TECHNOPATH
CLINICAL DIAGNOSTICS

THE QUALITY CONTROL COMPANY

IAMQC®

Guide to **Six Sigma**

AUTOMATED REPORTS IN IAMQC PEER

Contents

> Sigma Metrics can be used to predict the quality of an instrument's test methods.
>
> Sigma Metric analysis of instruments allows for easy comparison of the quality of results that will be produced by the instrument
>
> It will predict which tests will require minimal QC rules and which tests will be of marginal or unacceptable quality.
>
> Significant savings in materials and labor resulting from changes made in QC program."
>
> Director Laboratory Services,
>
> Health System, US

Introduction

Is there an objective approach to monitoring laboratory performance?

Increasingly Laboratories seek objective assessment and comparison of analytical methods and instrumentation performance, to meet their quality goals and their accreditation requirements.

Commonly variation in the laboratory is monitored and measured as a technique to objectively and quantitatively assess performance of methods, instruments and laboratories.

For laboratories, measuring variation through the use of controls is part of the daily routine. Controls are a known value, so variation of an observed test result can be measured.

With multiple control results, information on the standard deviation of testing processes can be collected and the imprecision (coefficient of variation, % CV) can be calculated.

Information about the inaccuracy (bias) of an analytical testing process can readily be calculated by comparing results between the testing method and a reference method, or by analysing the results of the testing method in proficiency testing, peer group, or some other form of external quality assurance program.

Is Sigma Metric Analysis the solution?

Sigma Metric Analysis provides an excellent method for the measuring of variation and also provides the critical design information needed for optimal implementation.

The Sigma metric analysis process leads naturally to a quality control (QC) design scheme using quantitative tools to determine the necessary quality control procedures for routine monitoring of methods and instruments.

Laboratories implementing a Six Sigma program report significant cost savings while achieving better quality performance.

In this document we will share the practical implementation of such a Six Sigma scheme and demonstrate how it may be automated within the IAMQC Peer software.

What is Six Sigma and how does it apply to control materials?

Six Sigma is a well-known quality management approach that uses multiple tools to reduce errors and defects in any process. Six Sigma began in companies like General Electric and Motorola, but has spread to service sectors and even to healthcare institutions and the clinical laboratory.

The central focus of Six Sigma is to measure the number of defects-per-million opportunities (DPM, or DPMO) in any process. This DPM rate is then converted into a simple scale of 0 to 6, which is called the Sigma-metric of the process. Achieving Six Sigma on the short term scale means that only 3.4 defects are expected per million outcomes of the process.

To put it in laboratory terms, a Six Sigma test on that scale would only be expected to produce about 4 defective results per million tests run. At the quality level of Six Sigma, processes become highly efficient and effective, reducing the effort required to maintain them and maximizing the reliability and profitability of that process.

On the other hand, a three Sigma process is expected to produce more than 67,000 defects per million outcomes. Outside of healthcare, a process that is below three Sigma is often considered too costly and defect-prone to operate efficiently. In business and manufacturing, a process below three Sigma would be identified as a target for radical improvement, redesign or replacement.

For analytical processes, the Sigma-metric is calculated using data obtained from control materials. Imprecision from routine control performance and Bias (Trueness) can be obtained by comparing the control mean of the laboratory with the control mean of the peer group. Then a third variable is used, a quality requirement in the form of an allowable Total Error (TEa), which represents the goal for performance.

These three variables are arranged in the following equation to calculate the Sigma-metric:

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

[all parameters expressed as %]

More detailed discussion of the Sigma-metric equation can be found in the literature and reference manuals [1].

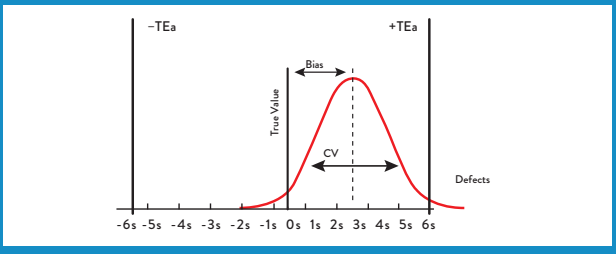
Total Error Allowable

In the clinical laboratory, the quality required by an analytical testing process must be defined. Tolerance limits in the laboratory are best expressed as a total allowable error (TEa) specification.

TEa is a well-accepted concept in healthcare laboratories as a model that combines both the imprecision and the inaccuracy (bias) of a method to calculate the total impact on a test result.

An allowable total error is the expression of how much combined imprecision and inaccuracy can be tolerated in the test result without negatively impacting patient care based on interpretation of that result.

The quantitative goal of Six Sigma is to create a process that minimizes variation until six standard deviations can fit within the tolerance limit (see below). At the level of Six Sigma performance (world class quality performance), approximately three defects will occur per million opportunities.



