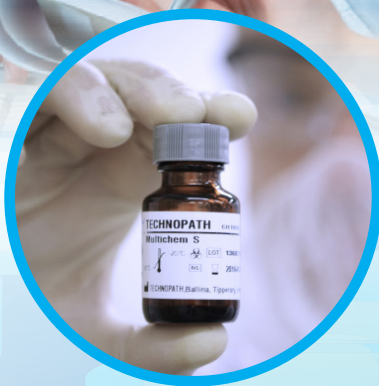




YOUR QUALITY CONTROL SOFTWARE

# QUALITY CONTROL SOFTWARE



QC Software Peer Programme

Powerful Reports

Trending & Analysis

Data Records & Compliance



T E C H N O P A T H

Brought to you by:  
TECHNOPATH Distribution Ltd, proudly partnering with you to provide the highest quality  
IQC products for your laboratories.

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# QC SOFTWARE SOLUTION



## IAMQC® Peer Software:

IAMQC® Peer is an innovative, real-time, Peer Comparison Software. TECHNOPATH's web based system facilitates laboratories testing the same lot number of quality control material to access valuable information from their colleagues through peer comparison.

The reports that are generated in IAMQC® Peer compare the accuracy and precision of analytical processes between laboratories and peer groups. This information can be extremely valuable, indicating the user's performance relative to their peer group and also providing powerful troubleshooting tools when attempting to resolve potential problems.



## The Multichem® Range of Quality Controls:

Compatible for use with the TECHNOPATH Multichem® range of Quality Controls. Track your Multichem® QC results on one centralised platform.

### Multichem® S Plus



Serum Chemistry & Immunology QC

### Multichem® S



Serum Chemistry & Immunology QC

### Multichem® P



Supplementary Immunoprotein QC

### Multichem® U



Urinary Chemistry QC

### Multichem® NB



Neonatal Bilirubin QC

### Multichem® AE



Ammonia & Ethanol QC

### Multichem® CSF



Cerebral Spinal Fluid QC

### Multichem® IA Plus



Immunoassay QC

### Multichem® IA



Immunoassay QC

### Multichem® IA Speciality



Speciality Peptide Hormone QC

### Multichem® hsTn



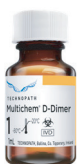
High Sensitive Troponin QC

### Multichem® WBT



Whole Blood Immunosuppressant QC

### Multichem® D-Dimer



D-Dimer QC

### Multichem® A1c



Diabetes Haemoglobin A1c QC

### Multichem® AMH



Anti-Müllerian Hormone QC



# JOIN THE IAMQC® PEER PROGRAMME

## What is the IAMQC® Peer Programme?

This web based system facilitates laboratories testing the same lot number of control material to access valuable information from their fellow colleagues through peer comparison.

The reports that are generated in IAMQC® Peer compare the accuracy and precision of analytical processes between laboratories and peer groups.

## Why should my laboratory partipate?

This information can be extremely valuable, indicating the user's performance relative to their peer group and also providing powerful troubleshooting tools when attempting to resolve potential problems.

The information provided by IAMQC® Peer can be used on a monthly basis to evaluate how well lab's methods are operating relative to the overall peer group.

Users can also look at this peer data in real-time interactive tables online, when they are investigating a potential problem with accuracy or precision in an individual method.

## How does my laboratory participate?

To participate in IAMQC® Peer, each individual laboratory submits their individual results or summary statistics (mean, standard deviation, and number of data points) to the central database maintained by TECHNOPATH.

Laboratories data may be submitted manually on-line or, alternatively, captured by one of our many live interfacing options. Speak with a TECHNOPATH representative today to learn more.

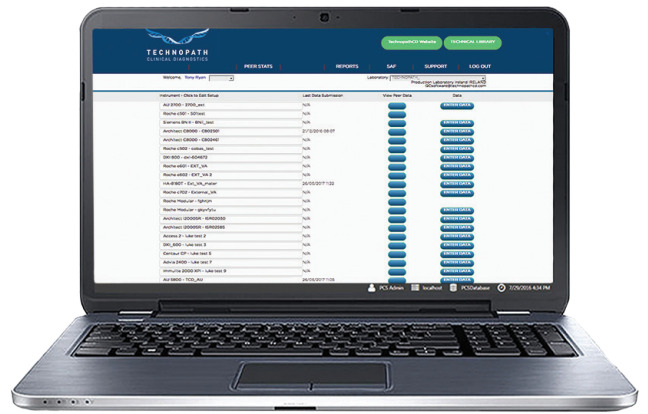




# IAMQC® REPORTS

Each one of the IAMQC® Peer comparison reports are generated in PDF format and are available on the web through the IAMQC® Peer online site. These reports can be generated by the user or automatically on a user defined schedule.

