 results, "Too Few" is printed).

6 Quantitative Results Histogram: This graph provides a quick visualisation of how your quantitative result falls into the overall picture for all methods and your method group.

7 All available method statistics for this sample.

Urinalysis Report

SCREENING RESULTS



- 1 Categories are stated in your unit.
- 2 Your method group and categories.
- 3 Results from all methods (dipsticks) returning results in the same categories as your lab.
- 4 Results from all methods for all available categories.
- 5 Your Result.
- 6 Performance Statement.
- 7 Your Categories Histogram: A quick visualisation of how your lab's result falls into the overall picture for your categories.
- 8 Possible reporting categories for your method.
- 9 All available methods for this parameter.
- 10 Your Result.
- 11 All categories (result options) available for this parameter for any method (dipstick).
- 12 Your categories (available result options for chosen dipstick and unit).
- 13 Comments Box.
- 14 All Categories Histogram: a quick visualisation of how your lab's result falls into the overall picture for all categories.
- 15 Results submitted from a category not applicable to your method.
- 16 Your categories.
- 17 Detailed summary of results: This table enables you to see how you compare to all other results.

Serology: Screening (Qualitative) Report

Your performance for multiple samples is presented in a convenient single report per quarterly distribution.

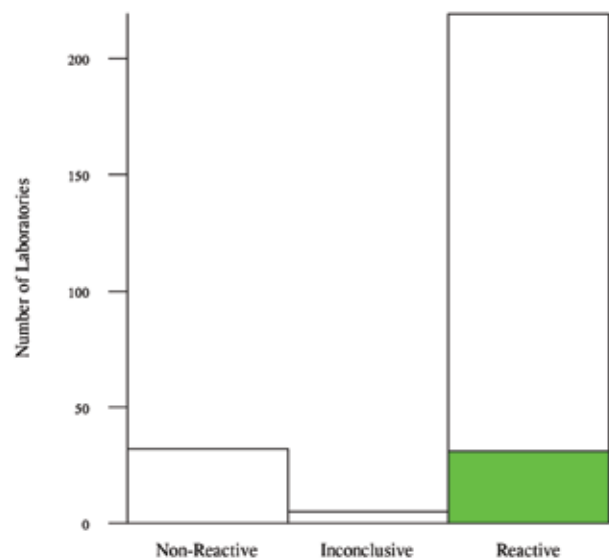
HBsAg

Sample 16

Your method: Roche Cobas 6000 / 8000
 Your result: Reactive
 Acceptable result (Method): Reactive

Overall results
 Non-Reactive: 32
 Inconclusive: 5
 Reactive: 219

| Method | N | Non-Reactive | Inconclusive | Reactive |
|--------------------------------|----|--------------|--------------|----------|
| Abbott Architect | 60 | 0 | 0 | 60 |
| Roche Cobas 4000/e411 | 34 | 1 | 0 | 33 |
| Roche Cobas 6000 / 8000 | 31 | 0 | 0 | 31 |
| Siemens/Bayer ADVIA Centaur | 22 | 0 | 0 | 22 |
| Roche Elecsys | 17 | 1 | 0 | 16 |
| Biomereux VIDAS | 15 | 1 | 0 | 14 |
| Abbott AxSYM | 11 | 2 | 0 | 9 |
| Beckman Dxl 600 / 800 | 11 | 1 | 2 | 8 |
| Ortho Vitros 3600/5600/ECI | 11 | 0 | 0 | 11 |
| TurkLab/Toyo Labmen Rapidest | 5 | 3 | 0 | 2 |
| Beckman Access/LXi725 | 4 | 0 | 2 | 2 |
| SD Bioline Rapid Test HBsAg | 4 | 3 | 0 | 1 |
| Bio-Rad HBs PLUS | 3 | 1 | 0 | 2 |
| Diasorin/Abbott Murex ELISA | 3 | 2 | 1 | 0 |
| Siemens/DPC Immulite 2000/2500 | 3 | 3 | 0 | 0 |
| Koroglu Laboquick HBsAg test | 3 | 3 | 0 | 0 |
| Roche Modular E170 | 3 | 0 | 0 | 3 |
| Biomereux Hepanostika | 2 | 0 | 0 | 2 |
| General Biologicals ELISA | 2 | 2 | 0 | 0 |



1 Your qualitative result and chosen method are presented along with the acceptable result based on an 80% consensus. This consensus will be at the method level if there are ≥ 5 labs in the group or if there are < 5 labs, will be at the all method level.

2 Overall Summary shows the number of results for this parameter and sample which are non-reactive, inconclusive or reactive.

3 Your Result is shown as a black triangle on the category chart compared to other laboratories in groups:

All Methods Your Method

4 Summary shows performance of all the methods used to analyse the parameter.

Serology: Screening (Quantitative) Report

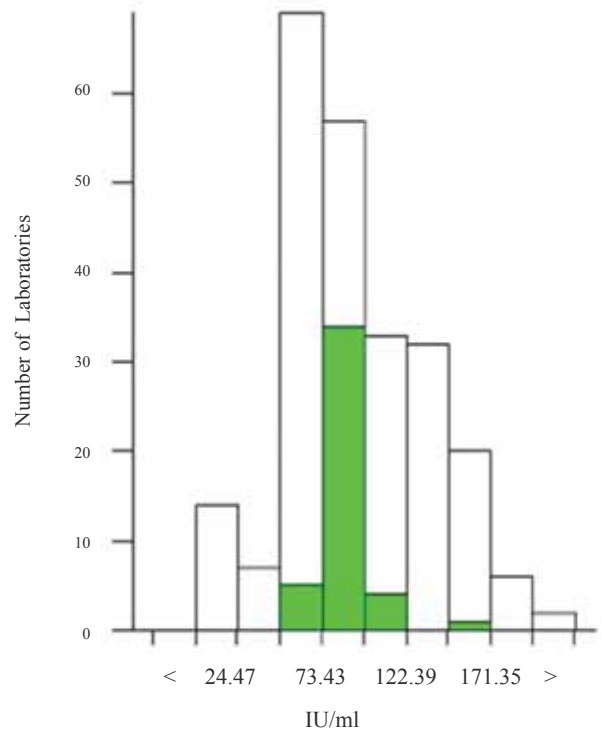
Your performance for multiple samples is presented in a convenient single report per quarterly distribution.