The relationship of imprecision (CV), inaccuracy (Bias) and allowable total error (TEa) in predicting defects

Using IAMQC® Peer to analyse your Sigma Metrics

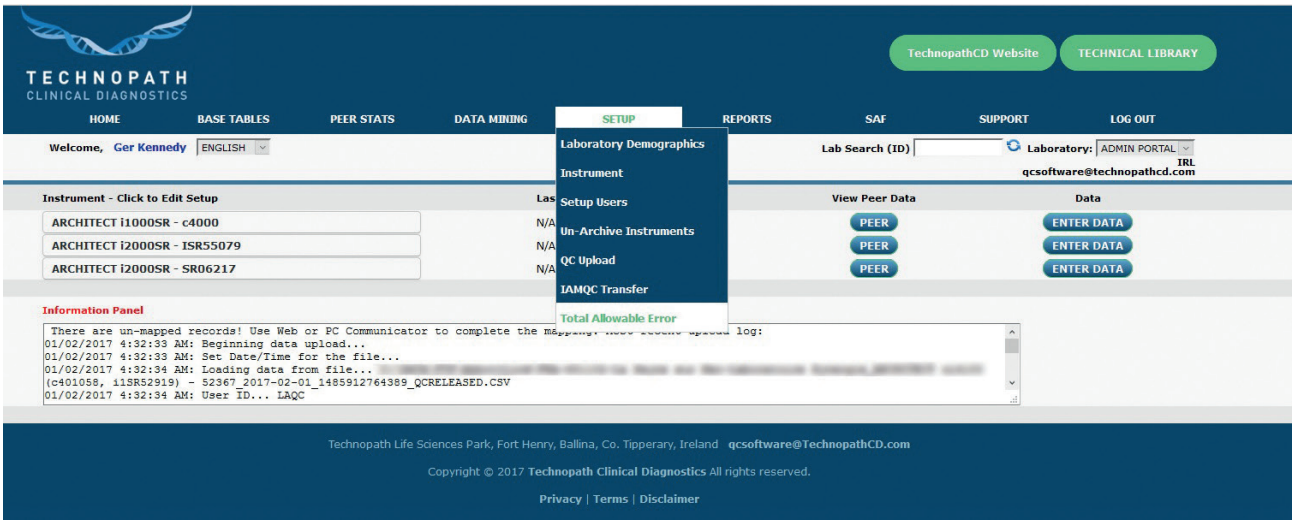
IAMQC® Peer now offers end-users the opportunity to automatically calculate and review their sigma metric performance. The system will automatically calculate imprecision and bias and once the end-user has defined their acceptability criteria (i.e. Total Allowable Error), the software will automatically calculate a sigma score for every assay that is tested in the laboratory (see example tables on page 12) using the following calculation:

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

[all parameters expressed as %]

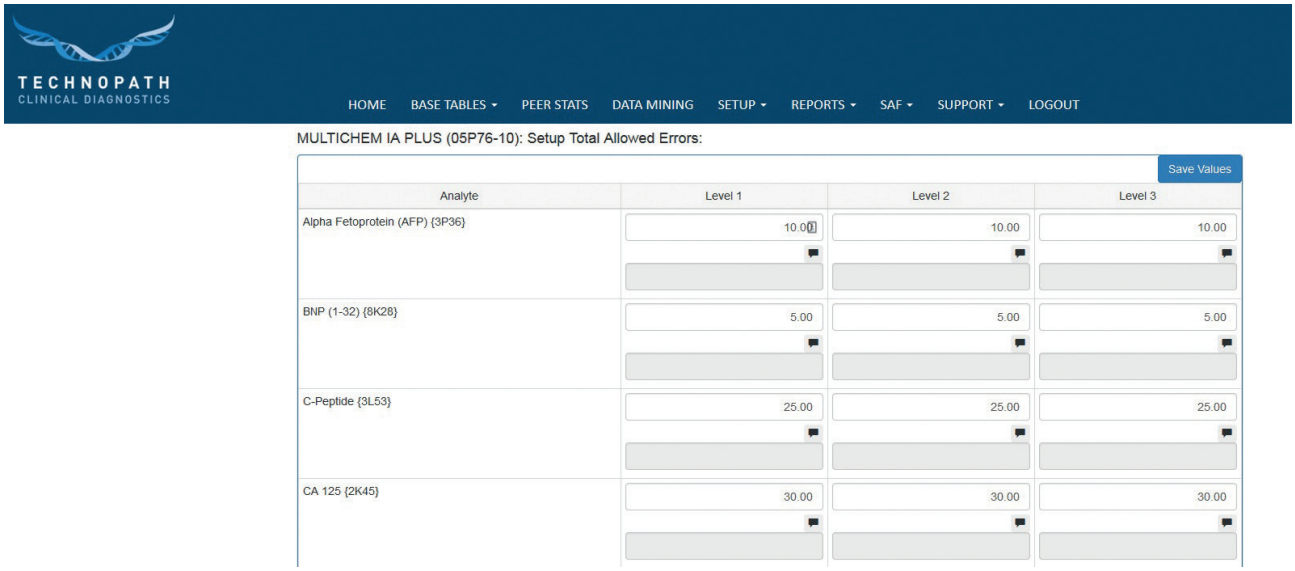
Step 1 - Select Total Allowable Error Tables:

Upon login the end-user selects SETUP>TOTAL ALLOWABLE ERROR:



Step 2 - Enter TEa values in the table:

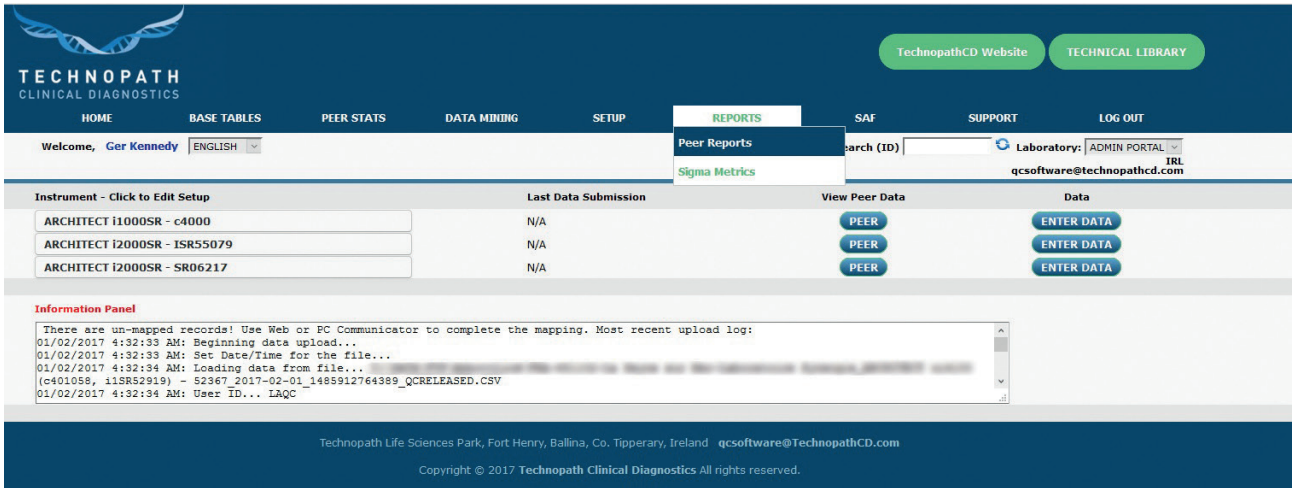
The system will display an entry table presenting the end-user with the opportunity to enter their Total Allowable Error (TEa) for each of the assays they test in their laboratory:



Click on each individual QC product to enter the TEa for the assays included in that product. The system facilitates a comment for each entry, if the end-user wants to cite the reference for the TEa that was entered (i.e. CLIA or Ricos Desirable or RiliBÄK etc.). Click SAVE VALUES to post entries to the database.

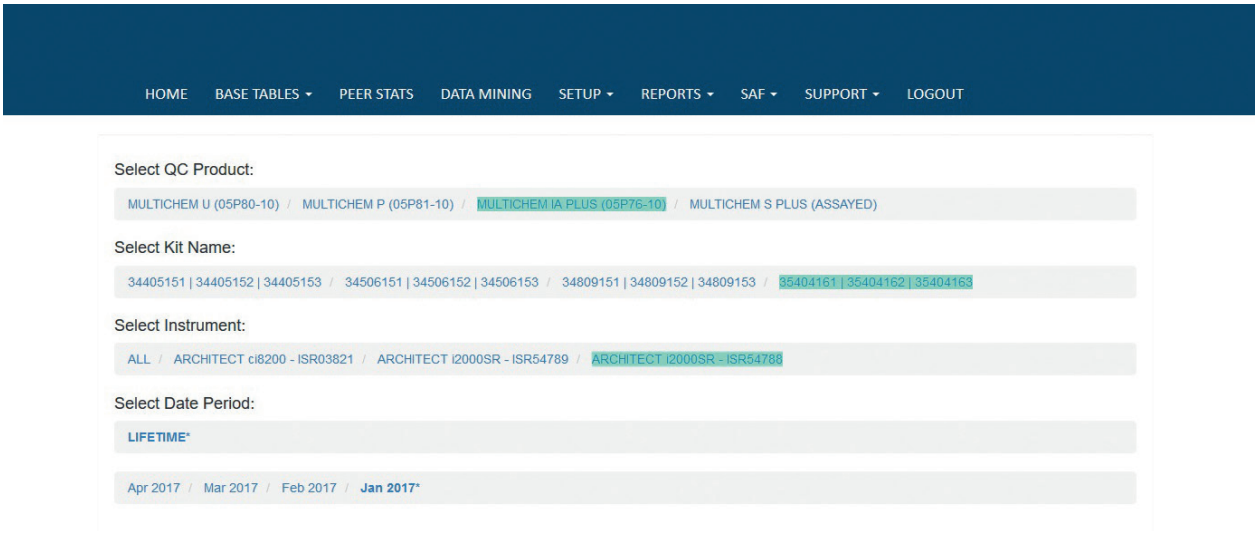
Step 3 - Select 'Sigma Metrics' from the IAMQC Reports Menu:

Once the TEa limits have been entered, the end-user can go to the sigma metric report section by clicking on REPORTS>SIGMA METRICS in the main menu:



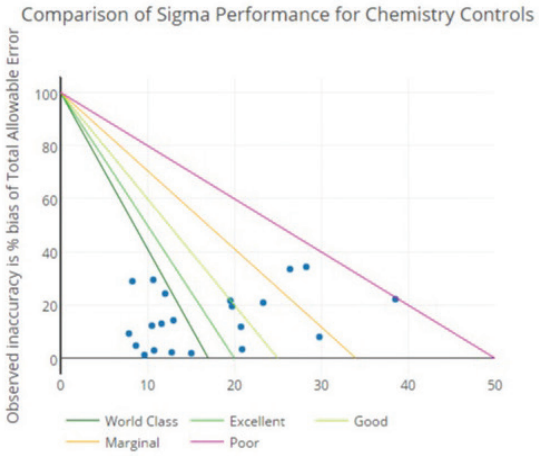
Step 4 - Select product, lot number and instrument of interest:

The system will display the Sigma Metric Report screen. Click on the product you would like to review, followed by the lot number of interest, then click on the instrument of interest or select ALL. Finally, click on the time period you wish to review:



Step 5 - Review Sigma Metrics summary report:

The system will automatically calculate and display the sigma metric report for the criteria selected:



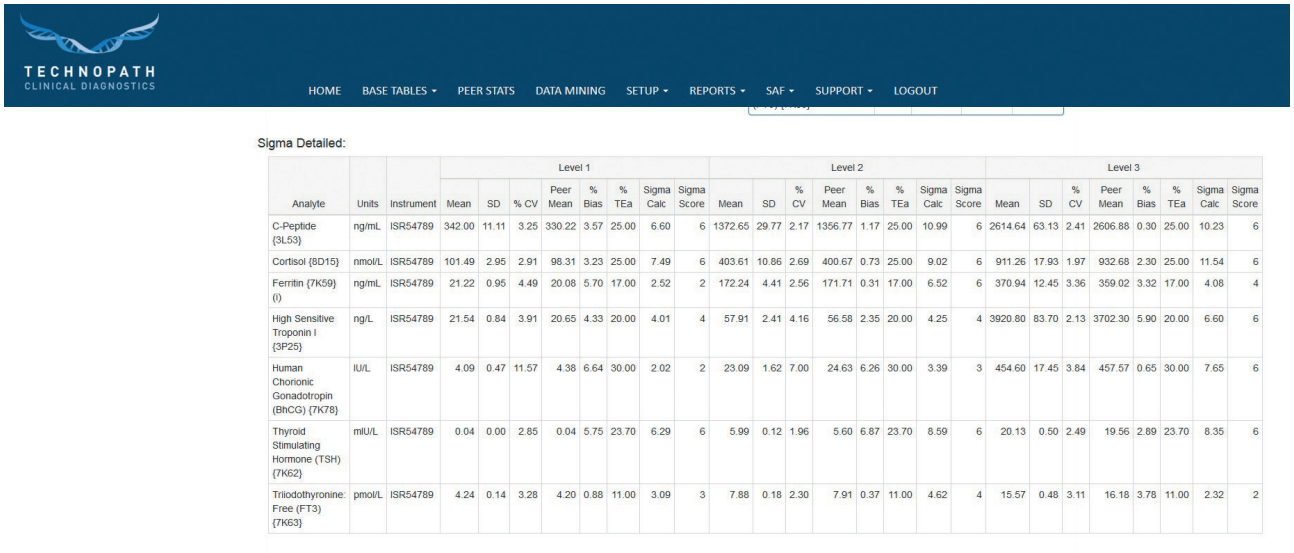
Sigma Metrics:

Sigma Summary:

Analyte	Units	TCD Level 1 Sigma Score	TCD Level 2 Sigma Score	TCD Level 3 Sigma Score
C-Peptide {3L53}	ng/mL	6	6	6
Cortisol {8D15}	nmol/L	6	6	6
Ferritin {7K59} (i)	ng/mL	2	6	4
High Sensitive Troponin I {3P25}	ng/L	4	4	6
Human Chorionic Gonadotropin (BhCG) {7K78}	IU/L	2	3	6
Thyroid Stimulating Hormone (TSH) {7K62}	mIU/L	6	6	6
Triiodothyronine: Free (FT3) {7K63}	pmol/L	3	4	2

This interactive report includes a normalised method decision chart (screen left) displaying all assays for the criteria selected previously, a Sigma Metric summary table (screen right) outlining the calculated sigma score for each assay and a detailed summary table displaying further information on the statistics used for the calculation (NOTE: the end-user must scroll down to review the detailed summary table – see the following screen shot). The end-user can click on an individual point on the normalised method decision chart to view the information associated with that point.