The generated reports can be emailed automatically, as well as printed. At any time, the reports are available online and can be downloaded by users using their login name and password.



## Available Reports

- Peer Groups Stats Report
- Group Coordinator Report
- Levey Jennings Report
- Youden Plot Report
- Monthly Summary Report
- Exceptions Report
- Measurement of Uncertainty Report
- Six Sigma Report

Generated Reports help with audit preparation and ISO 15189 requirements.

# Peer Group Stats Report

Compare performance to both method and instrument group against the world peer.

- Choose the month to view the results
- View **Mean, SD, & CV** for your instrument
- Comparisons can be made on both a monthly & cumulative base
- Gives your result an **SDI** and **CVI** score

The screenshot shows the 'Group Stats View' interface. At the top, navigation tabs include HOME, DEMOGRAPHICS, PEER STATS, SETUP, REPORTS, SAF, SUPPORT, and LOG OUT. The user is logged in as John Doe. The main section is titled 'Group Stats View' and includes filters for Product (Multichem S Plus), Instrument (Roche c701), and Period (Jun 2019). Below these are three columns for QC Levels (Level 1, 2, 3) with radio buttons for selection. The 'Analyte' is set to Sodium (NA), mmol/L, and the 'Method' is Indirect ISE. Two tables are displayed: 'Monthly Stats' and 'Cumulative Stats', both showing Mean, SD, % CV, N, and Peers for different peer groups. A 'VIEW ALL (PRINT)' button is located between the tables. Callouts point to various elements: 'Select Quality Control, Select Instrument, Select Time frame' points to the top filters; 'Select available QC Levels' points to the QC level radio buttons; 'Select Analyte' points to the Units and Analyte dropdowns; 'View Monthly Stats per QC Level' points to the 'VIEW' button; and 'View Cumulative Stats per QC Level' points to the 'VIEW ALL (PRINT)' button.

**Select Quality Control, Select Instrument, Select Time frame**

**Select available QC Levels**

**Select Analyte**

**View Monthly Stats per QC Level**

**View Cumulative Stats per QC Level**

Monthly Stats							Cumulative Stats				
Level	Mean	SD	% CV	N	Peers	Mean	SD	% CV	N	Peers	
Test System Peer	123.02	2.749	2.23	4165	21	123.14	2.356	1.91	63319	36	
Method Principle Peer	122.96	2.466	2.01	6415	55	123.12	2.061	1.67	123772	99	
All System Peer	122.96	2.466	2.01	6415	55	123.11	2.076	1.69	125087	106	
Test System Peer	146.62	1.704	1.16	6488	7	146.69	1.652	1.13	165030	15	
Method Principle Peer	146.62	1.671	1.14	7278	22	146.66	1.651	1.13	184553	48	
All System Peer	146.62	1.671	1.14	7278	22	146.65	1.665	1.14	185729	55	
Test System Peer	167.03	1.887	1.13	3967	21	167.30	2.062	1.23	59797	34	
Method Principle Peer	166.35	2.591	1.56	6217	55	166.31	4.082	2.45	122843	97	
All System Peer	166.35	2.591	1.56	6217	55	166.29	4.074	2.45	123941	101	

# Group Coordinator Report

Provides a test by test listing of statistics for the laboratory and its peer groups for up to 3 levels of control material. A peer group is a group of laboratories using the same control material and the same analytical method. The Group Coordinator Report documents all of the relevant data points submitted to IAMQC® and automatically provides a statistical analysis in table format.

This report provides a centralised review of all instruments, from the moment the customer begins to report data and thus facilitates users meeting accreditation requirements, with respect to the storage, retrieval and statistical analysis of quality control data.

