





RIQAS Explained

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 Support

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



RIQAS Programmes

- Ammonia/Ethanol
- Anti-TSH Receptor
- Blood Gas
- BNP
- Cardiac
- Cerebrospinal Fluid (CSF)
- Clinical Chemistry
- Coagulation
- CYFRA 21-1
- ESR
- Glycated Haemoglobin (HbA1c)
- Haematology
- Human Urine
- Immunoassay
- Immunoassay Speciality I
- Immunoassay Speciality 2

- Immunosuppressant
- Lipid
- Liquid Cardiac
- Maternal Screening
- Serology Epstein Barr Virus (EBV)
- Serology (HIV/Hepatitis)
- Serology (Syphilis)
- Serology (ToRCH)
- Specific Proteins
- Sweat Testing
- Therapeutic Drugs
- Trace Elements in Blood
- Trace Elements in Serum
- Trace Elements in Urine
- Urinalysis
- Urine Toxicology

RIQAS is the largest international EQA scheme in the world. It is used by more than 35,000 laboratory participants in 123 countries. 32 programmes 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'.

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

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 throug accreditation
- High quality material
- Regular reports with rapid turnaround times
- Independent advisory panel
- Flexible programme choice

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 allowing for programme consolidation.
- 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 selected parameters and lots.
 Samples spanning clinically relevant levels, allows identification of concentration related biases and ensures accurate instrument performance.

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.

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.

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.

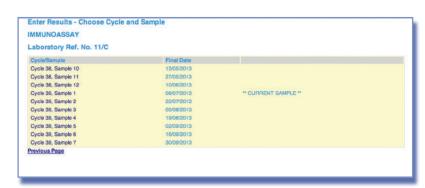
A retrospective statistics summary is also available four weeks after the final date, for parameters where a result has not been submitted on time.



RIQAS.Net offers easy, direct access for the submission of results and retrieval of reports direct from the RIQAS host server.



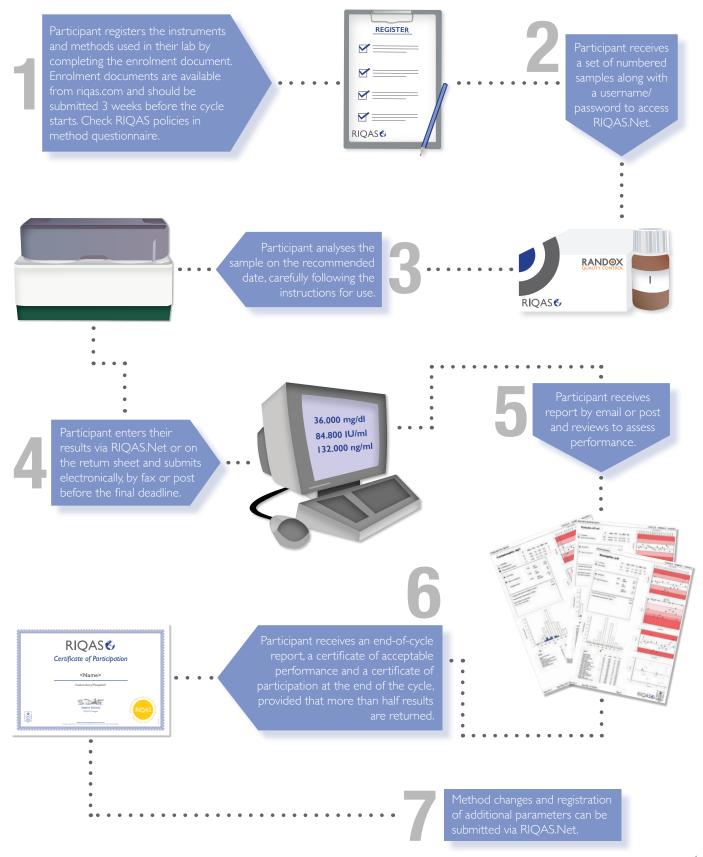




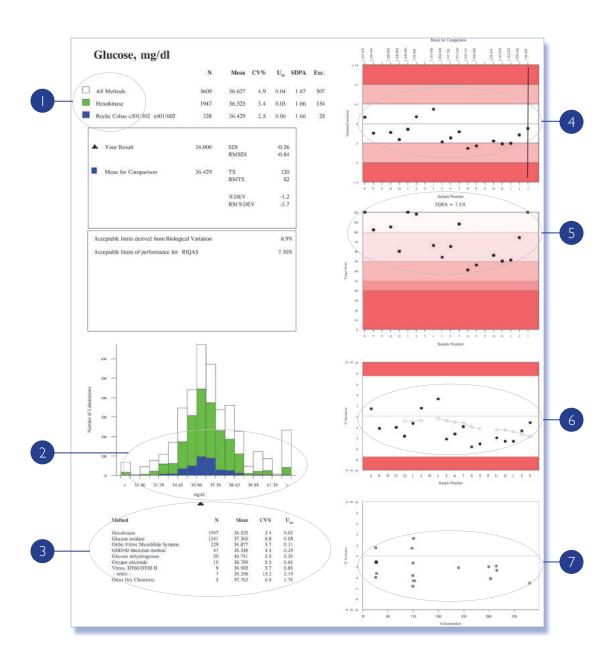


- Available in multiple languages.
- Confidentiality and security is maintained through the use of password protected access.
- Submit current, corrected and future results (normal policies apply), directly into the RIQAS database. Receipt of results is confirmed by e-mail.
- Multi-lingual registration identifier provides simple identification of multiple registrations.
- Additions and changes to assay details can be made quickly and easily online.
- Requests for new method, instrument and reagent codes can be made online.
- Reports are emailed in PDF format as soon as they are prepared.
- Reports for the previous two cycles can be downloaded from the website.
- View, print, store or distribute reports as you wish.
- Update your laboratory's 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 the system.
- No additional software required.

Participation in RIQAS follows these simple steps:

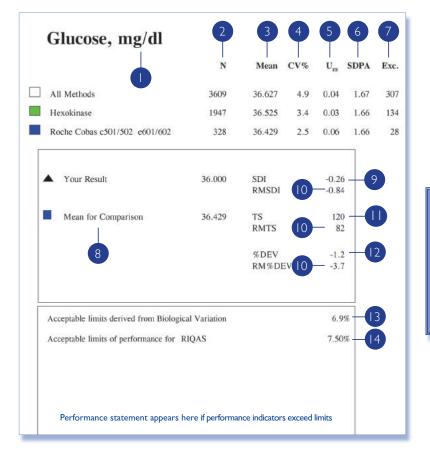


Performance data is presented in a one page format with up to seven sub-reports.



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

The text section summarises the statistical information for each parameter.