The end-user can scroll down to review the following detailed summary table:



Sigma Detailed:

Analyte	Units	Instrument	Level 1								Level 2							Level 3						
			Mean	SD	% CV	Peer Mean	% Bias	% TEa	Sigma Calc	Sigma Score	Mean	SD	% CV	Peer Mean	% Bias	% TEa	Sigma Calc	Sigma Score	Mean	SD	% CV	Peer Mean	% Bias	% TEa	Sigma Calc	Sigma Score
C-Peptide {3L53}	ng/mL	ISR54789	342.00	11.11	3.25	330.22	3.57	25.00	6.60	6	1372.65	29.77	2.17	1356.77	1.17	25.00	10.99	6	2614.64	63.13	2.41	2606.88	0.30	25.00	10.23	6
Cortisol {8D15}	nmol/L	ISR54789	101.49	2.95	2.91	98.31	3.23	25.00	7.49	6	403.61	10.86	2.69	400.67	0.73	25.00	9.02	6	911.26	17.93	1.97	932.68	2.30	25.00	11.54	6
Ferritin {7K59} (i)	ng/mL	ISR54789	21.22	0.95	4.49	20.08	5.70	17.00	2.52	2	172.24	4.41	2.56	171.71	0.31	17.00	6.52	6	370.94	12.45	3.36	359.02	3.32	17.00	4.08	4
High Sensitive Troponin I {3P25}	ng/L	ISR54789	21.54	0.84	3.91	20.65	4.33	20.00	4.01	4	57.91	2.41	4.16	56.58	2.35	20.00	4.25	4	3920.80	83.70	2.13	3702.30	5.90	20.00	6.60	6
Human Chorionic Gonadotropin (BhCG) {7K78}	IU/L	ISR54789	4.09	0.47	11.57	4.38	6.64	30.00	2.02	2	23.09	1.62	7.00	24.63	6.26	30.00	3.39	3	454.60	17.45	3.84	457.57	0.65	30.00	7.65	6
Thyroid Stimulating Hormone (TSH) {7K62}	mIU/L	ISR54789	0.04	0.00	2.85	0.04	5.75	23.70	6.29	6	5.99	0.12	1.96	5.60	6.87	23.70	8.59	6	20.13	0.50	2.49	19.56	2.89	23.70	8.35	6
Triiodothyronine: Free (FT3) {7K63}	pmol/L	ISR54789	4.24	0.14	3.28	4.20	0.88	11.00	3.09	3	7.88	0.18	2.30	7.91	0.37	11.00	4.62	4	15.57	0.48	3.11	16.18	3.78	11.00	2.32	2

This table includes details on the individual instrument statistics for each assay, each level, including; Mean, SD, CV, Peer Mean, % Bias from the peer mean, % TEa, Sigma Calculated score, Given sigma score based on the calculation.

Finally, the detailed Sigma Metrics report can be generated by clicking on the SIGMA DETAILED download button:

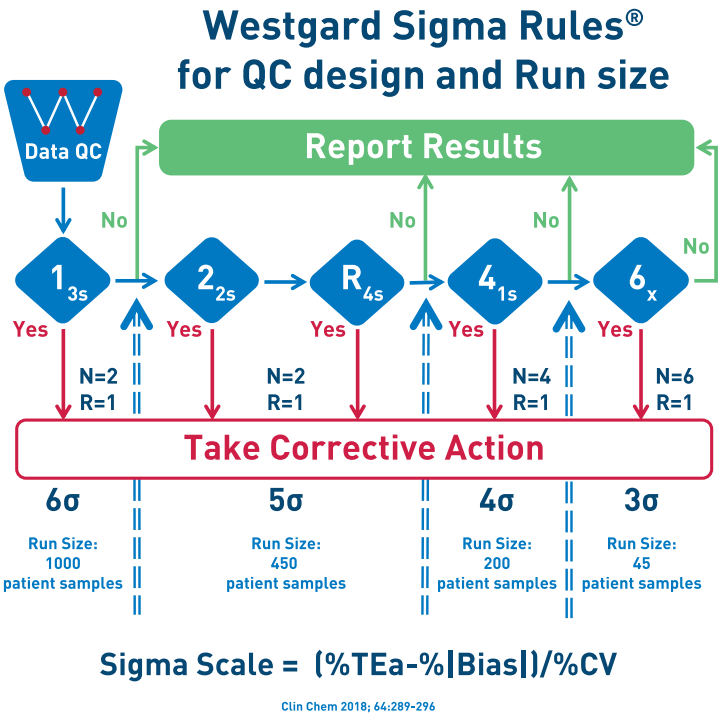
Reviewing Laboratory Quality Control frequency using Sigma Metrics.

In 2011 a collective opinion paper on findings of formal assembly of opinion leaders on laboratory quality policies and procedures was published in Clinical Chemistry Laboratory Medicine [(2)].