Anti-Rubella IgG, IU/ml

Sample 2

| | N | Mean | CV% | U _m | SDPA | Exc. |
|------------------|-----|--------|------|----------------|-------|------|
| All methods | 210 | 92.574 | 37.2 | 2.97 | 34.42 | 31 |
| Abbott Architect | 39 | 83.219 | 8.7 | 1.46 | 7.27 | 5 |

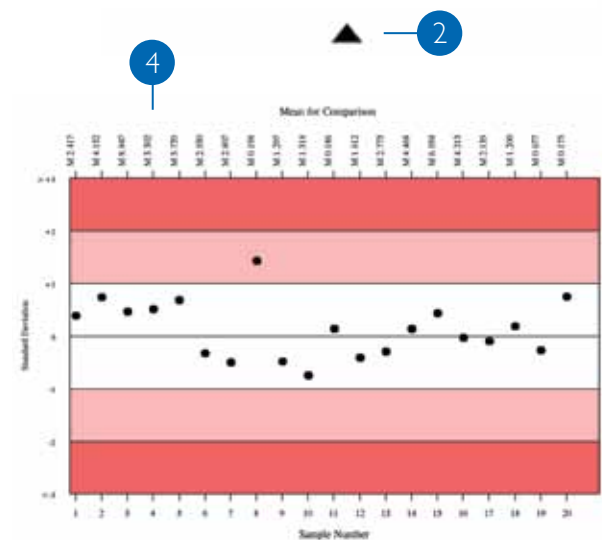
| | | | |
|-----------------------|--------|--------------|-----------------|
| ▲ Your Result | 84.800 | SDI RMSDI | 0.22 Too Few |
| ■ Mean for Comparison | 83.219 | | |



3

| Method | N | Mean | CV% | U _m |
|--------------------------------|----|---------|------|----------------|
| Biomerieux VIDAS | 48 | 150.979 | 9.8 | 2.97 |
| Abbott Architect | 44 | 83.219 | 8.7 | 1.46 |
| Roche Cobas 6000/8000 | 18 | 58.792 | 3.6 | 0.68 |
| Abbott AxSYM | 17 | 108.206 | 18.0 | 6.09 |
| Siemens/DPC Immulite 2000/2500 | 17 | 90.800 | 6.2 | 1.94 |
| Roche Cobas 4000/e411 | 17 | 59.973 | 7.0 | 1.35 |
| Siemens/Bayer ADVIA Centaur | 14 | 120.775 | 11.0 | 5.88 |
| Roche Elecsys | 11 | 57.043 | 3.9 | 1.05 |
| Diasorin Liaison | 9 | 52.388 | 18.0 | 4.16 |
| Roche Modular E170 | 9 | 58.949 | 3.9 | 1.08 |
| Beckman Dxl 600/800 | 6 | 125.817 | 7.4 | 4.75 |

4



1 Quantitative statistics for “All Methods” and “Your Method” are presented in your chosen unit along with your result and your performance scores (SDI and RMSDI).

2 Your result is presented on the bar graph as a black triangle, showing how you compare to the :

All Methods Your Method

3 Multi Method Statistics section provides an easy way of assessing the performance of the methods used to analyse the parameter.

4 Levey-Jennings chart - Your SDIs for previous 20 samples.

Quantitative end of cycle report

The end-of-cycle report is sent to all participants at the end of each cycle and provides a complete summary of statistics. Results can also be compared to the previous cycle.

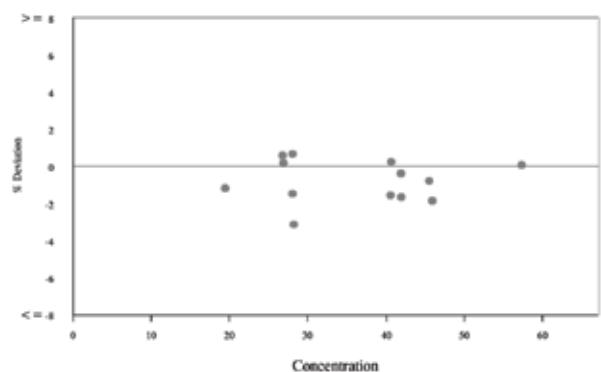
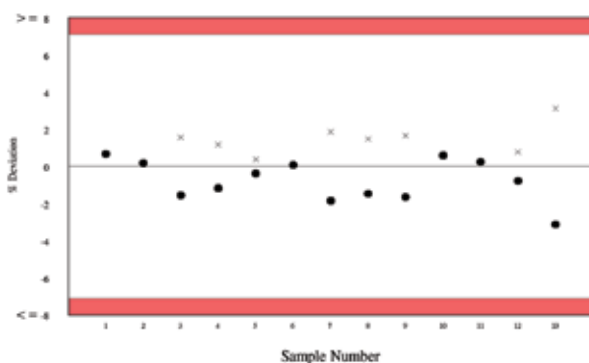
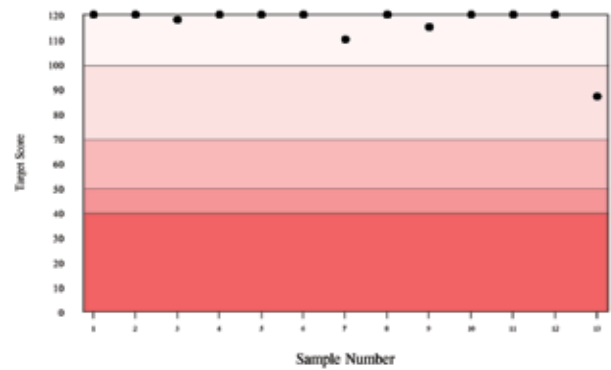
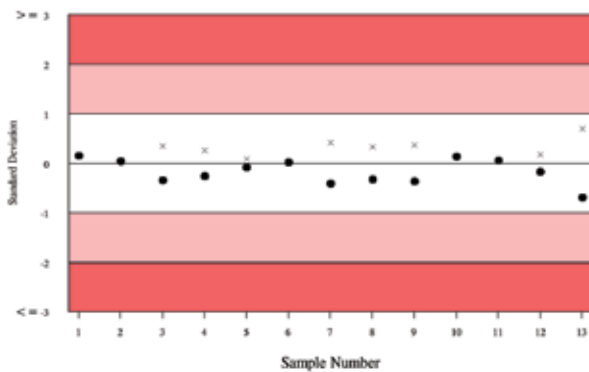
Albumin, g/l

Method: Bromocresol Purple
Instrument: Siemens/Dade Dimension RxL/Max/Xpand
Reagent: Siemens/Dade Behring

RIQAS TDPA: 7.1% **Biological Variation:** 3.9%

| Sample | Result | Unit | N | Mean for Comparison | CV% | Um | SDPA | SDI | TS | % Deviation |
|--------|--------|------|----|---------------------|-----|------|------|-------|-----|-------------|
| 1 | 28.200 | g/l | 68 | I 28.013 | 2.4 | 0.10 | 1.26 | 0.15 | 120 | 0.67 |
| 2 | 26.900 | g/l | 87 | I 26.853 | 2.7 | 0.10 | 1.21 | 0.04 | 120 | 0.17 |
| 3 | 39.900 | g/l | 71 | I 40.531 | 2.5 | 0.15 | 1.82 | -0.35 | 118 | -1.56 |
| 4 | 19.200 | g/l | 81 | I 19.429 | 2.5 | 0.07 | 0.87 | -0.26 | 120 | -1.18 |
| 5 | 41.700 | g/l | 67 | I 41.859 | 2.0 | 0.13 | 1.88 | -0.08 | 120 | -0.38 |
| 6 | 57.300 | g/l | 87 | I 57.257 | 2.7 | 0.21 | 2.58 | 0.02 | 120 | 0.08 |
| 7 | 45.000 | g/l | 72 | I 45.850 | 2.1 | 0.14 | 2.06 | -0.41 | 110 | -1.85 |
| 8 | 27.600 | g/l | 87 | I 28.013 | 2.5 | 0.09 | 1.26 | -0.33 | 120 | -1.47 |
| 9 | 41.200 | g/l | 70 | I 41.891 | 2.2 | 0.14 | 1.88 | -0.37 | 115 | -1.65 |
| 10 | 26.900 | g/l | 83 | I 26.742 | 3.3 | 0.12 | 1.20 | 0.13 | 120 | 0.59 |
| 11 | 40.700 | g/l | 71 | I 40.601 | 2.2 | 0.14 | 1.83 | 0.05 | 120 | 0.24 |
| 12 | 45.100 | g/l | 80 | I 45.456 | 2.2 | 0.14 | 2.04 | -0.17 | 120 | -0.78 |
| 13 | 27.300 | g/l | 63 | I 28.179 | 2.0 | 0.09 | 1.27 | -0.69 | 87 | -3.12 |