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

Acceptable performance criteria:

Target score > 50 %Deviation < defined acceptable limits

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

$$U_{m} = \frac{1.25 \times SD}{\sqrt{n}}$$

SDPA = Standard Deviation for Performance Assessment, calculated from the Target Deviation for Performance Assessment (TDPA) and the Mean for Comparison.

$$SDPA = \frac{TDPA \times Mean for Comparison}{t-value \times 100}$$

t-value = factor which represents the % of poor performers reflected in the TDPA (t-value \sim 1.645 when \sim 10% laboratories achieve poor performance) SDPA is combined with $U_{\rm m}$, where appropriate.

If U
$$_{\rm m}$$
 > (0.3 x SDPA) then SDPA $_{\rm adjusted}$ = $\sqrt{\rm (\,U_m^{\,\,2}+SDPA^2\,)}$ and the reported value is suffixed with "a"

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

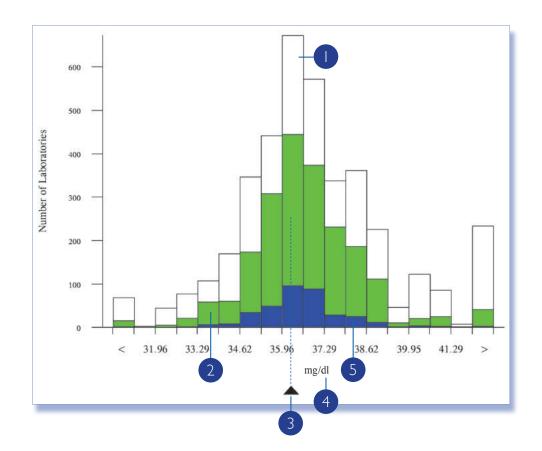
- After statistical reduction, some results are excluded.
- Ideally this will be your instrument group mean. If N<5 for instrument group, your method group Mean is selected as Mean for Comparison.
- Standard Deviation Index = Your Result Mean for Comparison SDPA adjusted
- Running Mean average of the last 10 performance indicators is used to monitor performance over time and concentration range.
- Target Score The closer a value is to 120, the better the performance.
- %Deviation from the Mean for Comparison the closer the value is to zero, the better the performance.
- Biological Variation stated for information purposes only.
- Performance limit set for this parameter.

The Bar Graph is intended as a quick visualisation of how your lab's result compares to the method mean, instrument mean and all method mean.

All methods

Your method group

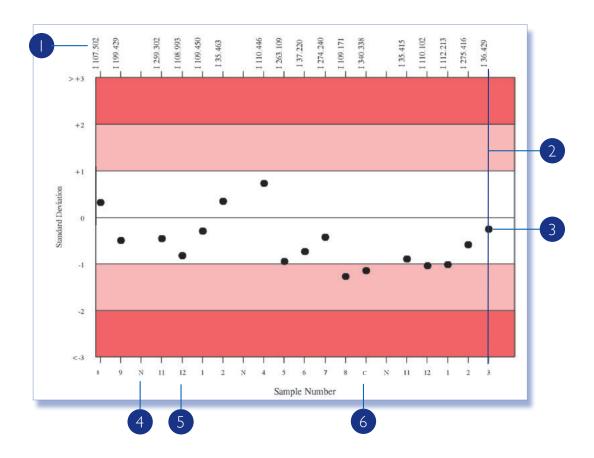
Your instrument group
(programme specific)

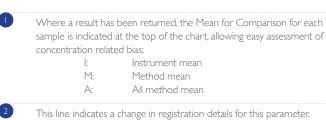


- Total of 673 laboratories reported values between 35.96 and 36.63.
- 58 laboratories reported values between 33.29 and 33.96 in your method group.
- 3 Your Result.

- 4 RIQAS reports show your unit of measurement.
- 25 laboratories reported values between 37.96 and 38.62 in your instrument group.

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



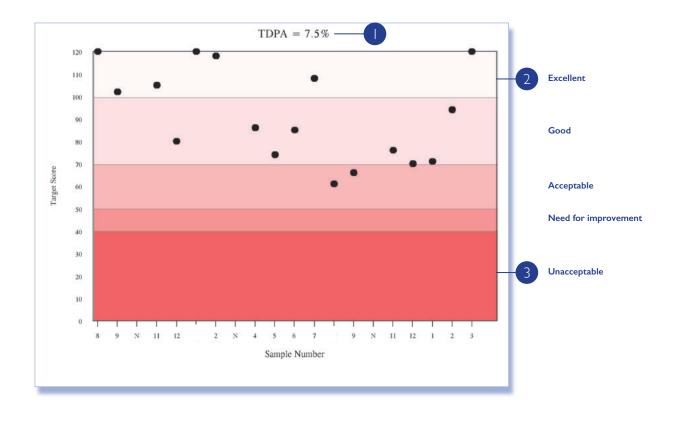


- Your SDI (Standard Deviation Index).

- N = No result returned from your laboratory. No statistics are shown.
- Sample number.
 - 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 Randox error.

R = Incorrect results can be removed retrospectively on request.

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). TDPAs are set to encourage participants to achieve and maintain acceptable performance. TDPAs are fit-for-purpose performance criteria which are set taking guidance from ISO/IEC17043, ISO13528 and IUPAC. Target Deviations for Performance Assessment are also used to calculate the Standard Deviation for Performance Assessment (SDPA).



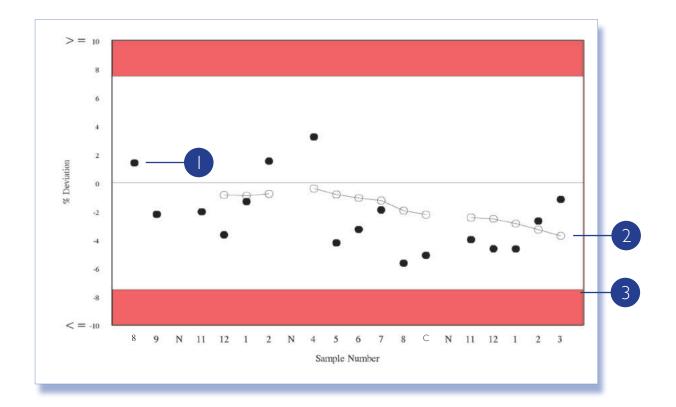
This is the upper deviation limit of performance for this parameter. TDPAs are reviewed regularly and deemed fit for purpose by the RIQAS Advisory Panel.

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

Heavy shading for values 10 to 50 signifies poor performance.

This chart helps to identify trends and shifts in performance.

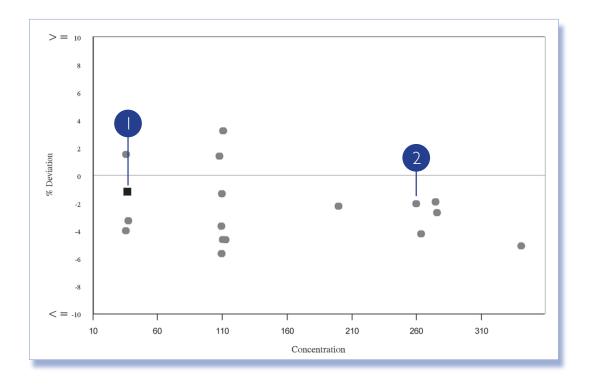
$$\text{\%Deviation} = \frac{\text{Your Result - Consensus Mean}}{\text{Consensus Mean}} \times 100\%$$





%Deviation by Concentration Chart

This chart enables rapid assessment of concentration related biases. Biases at low or high concentrations can be easily determined.