**Note:** When SDI and CVI goes above 1.5, these performance issues are highlighted for ease of review.

View all instruments within the group

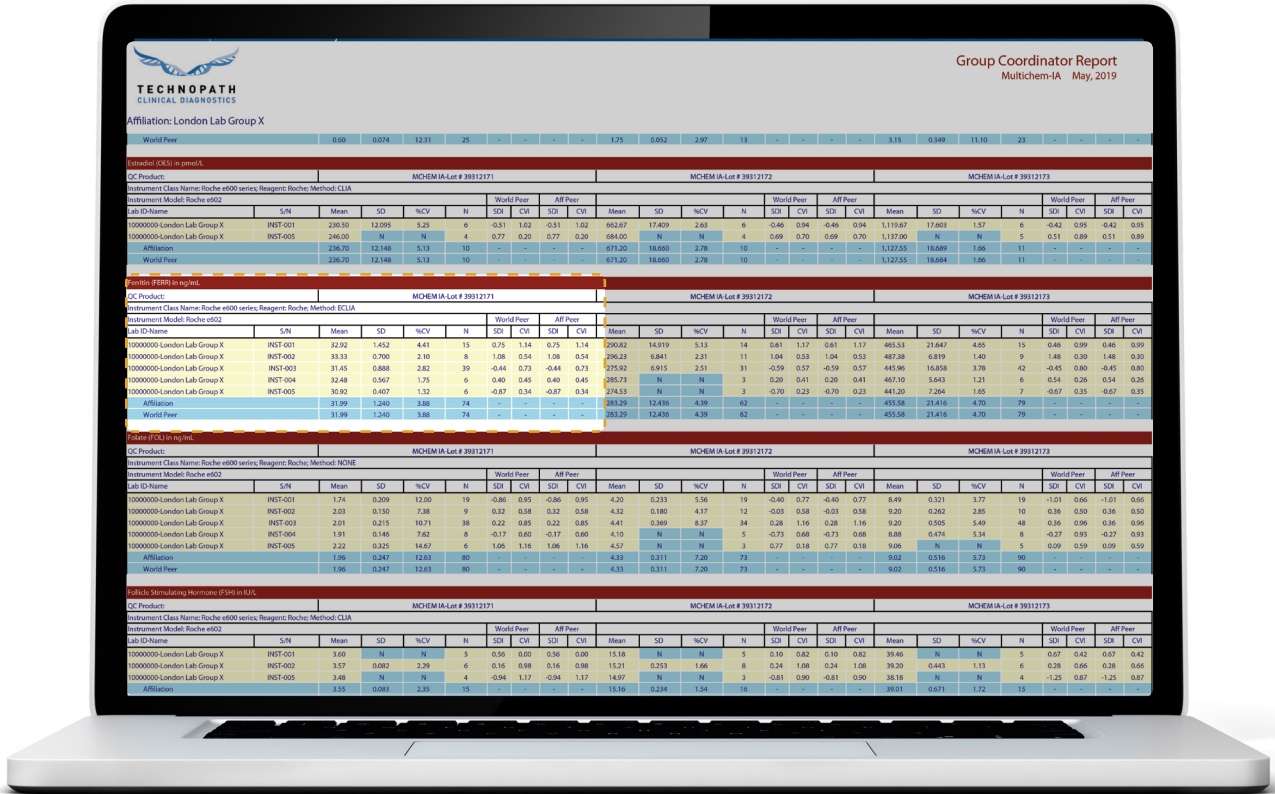
View up to 3 IQC levels on the one report

SDI and CVI scores against affiliate peers and world peers

Ferritin (FERR) in ng/mL									
QC Product:					MCHEM IA-Lot # 39312171				
Instrument Class Name: Roche e600 series; Reagent: Roche; Method: ECLIA									
Instrument Model: Roche e602									
Lab ID-Name	S/N	Mean	SD	%CV	N	World Peer	Aff Peer	SDI	CVI
10000000-London Lab Group X	INST-001	32.92	1.452	4.41	15	0.75	1.14	0.75	1.14
10000000-London Lab Group X	INST-002	33.33	0.700	2.10	8	1.08	0.54	1.08	0.54
10000000-London Lab Group X	INST-003	31.45	0.888	2.82	39	-0.44	0.73	-0.44	0.73
10000000-London Lab Group X	INST-004	32.48	0.567	1.75	6	0.40	0.45	0.40	0.45
10000000-London Lab Group X	INST-005	30.92	0.407	1.32	6	-0.87	0.34	-0.87	0.34
Affiliation		31.99	1.240	3.88	74	-	-	-	-
World Peer		31.99	1.240	3.88	74	-	-	-	-