| | Cycle 45 | Cycle 46 |
|-----------------------------|----------|----------|
| Cycle Average SDI | -0.23 | -0.18 |
| Cycle Average TS | 110 | 116 |
| Cycle Average %DEV | -1.05 | -0.79 |
| Cycle Average Absolute SDI | 0.36 | 0.24 |
| Cycle Average Absolute %DEV | 1.63 | 1.06 |



Text Section

1 Albumin, g/l

Method: Bromocresol Purple
 Instrument: Siemens/Dade Dimension RxL/Max/Xpand
 Reagent: Siemens/Dade Behring

RIQAS TDPA: 7.1% Biological Variation: 3.9%

Your assay details at the end of the cycle. The RIQAS TDPA and biological variation for the parameter is shown if available.

| Sample | Result | Unit | N | Mean | SDPA | U _m | CV% | SDI | TS | % Deviation |
|--------|--------|------|----|----------|------|----------------|-----|-------|-----|-------------|
| 1 | 28.200 | g/l | 68 | I 28.013 | 1.26 | 0.10 | 2.4 | 0.15 | 120 | 0.7 |
| 2 | 26.900 | g/l | 87 | I 26.853 | 1.21 | 0.10 | 2.7 | 0.04 | 120 | 0.2 |
| 3 | 39.900 | g/l | 71 | M 40.531 | 1.82 | 0.15 | 2.5 | -0.36 | 116 | -1.5 |
| 4 | 19.200 | g/l | 81 | I 19.429 | 0.87 | 0.07 | 2.5 | -0.27 | 120 | -1.2 |
| 5 | 41.700 | g/l | 67 | I 41.942 | 1.88 | 0.13 | 2.0 | -0.09 | 120 | -0.4 |
| 6 | 57.300 | g/l | 87 | I 57.257 | 2.58 | 0.21 | 2.7 | 0.02 | 120 | 0.1 |
| 7 | 45.000 | g/l | 72 | I 45.850 | 2.06 | 0.14 | 2.1 | -0.43 | 108 | -1.8 |
| 8 | 27.600 | g/l | 87 | I 28.011 | 1.26 | 0.09 | 2.5 | -0.34 | 118 | -1.5 |
| 9 | 41.200 | g/l | 70 | I 41.823 | 1.88 | 0.14 | 2.2 | -0.38 | 113 | -1.6 |
| 10 | 26.900 | g/l | 83 | I 26.742 | 1.20 | 0.12 | 3.3 | 0.14 | 120 | 0.6 |
| 11 | 40.700 | g/l | 71 | I 40.601 | 1.83 | 0.13 | 2.2 | 0.06 | 120 | 0.2 |
| 12 | 45.100 | g/l | 80 | I 45.119 | 2.05 | 0.14 | 2.2 | -0.18 | 120 | -0.8 |
| 13 | 27.300 | g/l | 63 | I 28.454 | 1.27 | 0.09 | 2.0 | -0.72 | 86 | -3.1 |

Summary of lab's results and statistics are shown, including Mean for Comparison, SDPA, %CV, U_m, SDI, Target Score, % Deviation

| | Cycle 45 | Cycle 46 |
|-------------------------------|----------|----------|
| 15 Cycle Average SDI | -0.23 | -0.18 |
| Cycle Average TS | 110 | 116 |
| Cycle Average %DEV | -1.05 | -0.79 |
| 16 Cycle Average Absolute SDI | 0.36 | 0.24 |
| Cycle Average Absolute %DEV | 1.63 | 1.06 |

Table containing a summary of the lab's performance for previous cycle and current cycle, including Average Absolute SDIs and % Deviations.

Text Section

- 1 Report presented in your chosen unit
- 2 Your assay details as of the last sample
- 3 RIQAS TDPA and Biological variation
- 4 Sample number
- 5 Your Results for each sample
- 6 Unit your result was returned in
- 7 Number of results used for statistical analysis
- 8 Mean for Comparison
- 9 SDPA = Standard Deviation for performance assessment
- 10 Uncertainty of Mean for Comparison
- 11 Coefficient of Variation (%)
- 12 Your Standard Deviation Index
- 13 Your Target Score
- 14 Your % Deviation

15 Cycle average of your performance indicators – Standard Deviation Index, Target Score and % Deviation

$$\text{Cycle Average SDI} = \frac{\text{(Sum of SDIs returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

$$\text{Cycle Average Target Score} = \frac{\text{(Sum of your Target Scores returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

$$\text{Cycle Average \% Deviation} = \frac{\text{(Sum of your \% Deviations returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