Current sample indicated by square.

2 %Deviation at specific concentration.

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

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
Vitros, DT60/DT60 II	9	34.905	5.7	0.83

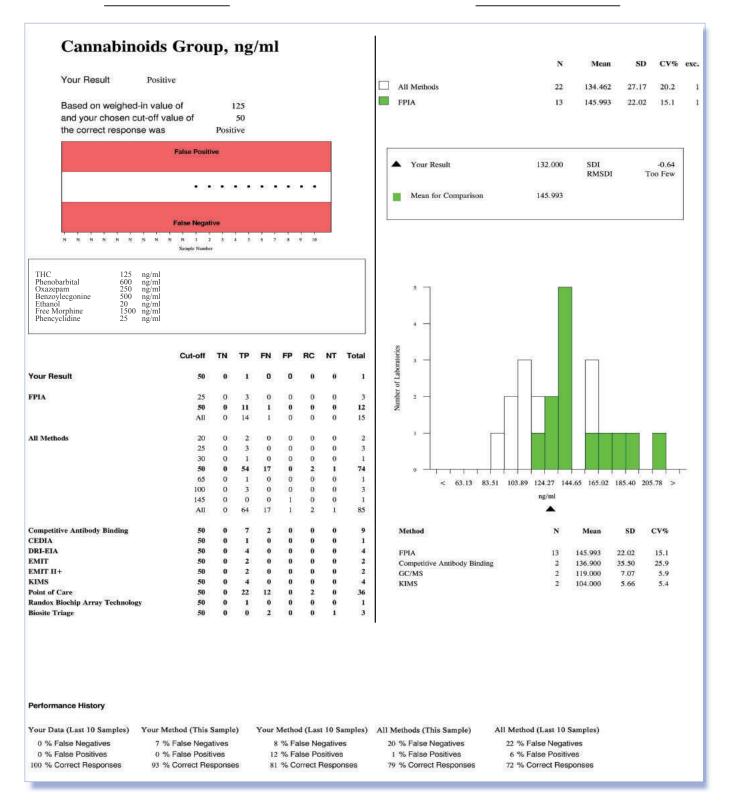
Located at the back of the RIQAS Report, the Summary Page collates the key information, allowing participants to review the performance of all parameters at-a-glance.

2.120 17.705 12.387 20.454 11.976 8.203 0.251 0.701 6.074 76.353 12.696 11.659	2.230 19.000 12.000 22.000 11.000 6.900 0.380 0.640 6.020 77.000 110.000	1.00 0.61 -0.33 0.72 -0.86 -1.48 <u>2.57</u> -0.91 -0.19	0.37 — -0.27 -0.47 -0.29 -0.03 0.15 2.64 -0.29 -0.40	5.2 7.3 -3.1 7.6 -8.2 -15.9 <u>51.3</u> -8.8	2.0 -2.9 -3.8 -2.5 -0.4 – 1.5 47.2	72 93 119 86 78 54 31	107 105 103 103 100 98	4
12.387 20.454 11.976 8.203 0.251 0.701 6.074 76.353 12.696	12.000 22.000 11.000 6.900 0.380 0.640 6.020 77.000	-0.33 0.72 -0.86 -1.48 <u>2.57</u> -0.91 -0.19	-0.47 -0.29 -0.03 0.15 2.64 -0.29	-3.1 7.6 -8.2 -15.9 <u>51.3</u>	-3.8 -2.5 -0.4 -1.5 47.2	119 86 78 54 <u>31</u>	103 103 100 —	4
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76.353 12.696	77.000		-0.40		400	76	101	
12.696		0.30	W. 10	-0.9	-1.8	120	92	
	110,000	0.50	-0.28	0.8	-0.8	120	98	
11.659		-0.55	0.05	<u>2.4</u>	0.2	97	115	
	111.000	-0.08	0.35	-0.6	2.5	120	107	
0.607	0.620	0.27	0.06	2.1	0.5	120	117	
36.429	36.000	-0.26	-0.84	-1.2	-3.7	120	82	
98.836	102.000	0.21	-0.04	3.2	-0.4	120	113	
97.374	99.000	0.28	0.01	1.7	0.1	120	114	
	No Result		Too Few		Too Few	N/A	N/A	
85.894	87.000	0.11	-0.70	1.3	-6.3	120	89	
1.313	1.390	0.79	-0.07	5.8	-0.5	82	107	
1.451	1.540	1.02	0.02	6.1	0.1	71	112	
1.770	1.840	1.10	-0.25	3.9	-0.7	67	99	
3.850	3.830	-0.11	0.07	-0.5	0.3	120	114	
12.537	114.000	0.58	-0.01	1.3	-0.0	95	104	
33.143	133.000	-0.01	-0.01	-0.1	-0.1	120	117	
23.626	24.000	0.18	-0.09	1.6	-0.6	120	114	
5.872	5.000	-2.02	-0.57	-14.9	-4.0	41	95	A
3.135	3.100	-0.20	-0.44	-1.1	-2.4	120	107	
		ORM	SDI -0.05	ORM	1%DEV 0.8	ORM	rs 102	
	97.374 85.894 1.313 1.451 1.770 3.850 12.537 33.143 23.626 5.872	97.374 99.000 No Result 85.894 87.000 1.313 1.390 1.451 1.540 1.770 1.840 3.850 3.830 12.537 114.000 33.143 133.000 23.626 24.000 5.872 5.000	97.374 99.000 0.28 No Result 85.894 87.000 0.11 1.313 1.390 0.79 1.451 1.540 1.02 1.770 1.840 1.10 3.850 3.830 -0.11 12.537 114.000 0.58 33.143 133.000 -0.01 23.626 24.000 0.18 5.872 5.000 -2.02 3.135 3.100 -0.20	97.374 99.000 0.28 0.01 No Result Too Few 85.894 87.000 0.11 -0.70 1.313 1.390 0.79 -0.07 1.451 1.540 1.02 0.02 1.770 1.840 1.10 -0.25 3.850 3.830 -0.11 0.07 12.537 114.000 0.58 -0.01 33.143 133.000 -0.01 -0.01 23.626 24.000 0.18 -0.09 5.872 5.000 -2.02 -0.57	97.374 99.000 0.28 0.01 1.7 No Result Too Few 85.894 87.000 0.11 -0.70 1.3 1.313 1.390 0.79 -0.07 5.8 1.451 1.540 1.02 0.02 6.1 1.770 1.840 1.10 -0.25 3.9 3.850 3.830 -0.11 0.07 -0.5 12.537 114.000 0.58 -0.01 1.3 33.143 133.000 -0.01 -0.01 -0.1 23.626 24.000 0.18 -0.09 1.6 5.872 5.000 -2.02 -0.57 -14.9 3.135 3.100 -0.20 -0.44 -1.1	97.374 99.000 0.28 0.01 1.7 0.1 No Result Too Few Too Few 85.894 87.000 0.11 -0.70 1.3 -6.3 1.313 1.390 0.79 -0.07 5.8 -0.5 1.451 1.540 1.02 0.02 6.1 0.1 1.770 1.840 1.10 -0.25 3.9 -0.7 3.850 3.830 -0.11 0.07 -0.5 0.3 12.537 114.000 0.58 -0.01 1.3 -0.0 33.143 133.000 -0.01 -0.01 -0.1 -0.1 23.626 24.000 0.18 -0.09 1.6 -0.6 5.872 5.000 -2.02 -0.57 -14.9 -4.0 3.135 3.100 -0.20 -0.44 -1.1 -2.4	97.374 99.000 0.28 0.01 1.7 0.1 120 No Result Too Few Too Few N/A 85.894 87.000 0.11 -0.70 1.3 -6.3 120 1.313 1.390 0.79 -0.07 5.8 -0.5 82 1.451 1.540 1.02 0.02 6.1 0.1 71 1.770 1.840 1.10 -0.25 3.9 -0.7 67 3.850 3.830 -0.11 0.07 -0.5 0.3 120 12.537 114.000 0.58 -0.01 1.3 -0.0 95 33.143 133.000 -0.01 -0.01 -0.1 -0.1 120 23.626 24.000 0.18 -0.09 1.6 -0.6 120 5.872 5.000 -2.02 -0.57 -14.9 -4.0 41 3.135 3.100 -0.20 -0.44 -1.1 -2.4 120	97.374 99.000 0.28 0.01 1.7 0.1 120 114 No Result Too Few Too Few N/A N/A 85.894 87.000 0.11 -0.70 1.3 -6.3 120 89 1.313 1.390 0.79 -0.07 5.8 -0.5 82 107 1.451 1.540 1.02 0.02 6.1 0.1 71 112 1.770 1.840 1.10 -0.25 3.9 -0.7 67 99 3.850 3.830 -0.11 0.07 -0.5 0.3 120 114 12.537 114.000 0.58 -0.01 1.3 -0.0 95 104 33.143 133.000 -0.01 -0.01 -0.1 -0.1 120 117 23.626 24.000 0.18 -0.09 1.6 -0.6 120 114 5.872 5.000 -2.02 -0.57 -14.9 -4.0 41 95 3.135 3.100 -0.20 -0.44 -1.1 -2.4 120 107