Folate (FOL) in ng/mL									
QC Product:					MCHEM IA-Lot # 39312171				

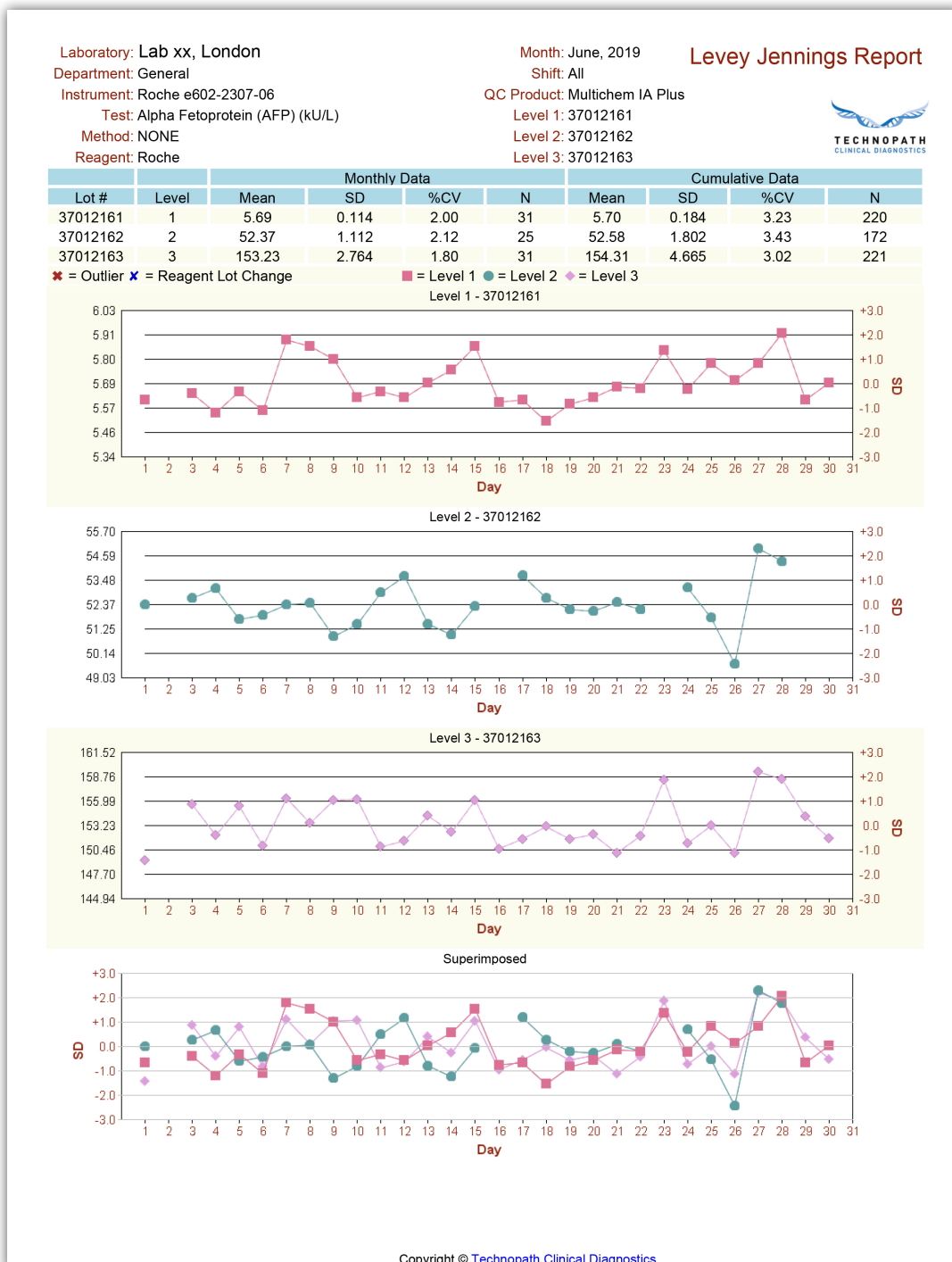
Shows Mean, SD, & CV for all instruments per affiliation with world peer comparison



# Levey Jennings Report

The Levey Jennings Report displays individual daily QC means for the selected month for a specific analyte. The report can be generated for two or three levels of QC material. This report also provides a super-imposed version of all QC levels at the bottom of each sheet, highlighting any level specific bias. The top of the graph displays a summary of both monthly and cumulative data, including all of the relevant statistics for the laboratory.

- Select month to view QC results
- Monthly **Mean, SD, & CV** given for all levels
- Results shown as a daily mean
- Levey Jenning for up to 3 levels of results
- Bottom chart superimposes multiple levels on the same chart, showing any level specific bias





# Monthly Summary Report

For each test, and control level, this report displays summary statistics for the last twelve individual months and Lot-to-Date period for the laboratory and its peer groups. This data is useful for long-term intra-laboratory and inter-laboratory comparisons.

This report provides the customer with an indication of the 'usual' method accuracy and precision, allowing them to view any unexpected trending or increases in imprecision. The report also displays the customer's monthly SDI and CVI, indicating any shifts from the peer group. The 'monthly summary' report facilitates the user investigating changes in performance over time.