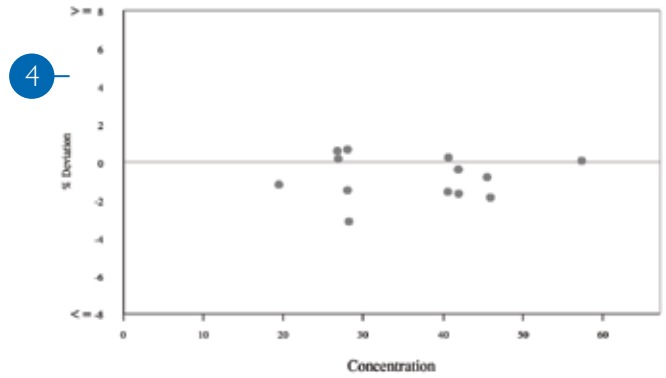
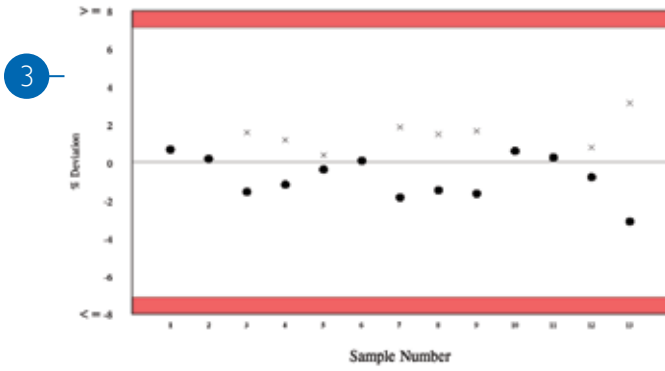
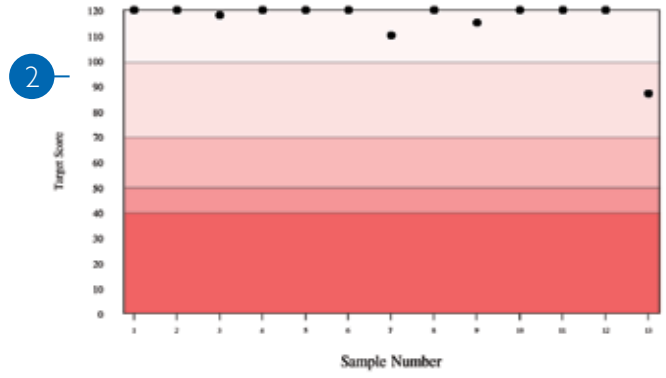
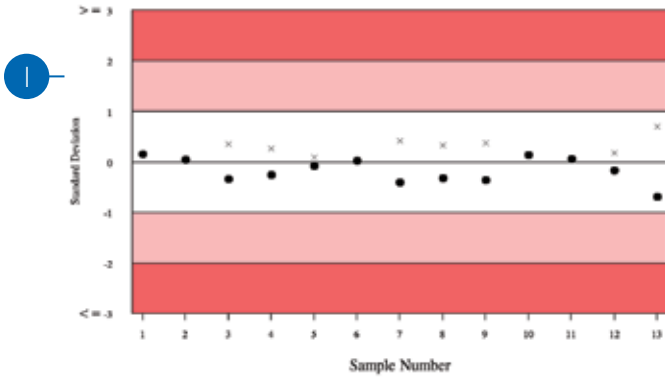
16 Cycle average for Absolute values of the lab's SDI and % Deviation. Absolute values show how far a value is from zero regardless of the sign. This is an indication of the magnitude of accuracy.

$$\text{Cycle Average Absolute SDI} = \frac{\text{(Sum of your Absolute SDIs returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

$$\text{Cycle Average Absolute \% Deviation} = \frac{\text{(Sum of your Absolute \% Deviations returned for the completed cycle)}}{\text{(Number of samples returned in cycle)}}$$

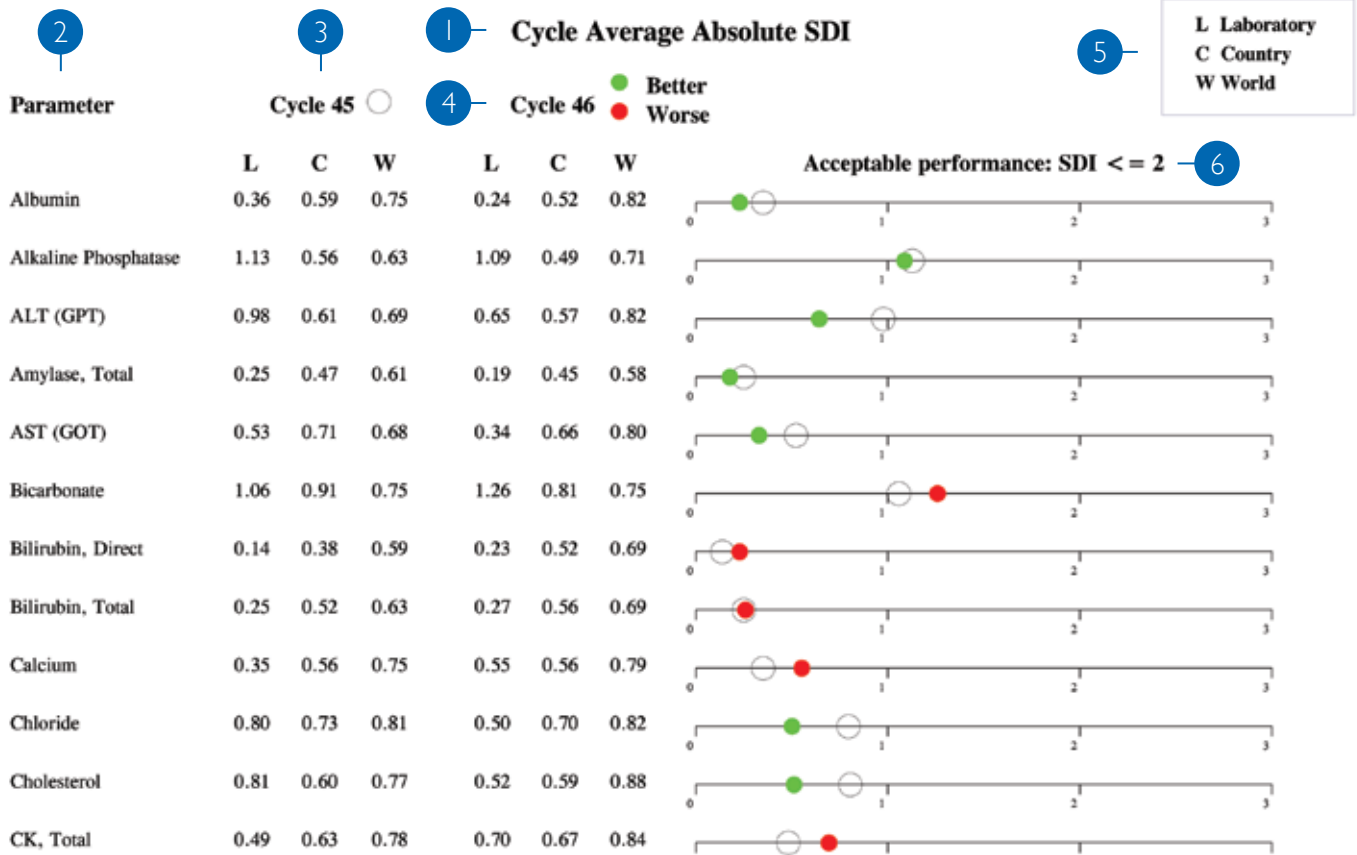
Chart Section

Lab's results for current cycle shown in various diagrams.



- | | | |
|---|------------------------------------|---|
| 1 | Levey-Jennings chart | Shows your SDIs for a full cycle |
| | | <ul style="list-style-type: none"> • Shows SDI (positive and negative) x Shows absolute SDI |
| 2 | Target Score chart | Shows your Target Scores for a full cycle |
| 3 | % Deviation by sample chart | Shows your % Deviations for a full cycle Acceptable limits equal to TDPA unless alternative limits are registered by the lab |
| | | <ul style="list-style-type: none"> • Shows % deviation (positive and negative) x Shows absolute % Deviation |
| 4 | % Deviation by Concentration chart | Shows your results for a full cycle |

Current & previous Cycle Absolute SDIs



- 1** Report title - Cycle Average Absolute SDI. This shows your performance this cycle compared to the previous cycle.
- 2** Parameter list List of all parameters registered
- 3** Results for previous cycle Indicated by open circle on the chart
- 4** Results for current cycle Indicated by a closed circle on the chart
- 5** Legend Cycle Average Absolute SDIs are shown for:
 - L Your results throughout the cycle
 - C All labs within your own country
 - W All labs Worldwide
- 6** Graphical representation of Absolute SDIs

Acceptable performance is ≤ 2 .