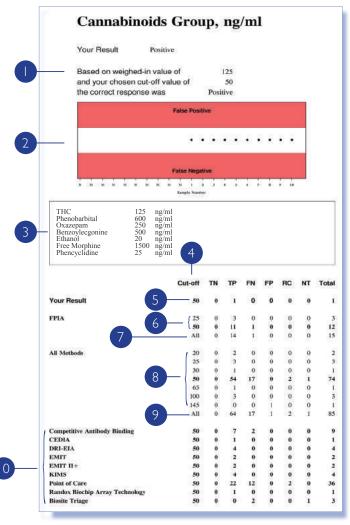
Laboratory performance is presented in both quantitative and qualitative screening formats, allowing for easy interpretation at-a-glance.

Screening Section

Quantitative Section



Qualitative comparison of screening results available for each parameter.





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.
 Comment section for RIQAS to provide your laboratory with additional relevant information regarding this sample, such as spiked metabolite concentration.
 Screening result response categories. All abbreviations indicated at the bottom of the report page.
 Key
 TN - true negative
 TP - true positive
 FN - false negative

Screening Text Section.

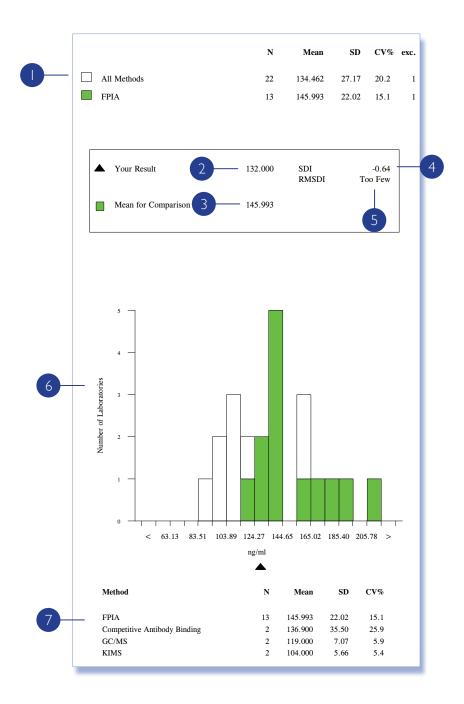
Screening Summary: Your screening result shown in the appropriate response category and your cut off for this sample.

FP - false positive **RC** - sent for confirmation **NT** - not tested

6 Screening results for all cut-offs returned for this sample within your method group.

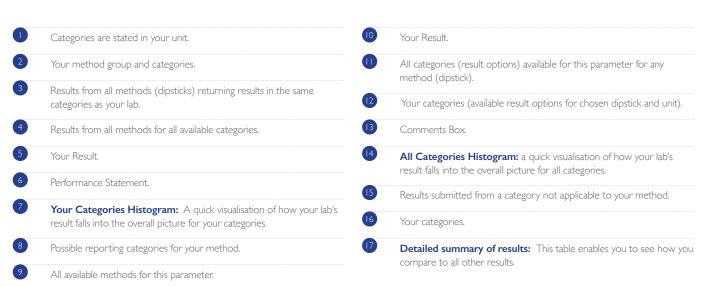
- Total screening results over all your cut-offs for your laboratory's method.
- 8 Screening results for all cut-offs returned for this sample over all methods.
- 9 Total screening results over all cut-offs for all methods.
- Screening results for other methods using same cut-off as your laboratory.
- Performance history for this parameter, based on previous 10 samples.
- Performance of your method over all cut-offs for this sample.
- Performance history of your method over all cut-offs, based on the previous 10 samples.
- Performance of all methods over all cut-offs for this sample.
- Performance history of all methods over all cut-offs, based on the previous 10 samples.

Quantitative statistical comparison available for each parameter.