The outcome of the discussions were that once an assay was assigned a Sigma score, and based on this analysis and risk assessment, that a recommendation could be made to outline recommended intervals for QC based on risk analysis. Assays could now be divided into different performance categories with different QC requirements:

Six Sigma group performance indicators

- >6σ (World Class quality assays), evaluate with QC with 2 control measurements per run and 1_{3s} control procedure.
- 5σ (Excellent quality assays), evaluate QC with 2 control measurements per run and $1_{3s}/2_{2s}/R_{4s}$
- 4σ (Good quality assays), evaluate QC with 4 control measurements per run and $1_{3s}/2_{2s}/R_{4s}/4_{1s}$
- 3σ (Minimal/Marginal quality assays, barely acceptable), evaluate QC with 6 control measurements per run and all the "Westgard Rules", $1_{3s}/2_{2s}/R_{4s}/4_{1s}/6_x$
- Below 3σ, evaluate QC with as many control measurements as possible, using all "Westgard Rules" and adding additional non-statistical QC techniques, such as moving averages.



Key:

N = number of control measurements

R = Run

N = 2 R=1 means 2 control measurements taken during the run (typically, one measurement on two separate controls).

Note that if a laboratory's daily test volume is less than the recommended QC frequency in the "Westgard Sigma Rules", the laboratory will have to perform the QC more often than the math indicates. For example, with the CLIA mandate that labs run QC every 24 hours for most tests, that directive trumps the recommendations here. A laboratory with a 6σ method, but only a daily method volume of 200, but with CLIA mandates or even the manufacturer guidance that dictate daily QC, the lab will have to run QC every 200 samples, not every 1000.

Next Steps

The Sigma Metric report in IAMQC® Peer allows end-users to review an automatic calculation of their sigma performance at any given time. This feature enables end-users to address poor assay performance, adjust their QC protocol according to the sigma value (see next section for more details) and continue to monitor their sigma performance on a regular basis. End-users can work toward improvement of performance using sigma metric trending.

Technopath is happy to offer practical options to introduce more efficient and robust QC procedures into the laboratory. Consolidated multi-analyte quality control materials, such as the Multichem® range available from Technopath Clinical Diagnostics (Technopath), enable clinical laboratories to significantly reduce handling requirements, reclaim storage space and minimise waste, leading to a more efficient quality control process. Now in addition multi-rules called "Westgard Sigma Rules" are available to optimise the number of rules and control measurements to take into account the analytical Sigma-metric of the test method.

Whether you have questions about our products, services, or support, Technopath is here to help. Choose from the options below. A Technopath representative will contact you.

IAMQC Software support: qcsoftware@technopathcd.com

Sigma Verification Program services: info@technopathcd.com

References

1. JO Westgard, *Six Sigma Quality Design and Control*, 2nd Edition. Westgard QC, Madison WI 2006
2. Cooper, et al. Collective opinion paper on findings of the 2010 convocation of experts on laboratory Quality. Clinical Chemistry Laboratory Medicine. 2011; 49(5):793-802

Glossary of Terms

Accuracy / Inaccuracy: Accuracy is defined as the closeness of measurements to the true value. Usually expressed in the same units as the result, as the difference between the true value and the measured value, or as a percentage of the true value that the difference represents - expressed this way the quantity is more correctly termed 'inaccuracy'.

Bias: Bias is defined as the difference between the expectation of a test result and an accepted reference value. It is a systematic difference or systematic error between an observed value and some measure of the truth. Generally used to describe the inaccuracy of a method relative to a comparative method in a method comparison test.

CV (Coefficient of Variation): Coefficient of variation, CV is the SD expressed as a percentage of the Mean (the relative SD). CV monitors precision and is used to compare methods. V = (Standard Deviation/ Mean)%.

Mean: Mean is the calculated average of all test values taken for a particular test over time. In practice this will be based on the same instrument, test method, and QC lot.

Precision / Imprecision: Precision is defined as the amount of variation in the measurements. Imprecision according to the CLSI is "The random dispersion of a set of replicate measurements and/or values expressed quantitatively by a statistic, such as standard deviation or coefficient of variation." IFCC has recommended that the mean value and number of replicates should also be stated, and the experimental design described in such a way that other workers can repeat it. This is particularly important whenever a specific term is used to denote a particular type of imprecision, such as within-run, within-day, day-to-day, total, or between-laboratories.

Standard Deviation: Standard Deviation is a well-established statistical formula to express variation. All test values will be symmetrically distributed around the mean in a characteristic bell-shaped curve.

Please note the following TEa values are provided as examples only and are subject continually to change. Please refer to your laboratory quality procedures for the assignment of TEa values.