If Absolute SDI for current cycle is less than that for the previous cycle, this is indicated by a green circle.

If Absolute SDI for current cycle is greater than that for the previous cycle, this is indicated by a red circle.

The closer the circle is to zero, the better the performance.

Certificate of Performance

The End of Cycle report will be issued for all registrations. However, the Certificate of Performance will only be available for parameters where results for at least 50% of samples in the cycle have been returned. Labs joining after the beginning of the cycle will only receive the Certificate of Performance if they meet this criteria. Any parameters not included on the Certificate of Acceptable Performance will be listed on the Notification of Unacceptable Performance.

RIQAS  **RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME**

CERTIFICATE OF ACCEPTABLE PERFORMANCE

XX/X

RIQAS Department
Randox Laboratories
CRUMLIN
COUNTY ANTRIM
BT29 4QY
UNITED KINGDOM

1

2 — LABORATORY REF. NO. 2246

3 — CLINICAL CHEMISTRY 4 — CYCLE 47

11/03/2013

This is to certify that the above participant took part in a cycle of external quality assessment and achieved an acceptable level of performance (Cycle Average Absolute SDI ≤ 2) for the following parameters:

5

6 — Cycle Average Absolute SDI

| | |
|--|------|
| Albumin - Bromocresol Purple - Siemens/Dade Dimension RxL/Max/Xpand | 0.50 |
| Alkaline Phosphatase - Dade Dimension, AMP buffer - Siemens/Dade Dimension RxL/Max/Xpand | 1.22 |
| ALT (GPT) - Tris buffer with P5P - Siemens/Dade Dimension RxL/Max/Xpand | 0.53 |
| Amylase, Total - Dade Behring 2-chloro-pNPG3 - Siemens/Dade Dimension RxL/Max/Xpand | 0.34 |
| AST (GOT) - Tris buffer with P5P - Siemens/Dade Dimension RxL/Max/Xpand | 0.55 |
| Bicarbonate - Enzymatic - Siemens/Dade Dimension RxL/Max/Xpand | 1.08 |
| Bilirubin, Direct - Diazo with Sulphanilic Acid - Siemens/Dade Dimension RxL/Max/Xpand | 0.19 |
| Bilirubin, Total - Diazo with Sulphanilic Acid - Siemens/Dade Dimension RxL/Max/Xpand | 0.26 |
| Calcium - Cresolphthalein complexone - Siemens/Dade Dimension RxL/Max/Xpand | 0.49 |
| Chloride - ISE, indirect - Siemens/Dade Dimension RxL/Max/Xpand | 0.70 |
| Cholesterol - Dimension-Dade Behring reagents - Siemens/Dade Dimension RxL/Max/Xpand | 0.54 |
| CK, Total - CK-NAC (IFCC) - Siemens/Dade Dimension RxL/Max/Xpand | 0.26 |
| Creatinine - Alkaline picrate no deprot. - Siemens/Dade Dimension RxL/Max/Xpand | 0.44 |
| GGT - Gamma glut'3-carb'4-nitro (IFCC) - Siemens/Dade Dimension RxL/Max/Xpand | 0.25 |
| Glucose - Hexokinase - Siemens/Dade Dimension RxL/Max/Xpand | 0.70 |

| | | |
|---|---------------------------|---|
| 1 | Full registration address | Your full registration address details |
| 2 | Your lab reference number | Used to identify each lab |
| 3 | Programme / cycle number | Programme and current, completed cycle number |
| 4 | Date | Date End of Cycle report is issued |
| 5 | Parameters | List of parameters broken down for which cycle absolute SDI is ≤ 2 |
| 6 | Average Absolute SDI | Your Cycle Average Absolute SDI |

Monitoring EQA Performance

Each EQA report should be evaluated and any poor performance investigated. A step by step approach should be adopted consisting of the following three steps:



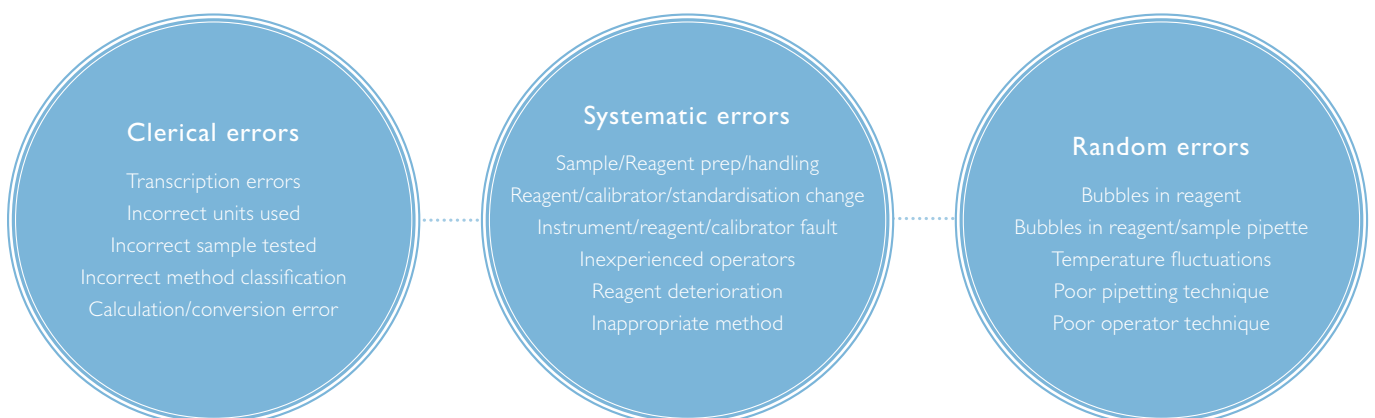
1. Investigate the source of the problem

In order to identify the source of the problem it is useful to be aware of the most common causes of poor EQA performance. Errors can occur at any stage of the testing process however EQA is most concerned with detecting analytical errors i.e. errors that occur during the analysis of the sample.

Most analytical errors can be easily divided into three main areas; clerical errors, systematic errors and random errors. Systematic errors result in inaccurate results that consistently show a positive or negative bias. Random errors on the other hand affect precision and result in fluctuations in either direction.

The flowchart (page 31) is designed to help you investigate any apparent poor performance.

It may be possible that, after extensive investigations, the root cause of the poor performance can not be established. Poor performance for a single sample could be attributed to random error. If poor performance has been noted for several samples, a systematic error is the most likely cause and the analytical process should be reviewed.



Monitoring EQA Performance

A checklist similar to the one below is extremely useful when investigating poor EQA performance and may help you to determine the root cause of the problem and initiate corrective actions.