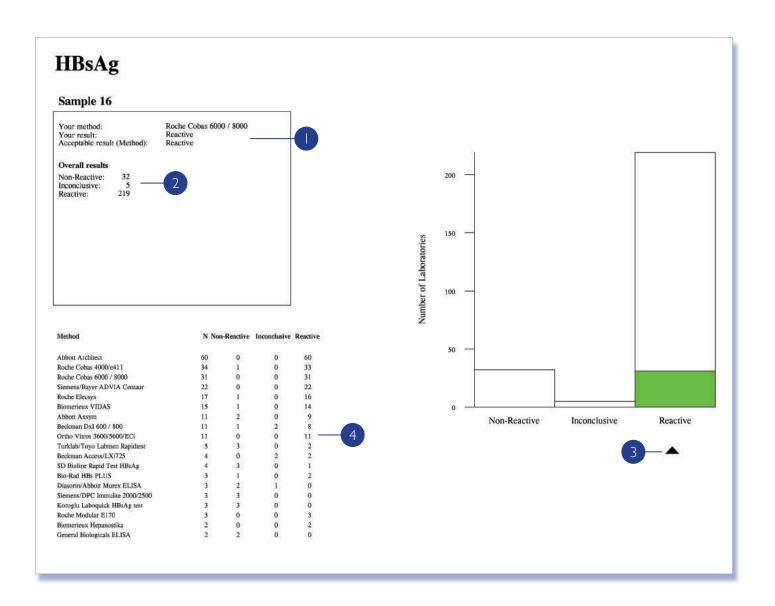




Your performance for each parameter is presented in a simple, convenient report.



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



- 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.
- Overall Summary shows the number of results for this parameter and sample which are non-reactive, inconclusive or reactive.
- Your Result is shown as a black triangle on the category chart compared to other laboratories in groups:

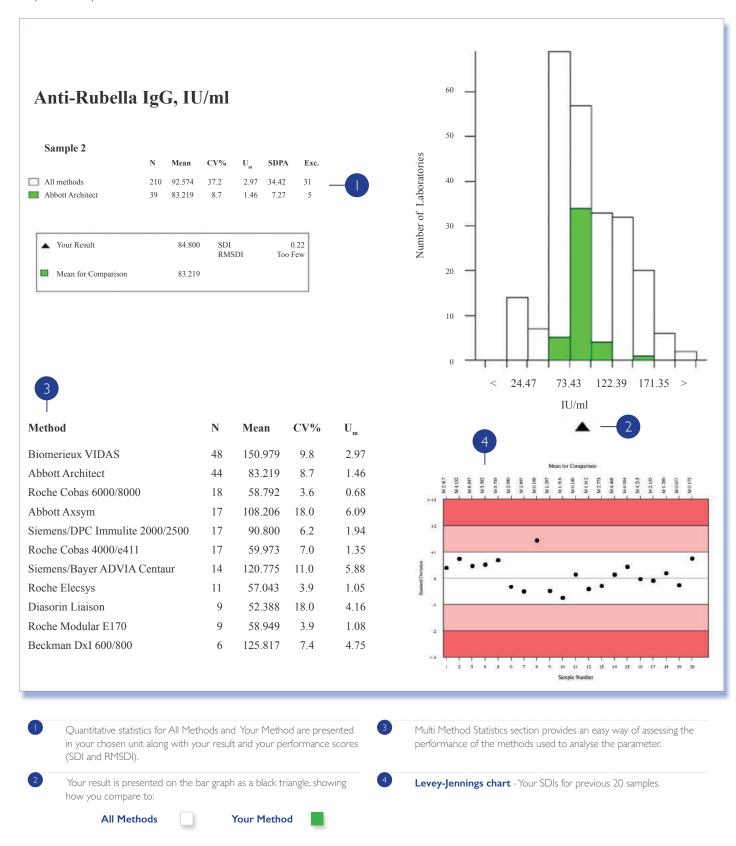
 All Methods

 Your Method

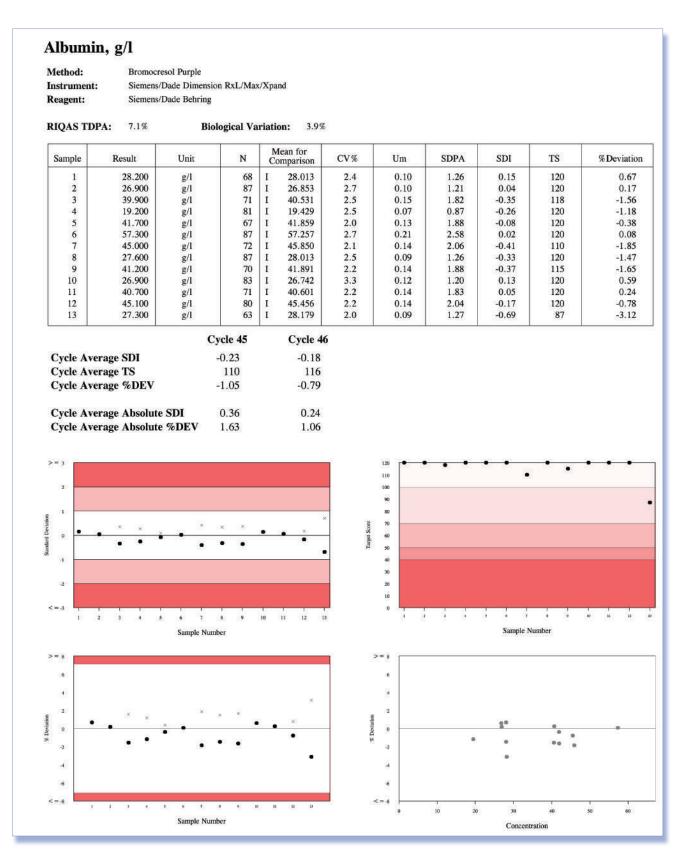
 Summary shows performance of all the methods used to analyse

the parameter.

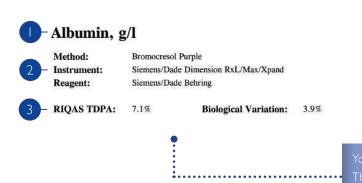
Your performance for multiple samples is presented in a convenient single report per quarterly distribution.

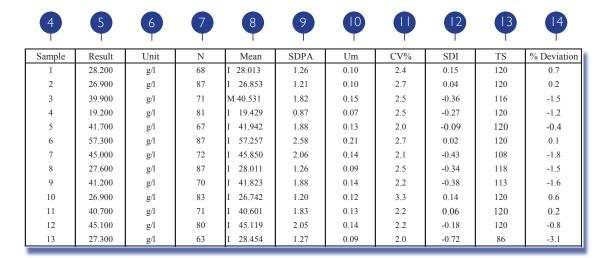


The End-of-Cycle Report is sent to all participants at the end of each cycle and provides a complete summary of statistics. Results can also be compared to the previous cycle.



The text section summarises the statistical information for all samples.