Quality control being reported

Test being reported

Lot # being reported

		LTD	Mar	Feb	Jan	Dec	Nov	Oct	Sep	Aug	Jul	Jun	May	Apr
		2018	2018	2018	2018	2017	2017	2017	2017	2017	2017	2017	2017	2017
<b>Alanine Aminotransferase (ALT) (U/L) - All Shift</b>														
MCEM S+-Lot # 15208151														
Your Lab		Roche c702 - GRA_C702, IFCC, Roche												
Mean		29.95	29.74	30.01	29.45	29.54	30.01	30.28	30.64	30.44	30.04	29.94	-	28.79
SD		1.221	0.991	1.182	1.058	1.054	0.994	1.250	1.292	1.222	1.165	1.345	N	0.975
%CV		4.08	3.33	3.94	3.59	3.57	3.31	4.13	4.22	4.02	3.88	4.49	-	3.39
N		1120	118	122	132	145	81	141	90	99	121	49	-	14
Test System Peer		Roche Cobas 8000, IFCC, Roche												
Mean		29.23	29.12	29.26	28.99	28.95	29.06	29.26	29.13	29.02	29.08	29.11	29.22	28.69
Peers		12	7	7	5	5	5	5	5	7	10	10	5	7
SDI		0.54	0.42	0.56	0.39	0.40	0.70	0.80	1.12	1.12	0.73	0.65	-	0.06
CVI		0.89	0.67	0.86	0.88	0.71	0.71	0.95	0.91	0.91	0.86	1.02	-	0.54
MCEM S+-Lot # 15208153														
Your Lab		Roche c702 - GRA_C702, IFCC, Roche												
Mean		216.72	216.96	215.84	215.15	216.46	217.53	218.21	219.84	219.12	217.59	217.32	-	214.08
SD		3.556	3.786	2.514	3.424	3.432	2.135	2.776	2.477	2.095	2.222	1.872	N	2.999
%CV		1.64	1.74	1.16	1.59	1.59	0.98	1.27	1.13	0.96	1.02	0.86	-	1.40
N		928	97	87	104	111	60	106	64	78	102	37	-	12
Test System Peer		Roche Cobas 8000, IFCC, Roche												
Mean		216.35	214.66	214.26	213.56	215.50	214.98	216.49	216.37	215.24	215.33	215.35	215.72	216.78
Peers		12	7	7	5	5	5	5	5	7	10	10	5	7
SDI		0.08	0.41	0.33	0.32	0.22	0.45	0.52	1.03	1.08	0.67	0.44	-	-1.04
CVI		0.76	0.67	0.53	0.68	0.78	0.37	0.84	0.72	0.57	0.65	0.41	-	1.17
MCEM S+-Lot # 15208151														
Your Lab		Roche c702 - GRI_C702, IFCC, Roche												
Mean		28.79	29.10	29.32	28.78	28.41	28.67	28.88	28.82	28.62	28.89	28.76	29.00	27.35
SD		1.424	1.841	1.521	1.147	1.592	1.467	1.075	1.092	1.146	1.241	1.454	2.683	1.482
%CV		4.95	6.33	5.19	3.98	5.60	5.12	3.72	3.79	4.00	4.30	5.06	9.25	5.42
N		2941	283	307	352	385	264	365	227	237	312	116	6	57
Test System Peer		Roche Cobas 8000, IFCC, Roche												
Mean		29.23	29.12	29.26	28.99	28.95	29.06	29.26	29.13	29.02	29.08	29.11	29.22	28.69
Peers		12	7	7	5	5	5	5	5	7	10	10	5	7
SDI		-0.33	-0.01	0.04	-0.18	-0.37	-0.29	-0.30	-0.23	-0.31	-0.15	-0.27	-0.18	-0.74
CVI		1.08	1.26	1.14	0.98	1.12	1.10	0.86	0.81	0.91	0.96	1.15	2.14**	0.80
MCEM S+-Lot # 15208153														
Your Lab		Roche c702 - GRI_C702, IFCC, Roche												
Mean		213.14	215.82	211.24	209.86	212.08	210.58	214.39	215.21	213.45	214.15	213.47	224.00	216.03
SD		4.736	7.857	4.832	4.261	3.310	6.510	2.243	2.609	2.489	3.117	5.826	N	1.740
%CV		2.22	3.64	2.29	2.03	1.56	3.09	1.05	1.21	1.17	1.46	2.73	0.00	0.81
N		2460	218	242	250	285	171	271	183	191	227	91	1	37
Test System Peer		Roche Cobas 8000, IFCC, Roche												
Mean		216.35	214.66	214.26	213.56	215.50	214.98	216.49	216.37	215.24	215.33	215.35	215.72	216.78
Peers		12	7	7	5	5	5	5	5	7	10	10	5	7
SDI		-0.69	0.21	-0.64	-0.74	-0.78	-0.77	-0.64	-0.34	-0.50	-0.35	-0.42	2.22*	-0.29
CVI		1.04	1.39	1.04	0.87	0.77	1.17	0.69	0.78	0.70	0.93	1.31	0.00	0.67

Performance issues are highlighted for ease of use

## Measurement of Uncertainty Report

IAMQC® Peer has added new features that will add significant value for the end user. Customers can now generate a Measurement of Uncertainty report in MS Excel format from their online IAMQC® Peer account. Measurement of Uncertainty has become an important consideration in many laboratories and is referred to by many of the accreditation bodies as a requirement during audits (ISO 15189 Section 5.6.2).