Laboratory:
 Cycle Number:
 Analysis Date:
 Mean for Comparison:

Sample Number:
 Analyte:
 Lab Result: SDI: % Dev:

1. Specimen Handling

- a. Samples received in good condition Y N
- b. Samples stored/prepared appropriately Y N
- c. Integrity of the sample is acceptable Y N

2. Clerical

- a. Correct result entered Y N
- b. Correct use of decimal point and units Y N
- c. Calculations, if any, performed correctly (even if automated) Y N
- d. Conversion factors applied to results before submission Y N

3. Registration and Mean for Comparison

- a. Registered in the correct method/instrument group Y N
- b. Changed method or instrument without advising RIQAS Y N
- c. Mean for comparison changed due to the number of participants returning results e.g. from method to instrument Y N
- d. An obvious bias between method and instrument means (check histogram and stats sections) Y N

4. Internal Quality Control

- a. % Deviation of IQC (at similar conc to that of EQA) on sample analysis date acceptable Y N
- b. Shift in IQC in the periods just before and after EQA sample analysis Y N
- c. Trends in IQC in the periods before and after EQA sample analysis Y N
- d. Random IQC variation on sample analysis date Y N

Conclusion:

- e. Error due to imprecision; check IQC in terms of % deviation compared to deviation observed in EQA Y N
- f. IQC target correctly assigned Y N

5. Calibration

- a. Date of last calibration
- b. Calibration frequency acceptable Y N
- c. Last calibration acceptable Y N

6. Instrument

- a. Daily maintenance performed on date of sample analysis Y N
- b. Special maintenance performed prior to sample analysis Y N
- c. Instrument operated correctly Y N
- d. Operator fully trained Y N

7. Reagents

- a. Reagents prepared and stored correctly Y N
- b. Reagents within open vial stability Y N

8. EQA sample

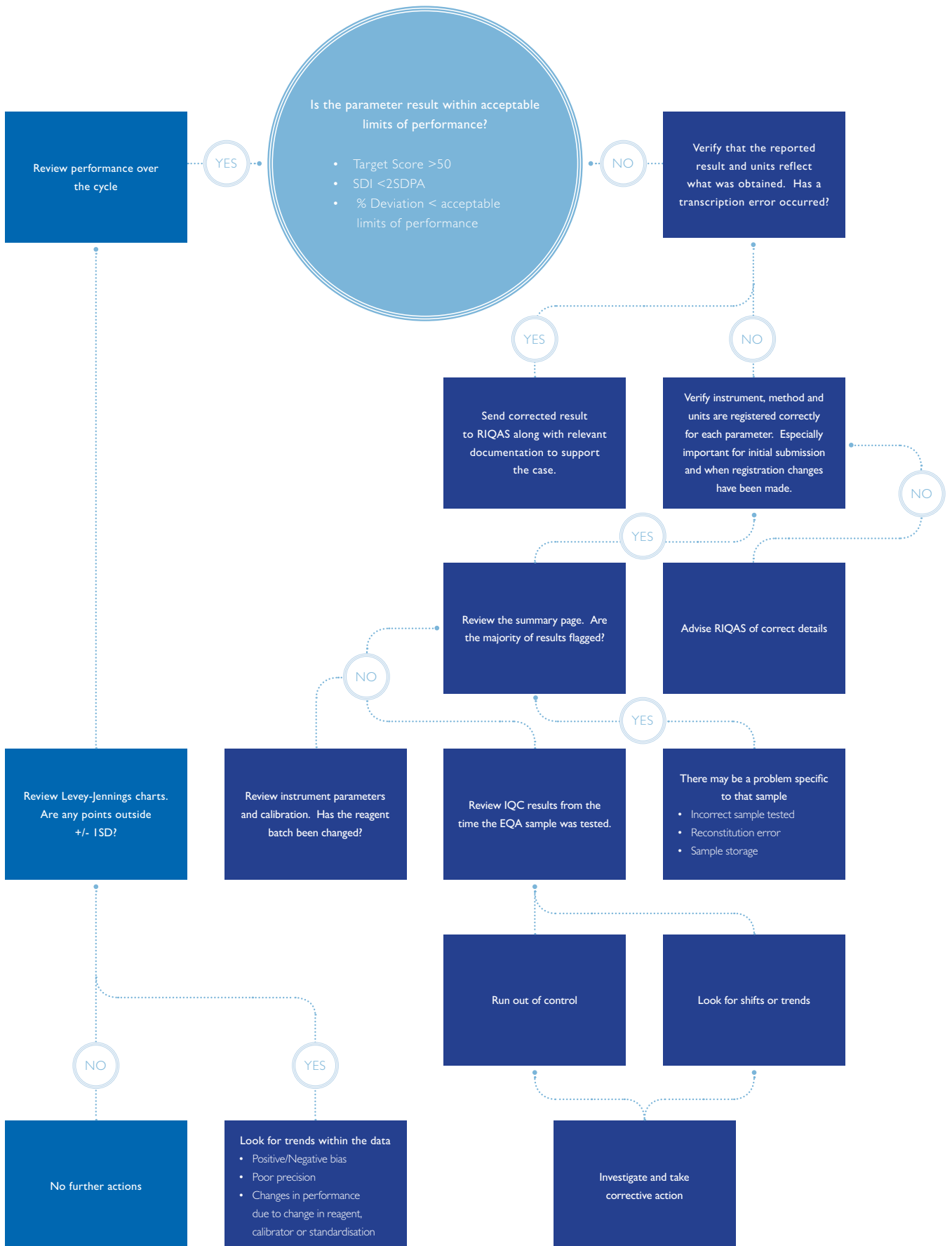
- a. Initial value
- b. Re-run value
- c. Issue observed in previous EQA samples at a similar concentration (check % deviation by concentration and Levey Jennings charts) Y N
- d. All parameters affected (to the same extent) - possible reconstitution error (check % deviation on summary pages) Y N

Remedial Action:

Lab Manager: Date:

Lab Director: Date:

Monitoring EQA Performance



Monitoring EQA Performance

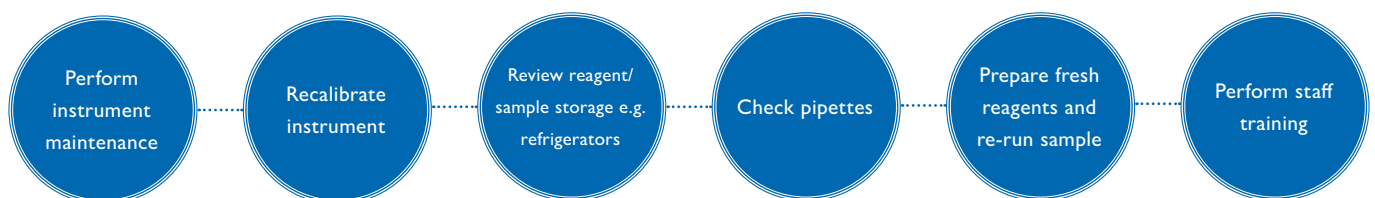


2. Implement corrective actions

A corrective action is an action taken to correct a problem or non conformance. Some errors can be readily recognised as simple clerical errors and easily corrected. If there is evidence of systematic or random error however more detailed corrective actions must be taken.