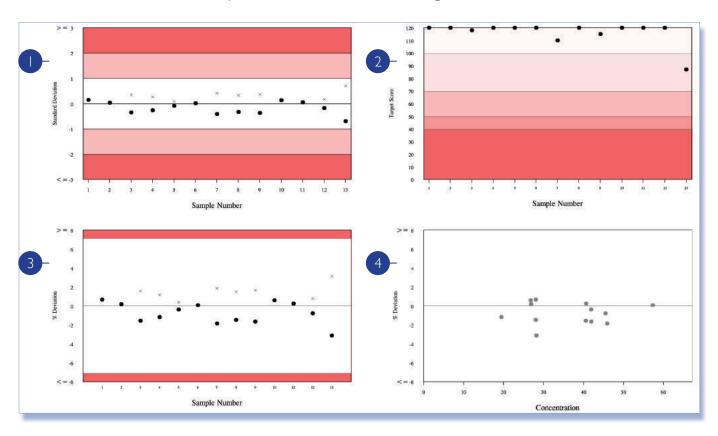
Summary of lab's results and statistics are shown including Mean for Comparison, SDPA, %CV, U_m, SDI, Target Score, %Deviation

		Cycle 45	Cycle 46	
15-	Cycle Average SDI Cycle Average TS Cycle Average %DEV	-0.23 110 -1.05	-0.18 116 -0.79	
16-	Cycle Average Absolute SDI Cycle Average Absolute %DEV	0.36 1.63	0.24 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 (End-of-Cycle Report)

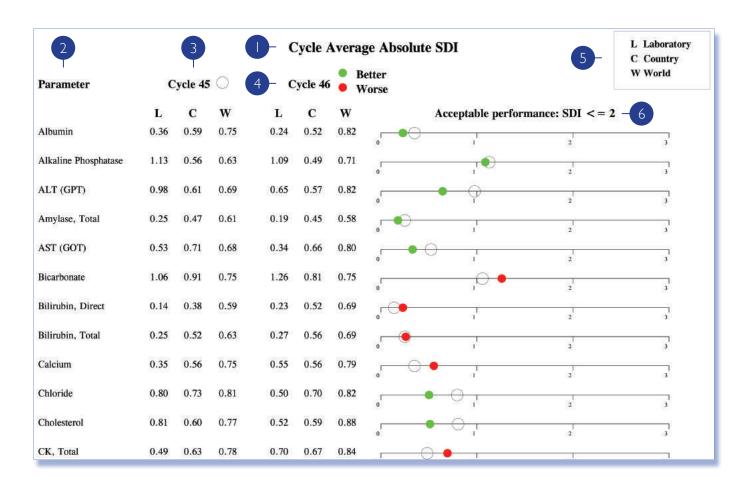
	Report presented in your chosen unit	Cycle average of your pe Index, Target Score and S	erformance indicators – Standard Deviation %Deviation
2	Your assay details as of the last sample		(Sum of SDIs returned for the completed cycle)
3	RIQASTDPA and Biological variation	Cycle Average SDI =	(Number of samples returned in cycle)
4	Sample number		(Sum of your Target Scores returned for the completed cycle)
5	Your results for each sample	Cycle Average Target Score =	(Number of samples returned in cycle)
6	Unit your result was returned in		(Sum of your %Deviations returned
7	Number of results used for statistical analysis	Cycle Average %Deviation =	for the completed cycle) (Number of samples returned in cycle)
8	Mean for Comparison		(
9	SDPA = Standard Deviation for performance assessment	Absolute values show he	ute values of the lab's SDI and %Deviation. bw far a value is from zero regardless of the of the magnitude of accuracy.
10	Uncertainty of Mean for Comparison	Sign. This is all indication	of the magnitude of accuracy.
	Coefficient of Variation (%)	Cycle Average	(Sum of your Absolute SDIs returned for the completed cycle)
	Coomercial of Variation (10)	Absolute SDI =	(Number of samples returned in cycle)
12	Your Standard Deviation Index		
13	Your Target Score	Cycle Average Absolute %Deviation	(Sum of your Absolute %Deviations returned for the completed cycle)
	Your %Deviation	Absolute %Deviation	(Number of samples returned in cycle)
14	Tour %Deviation		

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



	Levey-Jennings chart	Shows your SDIs for a full cycle.
		Shows SDI (positive and negative) 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.
		Shows %Deviation (positive and negative) Shows absolute %Deviation
4	%Deviation by Concentration chart	Shows your results for a full cycle.

Based on the cycle average absolute SDI, this chart provides a visual representation of your laboratory's performance compared to the previous cycle.



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

An 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.



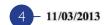
RIOAS & RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME

CERTIFICATE OF ACCEPTABLE PERFORMANCE

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







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:





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

	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

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:



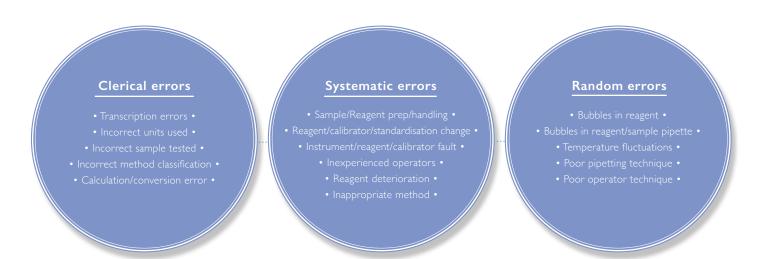
1. Investigate the source of the problem

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 30) is designed to help you investigate any apparent poor performance.

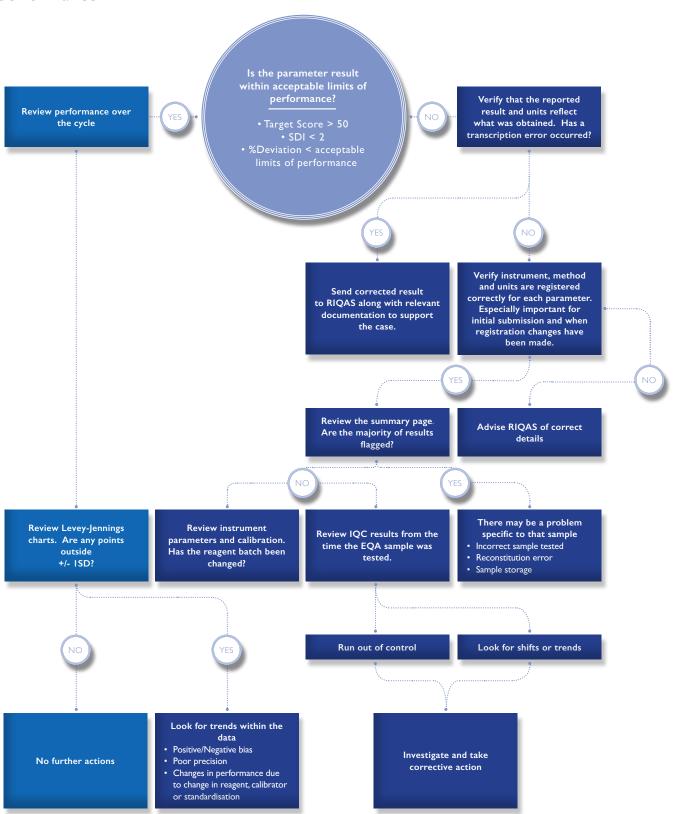
It may be possible that, after extensive investigations, the root cause of the poor performance cannot be established. Poor performance for a single sample could be attributed to random error. If poor performance has been noted for several samples, a systematic error is the most likely cause and the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