*“The laboratory shall determine measurement uncertainty for each measurement procedure, in the examination phases used to report measured quantity values on patients’ samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.”*

ISO 15189 Section 5.6.2

### Measuring Uncertainty

To measure uncertainty (**u**) the clinical pathology laboratory must first calculate the standard error of mean (SEM) of the intra assay precision (**A**) and the SD of the inter assay precision (**B**).

Once calculated, both A and B now need to be squared, add together and then a final calculation of the square root (see below).

$$u = \sqrt{A^2 + B^2}$$

### The K Factor

Once clinical pathology laboratories have determined the uncertainty they may then want to re-scale the result. The standard uncertainty may be thought of as equivalent to ‘one standard deviation’, but we may wish to have an overall uncertainty stated at another level of confidence, e.g. 95 percent. This re-scaling can be done using a coverage factor, k.

Multiplying the standard uncertainty, u , by a coverage factor gives a result which is called the expanded uncertainty, usually shown by the symbol U.

A particular value of coverage factor gives a particular confidence level for the expanded uncertainty. Most commonly, we scale the overall uncertainty by using the coverage factor k = 2, to give a level of confidence of approximately 95 percent. (k = 2 is correct if the combined standard uncertainty is normally distributed).

Some other coverage factors (for a normal distribution) are:

k = 1 for a confidence level of approximately 68 percent

k = 2.58 for a confidence level of 99 percent

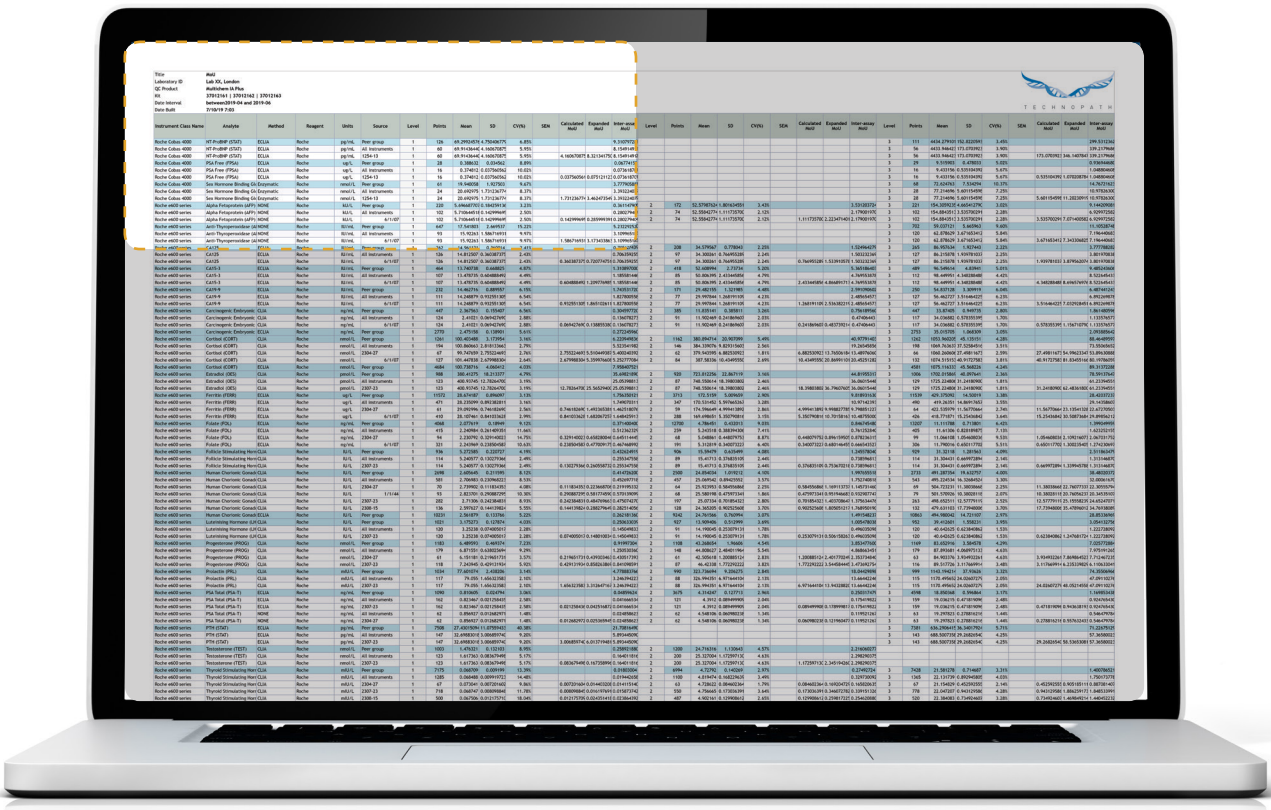
k = 3 for a confidence level of 99.7 percent

# Example Measurement of Uncertainty Report

Your Measurement of Uncertainty report is generated in MS Excel format and available online to download from your IAMQC® Peer account.