Systematic Error

In the event of a systematic error the following suggested actions may help to resolve the problem:



Random Error

If all possible causes have been excluded, a single unacceptable result is most likely due to random error. Re-run the sample, if the result of repeat analysis is acceptable then corrective action is not required. If the issue persists, investigate possible sources of systematic error.

3. Check the effectiveness of corrective actions

The effectiveness or impact of any corrective actions taken can be assessed by continuing to monitor analytical performance over time.

RIQAS Programmes

AMMONIA/ETHANOL PROGRAMME+

RQ9164
2 parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

Ammonia Ethanol

BLOOD GAS PROGRAMME *With target scoring*

RQ9134 First registered instrument
10 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

RQ9134/A Subsequent instruments
10 Parameters

pCO₂ tCO₂ K+ Lactate
pH Ca⁺⁺ Na+
pO₂ Cl- Glucose

BNP PROGRAMME+

RQ9165 1 parameter (BNP alone)
Samples every month, 1 x 12 month cycle, 12 month subscription

RQ9165/a Order with RQ9136/a when BNP and Liquid Cardiac parameters are required

BNP*

CARDIAC PROGRAMME *With target scoring*

RQ9127/a 2 Parameters only (choose from 7)
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

RQ9127/b Full 7 Parameters

CK, Total CK-MB Mass units Myoglobin Troponin T
CK-MB Activity units Homocysteine Troponin I

COAGULATION PROGRAMME *With target scoring*

RQ9135/a 5 selected Parameters only
(aPTT, PT, TT, Fibrinogen, Antithrombin III)
Samples every month, 1 x 12 month cycle, 12 month subscription

RQ9135/b Full 17 parameters

aPTT Plasminogen Factor VII Factor XII
PT (including INR) Protein C Factor VIII D-Dimer*
TT Protein S Factor IX
Fibrinogen Factor II Factor X
Antithrombin III Factor V Factor XI

GENERAL CLINICAL CHEMISTRY PROGRAMMES *With target scoring*

RQ9112 10 Parameters only
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, Reference Method Values

RQ9112/S 17 Parameters only

RQ9113 Full 50 Parameters

Acid phosphatase, prostatic Calcium, ionised HDL-Cholesterol Sodium
Acid phosphatase, total Chloride TIBC
Albumin Cholesterol Lactate* Free T3
Alkaline phosphatase Cholinesterase* LD (LDH) Total T3
ALT (ALAT) CK, total (CPK) Lipase Free T4
Amylase, pancreatic Copper Lithium Total T4
Amylase, total Creatinine Magnesium Triglycerides
AST (ASAT) D-3-hydroxybutyrate NEFA* TSH
Bicarbonate Fructosamine* Osmolality Urea
Bile acids Gamma GT Phosphate, inorganic Uric acid
Bilirubin, direct GLDH Potassium Zinc
Bilirubin, total Glucose Protein, total
Calcium HBDH PSA

GLYCATED HAEMOGLOBIN PROGRAMME (HbA1c) *With target scoring*

RQ9129 2 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription

HbA1c Total Haemoglobin

HAEMATOLOGY PROGRAMME *With target scoring*

RQ9118 12 Parameters
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

Haematocrit (HCT) Packed Cell Volume* (PCV)
Haemoglobin (Hb) Platelets (PLT)
Mean Cell Haemoglobin (MCH) Plateletcrit* (PCT)
Mean Cell Haemoglobin Concentration (MCHC) Red Blood Cell Count (RBC)
Mean Cell Volume (MCV) Red Cell Distribution Width* (RDW)
Mean Platelet Volume* (MPV) Total White Blood Cell Count (WBC)

RED = Parameters with Reference Method Values

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

* = Pilot study ongoing

RIQAS Programmes

HUMAN URINE PROGRAMME *With target scoring*

RQ9115

24 Parameters

Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

| | | | |
|----------------------|----------------|----------------------|----------------|
| Albumin/Microalbumin | Creatinine | Normetanephrine | Protein, total |
| Amylase | Dopamine | Magnesium | Sodium |
| Calcium | Epinephrine | Osmolality | Urea |
| Chloride | Glucose | Oxalate | Uric acid |
| Copper | Metanephrine | Phosphate, inorganic | VMA |
| Cortisol | Norepinephrine | Potassium | 5-HIAA |

IMMUNOASSAY PROGRAMMES *With target scoring*

RQ9125/a

4 Parameters only (choose from 55)

RQ9125/b

13 Parameters only (choose from 55)

RQ9125/c

Full 55 Parameters

RQ9130

Full 55 Parameters

Samples every two weeks, 2 x 6 monthly cycles (RQ9125/a, RQ9125/b, RQ9125/c), 12 month subscription

Samples every month, 1 x 12 month cycle (RQ9130), 12 month subscription

| | | | |
|----------------------|-------------------|--------------------|------------------------------------|
| ACTH* | DHEA Unconjugated | 17-OH-progesterone | Free T4 |
| AFP | Digoxin | Paracetamol* | Total T4 |
| Aldosterone* | Estril Total* | Phenobarbital* | Testosterone, free |
| Amikacin* | Ethosuximide* | Phenytoin | Testosterone, total |
| Androstenedione* | Ferritin | Primidone* | Theophylline |
| Beta-2-microglobulin | Folate | Progesterone | Thyroglobulin |
| CA125 | FSH | Prolactin | Tobramycin* |
| CA15-3 | Gentamicin* | Free PSA | TSH |
| CA19-9 | GH | Total PSA | Valproic acid |
| Carbamazepine | hCG | PTH | Vancomycin* |
| CEA | IgE | Salicylate* | Vitamin B12 |
| Cortisol | Insulin | SHBG | 1-25-(OH) ₂ -Vitamin D* |
| C-peptide* | LH | Free T3 | 25-OH-Vitamin D* |
| DHEA-S | Oestradiol | Total T3 | |

IMMUNOASSAY SPECIALITY 1 PROGRAMME+

RQ9141

10 parameters

Samples every month, 1 x 12 month cycle, 12 month subscription

| | | |
|-----------------------------------|---------------|---------|
| 1-25-(OH) ₂ -Vitamin D | Anti-TPO | PTH |
| 25-OH-Vitamin D | IGF-1 | Insulin |
| C-Peptide | Osteocalcin | |
| Anti-TG | Procalcitonin | |

IMMUNOASSAY SPECIALITY 2 PROGRAMME+

RQ9142

5 parameters

Samples every month, 1 x 12 month cycle, 12 month subscription

| | | |
|------------|-----------------------|-----------------------------|
| Calcitonin | Procalcitonin | Renin, direct concentration |
| Gastrin | Plasma Renin Activity | |

LIPID PROGRAMME *With target scoring*

RQ9126/a

3 Parameters only (choose from 7)

RQ9126/b

Full 7 Parameters

Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

| | | | |
|-------------------|--------------------|------------------|---------------|
| Apolipoprotein A1 | Cholesterol, total | LDL-Cholesterol | Triglycerides |
| Apolipoprotein B | HDL-Cholesterol | Lipoprotein (a)* | |