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:	Sample Number: Analyte:				
Analysis Date:					
Mean for Comparison:					
I Specimen Hendling		d Pandam IOC varietian an assaula analysis data		N	
I. Specimen Handling		 d. Random IQC variation on sample analysis date e. Error due to imprecision; check IQC in terms of 			
a. Samples received in good condition b. Samples stored/prepared appropriately		%Deviation compared to deviation observed in EQA		N	
c. Integrity of the sample is acceptable		f. IQC target correctly assigned		N	
c. Integrity of the sample is acceptable		i. i.Q.C. tal get correctly assigned			
2. Clerical		5. Calibration			
a. Correct result entered		a. Date of last calibration			
b. Correct use of decimal point and units		b. Calibration frequency acceptable	Y	N	
c. Calculations, if any, performed correctly		c. Last calibration acceptable	Y	N	
(even if automated)					
d. Conversion factors applied to results before submission		6. Instrument			
		a. Daily maintenance performed on date of sample analysis	M	N	
3. Registration and Mean for Comparison		b. Special maintenance performed prior to sample analysis	Y	N	
a. Registered in the correct method/instrument group		c. Instrument operated correctly	Y	N	
b. Changed method or instrument without advising		d. Operator fully trained	Y	N	
RIQAS					
c. Mean for comparison changed due to the number of		7. Reagents			
participants returning results e.g. from method to instrument		a. Reagents prepared and stored correctly			
d. An obvious bias between method and instrument means		b. Reagents within open vial stability	U	IN	
(check histogram and stats sections)					
		8. EQA sample			
4. Internal Quality Control		a. Initial value			
a. %Deviation of IQC (at similar conc to that of EQA) on		b. Re-run value			
sample analysis date acceptable		c. Issue observed in previous EQA samples at a similar			
b. Shift in IQC in the periods just before and after EQA		concentration (check %Deviation by concentration and Levey Jennings charts)		N	
sample analysis c.Trends in IQC in the periods before and after EQA	•	d. All parameters affected (to the same extent) - possible			
sample analysis		reconstitution error (check %Deviation on summary pages)		N	
запріе апаузіз		reconstitution error (crices /obeviation on summary pages)			
Conclusion:		Remedial Action:			
	•••••		• • • • • •	•••••	
Lab Manager: Date:		Lab Director: Date:			

The flow chart below can be used to help identify a possible root cause for poor EQA performance.



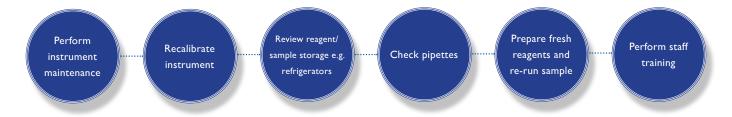
Monitoring EQA Performance

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.



AMMONIA/ETHANOL PROGRAMME+

2 Parameters Samples every month, I x I2 month cycle, I2 month subscription, liquid ready-to-use samples

Ethanol

ANTI-TSH RECEPTOR PROGRAMME+

RQ9174 (1 ml)

I Parameter Samples every month, I \times I2 month cycle, I2 month subscription, lyophilised samples

Anti-TSH Receptor (TRAb)

BLOOD GAS PROGRAMME With target scoring

RQ9134/A (1.8 ml) First registered instrument

10 Parameters

Subsequent instruments

10 Parameters

Samples every month, 1 x 12 month cycle, 12 month subscription, liquid ready-to-use samples

CO₂(Total) рΗ Na+ pO, CI-Glucose

BNP PROGRAMME+

I Parameter Samples every month, I \times I2 month cycle, I2 month subscription, liquid ready-to-use samples

CARDIAC PROGRAMME With target scoring

2 Parameters only (choose from 7) Full 7 Parameters
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, lyophilised samples

CK,Total CK-MB (Mass) Myoglobin CK-MB (Activity) Homocysteine Troponin I

CEREBROSPINAL FLUID PROGRAMME+

12 Parameters Samples every month, 1 \times 12 month cycle, 12 month subscription, liquid ready-to-use samples

 α -2-globulin (electrophoresis) γ-globulin (electrophoresis) Lactate Albumin (electrophoresis) β -globulin (electrophoresis) Glucose Protein (Total) α-I-globulin (electrophoresis) Chloride lgG Sodium

COAGULATION PROGRAMME With target scoring

RQ9135/a (1 ml) RQ9135/b (1 ml) Full 17 Parameters

5 Selected parameters only Full 17 Parameters
(aPTT, PT, TT, Fibrinogen, Antithrombin III)
Samples every month, 1 x 12 month cycle, 12 month subscription, lyophilised samples

Plasminogen Factor VII PT (including INR) Protein C ${\sf FactorVIII}$ Protein S Factor IX

Fibrinogen Factor X Factor II Antithrombin III Factor XI Factor V

Factor XII

D-dimer*

Lactate

CYFRA 21-1 PROGRAMME+

| Parameter | Samples every month, | x | 12 month cycle, | 12 month subscription, lyophilised samples

ESR PROGRAMME+

RQ9163 (4.5 ml)
I Parameter (ESR)
2 samples per quarterly distribution, I x I2 month cycle, I2 months subcription, liquid ready-to-use samples

FSR

GENERAL CLINICAL CHEMISTRY PROGRAMME With target scoring

10 Parameters only Full 52 Parameters
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, reference method values, lyophilised samples

ACE (Angiotensin Converting Enzyme)*
Acid Phosphatase (Prostatic) Calcium **HBDH PSA** Calcium (Ionised) HDL-Cholesterol Sodium Acid Phosphatase (Total) Chloride TIBC Iron T₃ (Free) T₃ (Total) Albumin Cholesterol Lactate Alkaline Phosphatase LD (LDH) Cholinesterase T₄ (Free) T₄ (Total) ALT (ALAT) CK, Total (CPK) Lipase Amylase (Pancreatic) Lithium Copper Amylase (Total) Creatinine Magnesium Triglycerides AST (ASAT) D-3-Hydroxybutyrate NEFA* TSH Bicarbonate Fructosamine Osmolality UIBC Phosphate (Inorganic) Bile Acids γGT Urea Bilirubin (Direct) GLDH Potassium Uric Acid Protein (Total) Bilirubin (Total) Glucose Zinc

GLYCATED HAEMOGLOBIN PROGRAMME (HbAIc) With target scoring

RQ9129 (0.5ml)

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

HbA1c Total Haemoglobin

HAEMATOLOGY PROGRAMME With target scoring

I I Parameters
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, liquid ready-to-use samples

Mean Cell Haemoglobin Concentration (MCHC) Red Cell Distribution Width (RDW) Haemoglobin (Hb) Mean Cell Volume (MCV) Plateletcrit (PCT) Total White Blood Cell Count (WBC) Mean Platelet Volume (MPV) Red Blood Cell Count (RBC) Mean Cell Haemoglobin (MCH)