## Calculated MOU, Expanded MOU, Interassay MOU

Instrument Class Name	Analyte	Method	Reagent	Units	Source	Level	Points	Mean	SD	CV(%)	SEM	Calculated MoU	Expanded MoU	Inter-assay MoU
Roche Cobas 4000	NT-ProBNP (STAT)	ECLIA	Roche	pg/mL	Peer group	1	126	69.29924576	4.750406775	6.85%				9.310797282
Roche Cobas 4000	NT-ProBNP (STAT)	ECLIA	Roche	pg/mL	All instruments	1	60	69.91436440	4.160670875	5.95%				8.154914912
Roche Cobas 4000	NT-ProBNP (STAT)	ECLIA	Roche	pg/mL	1254-13	1	60	69.91436440	4.160670875	5.95%	4.160670875	8.32134750	8.154914912	
Roche Cobas 4000	PSA Free (FPSA)	ECLIA	Roche	ug/L	Peer group	1	28	0.388632	0.034562	8.89%				0.06774152
Roche Cobas 4000	PSA Free (FPSA)	ECLIA	Roche	ug/L	All instruments	1	16	0.374812	0.037560562	10.02%				0.073618701
Roche Cobas 4000	PSA Free (FPSA)	ECLIA	Roche	ug/L	1254-13	1	16	0.374812	0.037560562	10.02%	0.037560562	0.075121123	0.073618701	
Roche Cobas 4000	Sex Hormone Binding Glc Enzymatic	Roche	Roche	nmol/L	Peer group	1	61	19.940058	1.927503	9.67%				3.777905881
Roche Cobas 4000	Sex Hormone Binding Glc Enzymatic	Roche	Roche	nmol/L	All instruments	1	24	20.692975	1.731236774	8.37%				3.393224075
Roche Cobas 4000	Sex Hormone Binding Glc Enzymatic	Roche	Roche	nmol/L	1254-13	1	24	20.692975	1.731236774	8.37%	1.731236774	3.462473545	3.393224075	
Roche e600 series	Alpha Fetoprotein (AFP) NONE	NONE	Roche	ku/L	Peer group	1	220	5.696687707	0.184259136	3.23%				0.36117906
Roche e600 series	Alpha Fetoprotein (AFP) NONE	NONE	Roche	ku/L	All instruments	1	102	5.710644518	0.142999695	2.50%				0.280279400
Roche e600 series	Alpha Fetoprotein (AFP) NONE	NONE	Roche	ku/L	6/1/07	1	102	5.710644518	0.142999695	2.50%	0.142999695	0.285999391	0.280279400	



# Six Sigma Report

IAMQC® Peer now offers end-users the opportunity to automatically calculate and review their sigma metric performance. The system will automatically calculate imprecision and bias and once the end-user has defined their acceptability criteria (i.e Total Allowable Error), the software will automatically calculate a sigma score for every assay that is tested in the laboratory using the following calculation:

$$\text{Sigma-metric} = (\text{TEa} - \text{Bias}) / \text{CV}$$

[all parameters expressed as %]

The new interactive report includes a normalised method decision chart displaying all assays, a Sigma Metric summary table outlining the calculated sigma score for each assay and a detailed summary table displaying further information on the statistics used for the calculation.

Select criteria for Review: **Quality Control, Lot, Instrument, and Time frame**

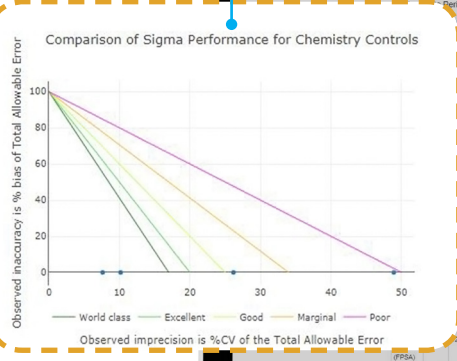
Select Kit Name:  
 37012161 | 37012162 | 37012163

Select Instrument:  
 ALL / Roche E411 - 1254-13 / Roche e601 - 2304-27 / Roche e601 - 2444-01 / Roche e602 - 2308-15 / Roche e602 - 2307-06 / Roche e602 - 2307-23

Select Date Period:  
 June 2019 / May 2019 / April 2019\* / **March 2019\*** / February 2019\* / January 2019\*