Multichem **IA Plus** - Analytes, Value Assigned

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Alpha Fetoprotein (AFP)	21.9	Ricos 2014	20	5 kIU/L or 20%	range	range	15.00	21.90	34.8
Human Chorionic Gonadotropin (BhCG)	18% or positive/ negative	CLIA 2019 prop				range	18% or positive/ negative		
BNP (1-32)				20 ng/L or 20%	3 SD or 10%				
CA 125	35.4	Ricos 2014		6 kU/L or 12%			20	35.4	16.1
CA 15-3	20.8	Ricos 2014		6 kU/L or 12%				20.8	
CA 19-9	46.03	Ricos 2014		6 kU/L or 15%				46.03	37.9
Carbamazepine	25	CLIA and CAP		0.5 mg/L or 10%	25	25	20		
Carcinogenic Embryonic Antigen (CEA)	24.7	Ricos 2014	16	0.6 ug/L or 12%			15	24.7	26.9
CK-MB (STAT)	25	CLIA		3 U/L or 20%	range	25	25	16.5	
Cortisol	22.8	Ricos 2014	28	15 nmol/L or 15%	25	25	20	22.8	
C-Peptide	20.8	Ricos 2014		0.15 nmol/L or 12%	3 SD or 0.2 ng/mL			20.8	
DHEA-Sulfate	10.4	Ricos 2014		1.2 umol/L or 12%	range			10.4	
Digoxin	20	CLIA and CAP	20	0.2 ug/L or 10%	0.2 ng/mL or 20%	0.2 ng/mL or 20%	20		
Estradiol	26.86	Ricos 2014	26	25 pmol/L or 25%	range		30	26.86	17.3
Ferritin	16.9	Ricos 2014	21	4.0 ug/L or 15%	range		20	16.9	13.8
Folate	39	Ricos 2014		1.5 nmol/L or 25%	range		1 ng/mL or 30%	39	
Prostate Specific Antigen, Free	33.6	Ricos 2014		0.2 ug/L or 15%	3 SD or 0.2 ng/mL		0.2 ng/dL or 20%	33.6	17.5
Follicle Stimulating Hormone (FSH)	21.19	Ricos 2014	14	1.0 IU/L or 10%			2 IU/L or 18%	21.19	21.2
Triiodothyronine, Free (FT3)	11.3	Ricos 2014		0.7 pmol/L or 20%	range	range	30% not free	11.3	9.3
Thyroxine, Free (FT4)	8.74	Ricos 2014		1.5 pmol/L or 12%	range		0.3 ng/dL or 15%	8.74	9.6
Gentamicin	25	CLIA and CAP		0.2 mg/L or 10%	25	25	25		
Homocysteine	15.4	Ricos 2014		1.5 umol/L or 10%				15.48	
Immunoglobulin E	20	CLIA 2019 prop			range	range	20		
Insulin	32.9	Ricos 2014		0.6 mU/L or 12%	3 SD or 0.2 uIU/mL			32.9	35.9
Luteinizing Hormone	27.92	Ricos 2014		1.5 IU/L or 15%			20	27.92	28.4
Myoglobin (STAT)	19.6	Ricos 2014			3 SD or 30%			19.6	
Parathyroid Hormone (PTH) (1-84)	30.2	Ricos 2014		1.0 pmol/L or 12%	range		30	30.2	20
Parathyroid Hormone (PTH) (1-84) (STAT)	30	CLIA 2019 prop			range		30		
Phenobarbital	20	CLIA and CAP	15	0.7 mg/L or 10%	20	20	15		

Reference: https://www.westgard.com/consolidated-goals-immunoassay.htm

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Multichem **IA Plus** - Analytes, Value Assigned

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Phenytoin	25	CLIA and CAP	13	0.8 mg/L or 10%	25	25	2 mcg/dL or 15%		
Progesterone	25	CLIA and CAP	26	2 nmol/L or 15%	25	25			
Prolactin	20	CLIA and CAP	22	40 mIU/L or 10%	20	20		29.4	37.4
Prostate Specific Antigen, Total	33.6	Ricos 2014	17	0.4 ug/L or 8%	3 SD or 0.2 ng/mL		0.2 ng/dL or 20%	33.6	16.2
Sex Hormone Binding Globulin	20.42	Ricos 2014		6 nmol/L or 12%				20.42	17.2
T-Uptake	18	CLIA 2019 prop			3 SD or 0.2 nmol/L	range	18		
Testosterone	23	Spanish min	23	0.4 nmol/L or 15%			20 ng/dL or 30%	13.61	16.5
Theophylline	25	CLIA and CAP		0.5 mg/L or 10%	25	25	20		
Troponin I	27.91	Ricos 2014		20%	3 SD or 30%		0.2 ng/mL or 30%	27.91	
High Sensitive Troponin I					3 SD or 30%				
High Sensitivity Troponin I					3 SD or 30%				
Thyroid Stimulating Hormone (TSH)	23.7	EFLM 2021	15	0.1 mU/L or 20%	range	range	2 mIU/L or 20%	23.7	27.7
Triiodothyronine, Total (TT3)	11.6	EFLM 2021		0.2 nmol/L or 15%	range	range		9.22	11.6
Thyroxine, Total (TT4)	24	Spanish min	24	12 nmol/L or 10%	1.0 mcg/dL or 20%	1.0 mcg/dL or 20%	1.0 mcg/dL or 20%	7	8.7
Valproic Acid	25	CLIA and CAP		4.0 mg/L or 10%	25	25	29		
Vancomycin	2.0 mcg/dL or 20%	CLIA 2019 prop		0.2 mg/L or 10%	10% or 3 SD		2.0 mcg/dL or 20%		
Vitamin B12	30	Ricos 2014		18 pmol/L or 15%	range	30	25	30	
25-OH Vitamin D	20.5	EFLM 2021			5 ng/mL or 25%				20.5

Please note the following TEa values are provided as examples only and are subject continually to change. Please refer to your laboratory quality procedures for the assignment of TEa values.