HUMAN URINE PROGRAMME With target scoring

Cortisol

25 Parameters
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, lyophilised samples

Creatinine Normetanephrine Protein (Total) Albumin/Microalbumin Dopamine Magnesium Sodium Amylase Epinephrine Osmolality Urea Uric Acid Calcium Glucose Oxalate VMA Phosphate (Inorganic) Metanephrine Chloride Potassium 5-HIAA Norepinephrine Copper

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

* = Pilot study ongoing

IMMUNOASSAY PROGRAMME With target scoring

RQ9130 (5 ml) Full 55 Parameters

T₄ (Free) T₄ (Total) DHEA Unconjugated 17-OH-Progesterone AFP Digoxin Paracetamol Aldosterone Estriol Total* Phenobarbital Testosterone (Free)* Amikacin* Ethosuximide* Phenytoin Testosterone (Total) Androstenedione* Ferritin Primidone* Theophylline Thyroglobulin Tobramycin* β -2-Microglobulin Progesterone Folate . CA125 FSH Prolactin CA15-3 PSA (Free) Gentamicin TSH CA19-9 GH PSA (Total) Valproic Acid Carbamazepine hCG PTH Vancomycin CFA IgE Salicylate* Vitamin B12 SHBG I-25-(OH),-Vitamin D* Insulin Cortisol C-Peptide LH T₃ (Free) T₃ (Total) 25-OH-Vitamin D DHEA-Sulphate Oestradiol

IMMUNOASSAY SPECIALITY I PROGRAMME+ With target scoring

10 Parameters Samples every month, 1 \times 12 month cycle, 12 month subscription, lyophilised samples

I-25-(OH)₂-Vitamin D 25-OH-Vitamin D Anti-TG Osteocalcin

Anti-TPO Procalcitonin PTH C-Peptide

IMMUNOASSAY SPECIALITY 2 PROGRAMME+

5 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription, lyophilised samples

Calcitonin **Procalcitonin** Plasma Renin Activity Renin (Direct Concentration)

Gastrin

IMMUNOSUPPRESSANT PROGRAMME+

RQ9159 (2 ml)

4 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription, lyophilised samples

Sirolimus Tacrolimus

LIPID PROGRAMME With target scoring

3 Parameters only (choose from 7) Full 7 Parameters
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, lyophilised samples

LDL-Cholesterol Apolipoprotein A I Cholesterol (Total) Triglycerides Apolipoprotein B HDL-Cholesterol Lipoprotein (a)

LIQUID CARDIAC PROGRAMME With target scoring

RQ9136 (3 ml)

9 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription, liquid ready-to-use samples

CK-MB Mass Homocysteine Myoglobin Troponin I D-dimer hsCRP NT proBNP Troponin T

Digoxin

MATERNAL SCREENING PROGRAMME With target scoring

6 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription, lyophilised samples

PAPP-A Unconjugated Oestriol Total hCG

free β-hCG Inhibin A

SEROLOGY (EBV) PROGRAMME+

RQ9153 (1 ml)

3 Parameters
3 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results, liquid ready-to-use samples

Anti-EBNA IgG Anti-EBV VCA IgM

SEROLOGY (HIV-HEPATITIS) PROGRAMME+

10 Parameters
5 samples per quarterly distribution, 1 × 12 month cycle, 12 month subscription, Quantitative and Qualitative results, liquid ready-to-use samples

Anti-HIV-I Anti-HCV Anti-HTI V-II HBsAg

Anti-HTLV-1&2 Combined Anti-HIV-2 Anti-HBc

Anti-HTLV-I Anti-HIV-1&2 Combined Anti-CMV

SEROLOGY (SYPHILIS) PROGRAMME+

I Parameter 3 samples per quarterly distribution, I x I2 month cycle, I2 month subscription, Quantitative and Qualitative results, liquid ready-to-use samples

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

SEROLOGY (ToRCH) PROGRAMME+

12 Parameters
5 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results, liquid ready-to-use samples

Anti-Toxoplasma IgG Anti-Rubella IgM Anti-HSVI IgG Anti-HSV I IgM Anti-CMV lgG Anti-HSV2 lgG Anti-Toxoplasma IgM

Anti-HSV 2 IgM Anti-HSV I + 2 IgM Combined Anti-CMV IgM Anti-Rubella IgG Anti-HSV-1&2 IgG Combined

SPECIFIC PROTEINS PROGRAMME With target scoring

RQ9160 (2 ml)

Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, liquid ready-to-use samples

Haptoglobin

β-2-Microglobulin Lambda Light Chain (Total) lgΑ Albumin . Ceruloplasmin ΙgΕ Prealbumin (Transthyretin) α - I-Acid glycoprotein Complement C, lgG Retinol Binding Protein $\alpha\text{-I-Antitrypsin}$ Complement C lgΜ Rheumatoid Factor Kappa Light Chain (Free) $\alpha\text{-}2\text{-}Macroglobulin$ C-Reactive Protein Transferrin Kappa Light Chain (Total) Anti Streptolysin O Ferritin

SWEAT TESTING PROGRAMME+

Antithrombin III

3 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription, liquid ready-to-use samples

Chloride Conductivity Sodium

Lambda Light Chain (Free)

THERAPEUTIC DRUGS PROGRAMME With target scoring

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

Ethosuximide Phenobarbital Tobramycin Caffeine Gentamicin Valproic Acid Carbamazepine Lithium Primidone Vancomycin Cyclosporine Methotrexate Salicylic Acid

Digoxin Paracetamol (Acetaminophen) Theophylline

TRACE ELEMENTS IN BLOOD PROGRAMME+

7 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription, lyophilised samples

Lead Manganese

Magnesium

TRACE ELEMENTS IN SERUM PROGRAMME+

RQ9170 (3 ml) 10 Parameters Samples every month, 1 \times 12 month cycle, 12 month subscription, lyophilised samples

Copper Manganese Nickel lodine Cobalt Selenium Lead

TRACE ELEMENTS IN URINE PROGRAMME+

RQ9171 (3 ml)

I I Parameters
Samples every month, I x 12 month cycle, 12 month subscription, lyophilised samples

Cadmium Nickel Copper Magnesium Manganese Chromium lodine Thallium Molybdenum Cobalt Lead

URINALYSIS PROGRAMME+

RQ9138 (12 ml)

14 Parameters Samples every 2 months, 1 x 12 month cycle, 12 month subscription, liquid ready-to-use samples

Galactose Specific Gravity Albumin Leukocytes Bilirubin Glucose Nitrite Ürobilinogen hCG рΗ Creatinine Ketones Protein

URINE TOXICOLOGY PROGRAMME+

20 Parameters
Samples every month, 1 x 12 month cycle, 12 month subscription, liquid ready-to-use samples

d-Methamphetamine MDMA EDDP Methadone Buprenorphine Cannabinoids (THC) Ethanol Nortriptyline Cotinine* Free Morphine Norpropoxyphene

Creatinine Lorazepam Oxazepam d-Amphetamine LSD Phencyclidine Phenobarbital

Secobarbital



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