December 2018\* / November 2018 / October 2018 / September 2018 / August 2018 / July 2018 / June 2018 / May 2018 / April 2018 / March 2018

Interactive Report generates a normalised method decision chart based on criteria selected



Sigma Metric Summary Table calculates metric score for all assays

Sigma Metrics :

Lowest Sigma Score:				
Analyte	Units	TCD Level 1 Sigma Score	TCD Level 2 Sigma Score	TCD Level 3 Sigma Score
PSA Free (FPSA)	ug/L	6		6
Sex Hormone Binding Globulin (SHBG)	nmol/L	3		2

Sigma Detailed :

Analyte	Units	Instrument	Level 1							Level 2							Level 3										
			Mean	SD	%CV	Peer Avg. Mean	% Bias	% TEa	Sigma Calc	Sigma Score	Mean	SD	%CV	Peer Avg. Mean	% Bias	% TEa	Sigma Calc	Sigma Score	Mean	SD	%CV	Peer Avg. Mean	% Bias	% TEa	Sigma Calc	Sigma Score	
PSA Free (FPSA)	ug/L	1254-13	0.40	0.01	3.42	0.40	0.00	33.60	9.82	6																	
Sex Hormone Binding Globulin (SHBG)	nmol/L	1254-13	20.01	0.60	3.01	20.01	0.00	11.50	3.62	3																	

Detailed Summary Table includes details on the individual instrument statistics for each level of assay (Mean, SD, CV, Peer Mean, % Bias from the peer mean, % TEa, Sigma Calculated score). The end-user can click on an individual point on the normalised method decision chart to view the information associated with that point.



# FEATURES



## COMPLIANCE

- Report Generation & Storage.
- Audit Preparation.
- Facilitates meeting **ISO 15189** requirements.
- Increase confidence in your laboratory performance.



## INFORMATICS

- Designed to work alongside the laboratory middleware, providing additional features.
- IQC performance can be compared to the world peer group, giving increased confidence in IQC results.
- Web based system, meaning IQC data is available anywhere, anytime.



## USER-FRIENDLY

- Easy to read tables and reports.
- Submit data automatically via the laboratories middleware.
- Perfect for the modern day hub & spoke laboratory.



## TRENDING & ANALYSIS

- Compare IQC performance across multiple instruments within a laboratory or across a group of laboratories.
- Compare with world peer group.



## DATA RECORDS

- Centralised data management – review IQC performance of multiple instruments in one location.
- Defined reporting for record keeping & Real-Time Investigation.

Increase confidence  
in your laboratory's  
performance.

# BENEFITS

## **BENCH TECHNOLOGISTS:**

- Spend less time on false positive QC flags
- Concentrate on tests, which require their attention
- Spend less time trouble-shooting
- Know how to react when the mean shifts
- Assess the acceptability of new reagent lots and calibrations
- Solve QC problems
- Gain understanding and confidence in the QC process

## **LAB MANAGERS:**

- Choose QC rules to maximise true rejects and minimise false rejects
- Quickly see the tests that require their attention
- Skim graphics to quickly review current or historical data by lab, department, instrument or test
- Monitor performance in groups of laboratories
- Review problem tests and QA activities in local and remote labs

## **LAB OR HOSPITAL ADMINISTRATORS:**

- Save money
- Improve quality
- Improve service
- Review Administrative Summary Reports to ensure quality performance



# SERVICE EXCELLENCE

TECHNOPATH only partner with market-leading manufacturers of innovative products. Combined with these high quality product lines, TECHNOPATH provide unrivalled technical support. Our specialised teams are highly trained, providing the best possible standard of customer service and technical support along with a sophisticated supply chain management system.

Our customers take precedence and are at the forefront of everything we do.

## TECHNOPATH Distribution Ltd offer the following Service Excellence:

### DELIVERY

- ▶ Next day delivery policy via DHL Special Courier.
- ▶ Specialising in ambient, re Fridgerated and frozen product deliveries.

### SEQUESTER

- ▶ 18 months single Lot # reservation.
- ▶ Reduces frequency of mean establishment.
- ▶ Dedicated Sequester Manager available 5 days a week to monitor run rates and sequester volumes.

### FREEZER PROGRAMME

- ▶ Available on request.
- ▶ -30°C freezer provided for dedicated QC storage.

### SUPPORT

- ▶ We have a full UK based team including a dedicated Territory Manager in the North of the UK that is available 5 days a week to provide training and any local support required.
- ▶ Our head office customer service and technical support staff in Co. Tipperary, Ireland are also available 5 days a week via the telephone or email.



## CONTACT US

For further information on any of the clinical diagnostics product offerings from TECHNOPATH please contact us on the below details or check out our website: [www.techno-path.com](http://www.techno-path.com)



T E C H N O P A T H

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