LIQUID CARDIAC PROGRAMME *With target scoring*

RQ9136

9 Parameters

Samples every month, 1 x 12 month cycle, 12 month subscription

RQ9136/a

Order with RQ9165/a when BNP and Liquid Cardiac parameters are required

| | | |
|------------|--------------|------------|
| CK-MB Mass | Homocysteine | NT proBNP |
| D-Dimer* | hsCRP | Troponin I |
| Digoxin | Myoglobin | Troponin T |

MATERNAL SCREENING PROGRAMME *With target scoring*

RQ9137

6 Parameters

Samples every month, 1 x 12 month cycle, 12 month subscription

| | |
|---------------|----------------------|
| AFP | Inhibin A |
| free Beta hCG | PAPP-A |
| total hCG | Unconjugated Oestril |

RED = Parameters with Reference Method Values

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

* = Pilot study ongoing

RIQAS Programmes

SEROLOGY (EBV) PROGRAMME+

RQ9153

2 parameters

3 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-EBV VCA IgG

Anti-EBNA IgG

Anti-EBV VCA IgM

SEROLOGY (HIV-HEPATITIS) PROGRAMME+

RQ9151

10 parameters

5 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-HIV-1

Anti-HBc

Anti-CMV

Anti-HIV-2

Anti-HTLV-I

HBsAg

Anti-HIV-1&2 Combined

Anti-HTLV-II

Anti-HCV

Anti-HTLV-I&2 Combined

SEROLOGY (SYPHILIS) PROGRAMME+

RQ9154

1 parameter

3 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Syphilis (Methods available include immunoassay RPR, VDRL and TPHA)

SEROLOGY (ToRCH) PROGRAMME+

RQ9152

12 parameters

5 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-Toxoplasma IgG

Anti-CMV IgM

Anti-HSV 2 IgM

Anti-Toxoplasma IgM

Anti-HSV1 IgG

Anti-HSV 1 + 2 IgM Combined

Anti-Rubella IgG

Anti-HSV2 IgG

Anti-Rubella IgM

Anti-HSV-1&2 IgG Combined

Anti-CMV IgG

Anti-HSV 1 IgM

SPECIFIC PROTEINS PROGRAMME With target scoring

RQ9114 (3ml)

26 parameters,

Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

RQ9160 (2ml)

RQ9161 (1ml)

AFP
Albumin
Alpha-1-acid glycoprotein
Alpha-1-antitrypsin
Alpha-2-macroglobulin
Anti Streptolysin O
Antithrombin III

Beta-2-microglobulin
Ceruloplasmin
Complement, C3
Complement, C4
C-Reactive Protein
Ferritin
Haptoglobin

Immunoglobulin A
Immunoglobulin E
Immunoglobulin G
Immunoglobulin M
Free Kappa Light Chain
Total Kappa Light Chain
Free Lambda Light Chain

Total Lambda Light Chain
Prealbumin (Transthyretin)
Retinol Binding Protein
Rheumatoid Factor
Transferrin

THERAPEUTIC DRUGS PROGRAMME With target scoring

RQ9111

18 parameters

Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, Weighed-in values

Amikacin
Caffeine
Carbamazepine
Cyclosporine
Digoxin

Ethosuximide
Gentamicin
Lithium
Methotrexate
Paracetamol (Acetaminophen)

Phenobarbital
Phenytoin
Primidone
Salicylic acid
Theophylline

Tobramycin
Valproic acid
Vancomycin

URINALYSIS PROGRAMME+

RQ9138

14 Parameters

Samples every 2 months, 1 x 12 month cycle, 12 month subscription

Albumin
Bilirubin
Blood
Creatinine

Galactose
Glucose
hCG
Ketones

Leukocytes
Nitrite
pH
Protein

Specific Gravity
Urobilinogen

URINE TOXICOLOGY PROGRAMME+

RQ9139

20 Parameters

Samples every month, 1 x 12 month cycle, 12 month subscription

Benzoylcegonine
Buprenorphine
Cannabinoids (THC)
Cotinine*
Creatinine
d-Amphetamine

d-Methamphetamine
EDDP
Ethanol
Free Morphine
Lorazepam
LSD

MDMA
Methadone
Nortriptyline
Norpropoxyphene
Oxazepam
Phencyclidine

Phenobarbital
Secobarbital

RED = Parameters with Reference Method Values

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

* = Pilot study ongoing

RANDOX

International Headquarters

Randox Laboratories Limited, 55 Diamond Road, Crumlin, County Antrim, United Kingdom, BT29 4QY

T +44 (0) 28 9442 2413 F +44 (0) 28 9445 2912 E marketing@randox.com I www.randox.com



Australia

Randox (Australia) Pty Ltd.
Tel: +61 (0) 2 9615 4640



Brazil

Randox Brasil Ltda.
Tel: +55 11 5181-2024



China

Randox Laboratories Ltd.
Tel: +86 021 6288 6240



Czech Republic

Randox Laboratories S.R.O.
Tel: +420 2 1115 1661



France

Laboratoires Randox
Tel: +33 (0) 130 18 96 80



Germany

Randox Laboratories GmbH
Tel: +49 (0) 2151/93 706-11



Hong Kong

Randox Laboratories Hong Kong Limited
Tel: +852 3595 0515



Italy

Randox Laboratories Ltd.
Tel: +39 06 9896 8954



India

Randox Laboratories India Pvt Ltd.
Tel: +91 22 6714 0600



Poland

Randox Laboratories Polska Sp. z o.o.
Tel: +48 22 862 1080



Portugal

Irandox Laboratorios Quimica Analitica Ltda
Tel: +351 22 589 8320



Puerto Rico

Clinical Diagnostics of Puerto Rico, LLC
Tel: +1 787 701 7000



Republic of Ireland

Randox Teoranta
Tel: +353 7495 22600



Slovakia

Randox S.R.O.
Tel: +421 2 6381 3324



South Africa

Randox Laboratories SA (Pty) Ltd.
Tel: +27 (0) 11 312 3590



South Korea

Randox Korea
Tel: +82 (0) 31 478 3121



Spain

Laboratorios Randox S.L.
Tel: +34 93 475 09 64



Switzerland

Randox Laboratories Ltd. (Switzerland)
Tel: +41 41 810 48 89



USA

Randox Laboratories-US, Ltd.
Tel: +1 304 728 2890



Vietnam

Randox Laboratories Ltd.Vietnam
Tel: +84-8-39 11 09 04

RIQAS

T +44 (0) 28 9442 2413 E mail@riqas.com I RIQAS NET www.riqas.net I www.riqas.com

Information correct at time of print.

Randox Laboratories Limited is a subsidiary of Randox Holdings Limited a company registered within Northern Ireland with company number NI 614690. VAT Registered Number: GB 151 6827 08. Product availability may vary from country to country. Please contact your local Randox representative for information. Products may be for Research Use Only and not for use in diagnostic procedures in the USA.



LT033JUNE14