Multichem **IA Plus** - Analytes, No Value Claimed

ANALYTES (No Value Claimed)1	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
17-Hydroxyprogesterone	29.7	Ricos 2014		2 nmol/L or 20%	range			29.7	35.3
Acetaminophen	15	CLIA 2019 prop		3.0 mg/L or 10%			15		
Adrenocorticotrophic Hormone (ACTH)				2.0 pmol/L or 10%					
Aldosterone	36.7	Ricos 2014		75.0 pmol/L or 15%	range			36.7	42.8
Amikacin				2.0 mg/L or 10%					

Reference: https://www.westgard.com/consolidated-goals-immunoassay.htm

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Multichem **IA Plus** - Analytes, No Value Claimed

ANALYTES (No Value Claimed)1	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Androstenedione	23.51	Ricos 2014		1.5 nmol/L or 15%				23.51	
Caffeine					range				
Calcitonin				2 ng/L or 10%					
Carbamazepine, Free	20	CLIA 2019 prop		2.0 umol/L or 10%		25	20		
Cyclosporine				10 ug/L or 10%					
Disopyramide				2.0 umol/L or 10%					
Ethosuximide	20	CLIA				20			
Estriol, Free				0.9 nmol/L or 15%	range				
Human Growth Hormone				1.0 mU/L or 15%					
Insulin Like Growth Factor (IgF-1)	24	Ricos 2014		3 nmol/L or 12%	range			24	14.9
Lithium	0.3 mmol/L or 20%	CLIA and CAP	18	0.20 mmol/L or 10%	0.3 mmol/L or 20%	0.3 mmol/L or 20%	15		
NT Pro-BNP	13	Ricos 2014		25 ng/L or 20%				13	
Phenytoin, Free	25	CLIA	13	0.8 mg/L or 10%	10% or 3 SD	25	mixed		
Primidone	25	CLIA and CAP			25	25			
Procainamide	25	CLIA and CAP			25	25			
Quinidine	25	CLIA and CAP			25	25			
Renin									37.7
Salicylate	15	CLIA 2019 prop		15 mg/L or 10%	10% or 3 SD		15		
Testosterone, Free	20 ng/dL or 20%	CLIA 2019 prop		0.4 nmol/L or 15%			20 ng/dL or 20%		27.3
Thyroglobulin	29.8	EFLM 2021		0.2 ug/L or 12%					29.8
Thyroxine Binding Globulin	0.1	Ricos 2014						0.1	
Tobramycin	25	CLIA and CAP		0.2 mg/L or 10%	25	25	20		
Troponin T	48.9	Ricos 2014		0.01 ug/L or 20%	3 SD or 30%		0.2 ng/mL or 30%	48.9	
Ultra Sensitive CRP	10% or 3 SD	CLIA 2019 prop					1 mg/dL or 30% (hs)		
Valproic Acid, Free	20	CLIA 2019 prop		4.0 mg/L or 10%	10% or 3 SD		20		

Reference: https://www.westgard.com/consolidated-goals-immunoassay.htm

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Multichem **S Plus** - Analytes, Value Assigned

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Alpha-1 Acidglycoprotein								16.2	
Alpha-1 Antitrypsin	9.2	ricos 2014			range	range		9.2	6.2
Acetaminophen	10	CAP			3 SD range or 10%				
Acid Phosphatase	10.3	ricos 2014			range			10.3	
Activated Alanine Aminotransferase (AALT)					SAME AS ALT				
Activated Aspartate Aminotransferase (AAST)					SAME AS AST				
Albumin BCG	10	CAP & CLIA	14	2.0 g/L or 6%	10	10	10	4.07	3.4
Albumin BCP	10	CAP & CLIA	14	2.0 g/L or 6%	10	10	10	4.07	3,4
Alkaline Phosphatase (ALkP)	14.5	EFLM 2021	31	15 U/L or 12%	30	30	10	12.04	14.5
Alanine Aminotransferase (ALT)	16.1	EFLM 2021	23	5 U/L or 12%	20	20	15	27.48	16.1
Amikacin				2.0 mg or 10%	3 SD range or 10%				
Amylase	14.6	ricos 2014	35	10 U/L or 15%	30	30	10	14.6	13.2
Amylase Pancreatic					30			17.7	12.2
Apolipoprotein A1	9.1	ricos 2014		0.2 g/L or 10%	range			9.1	7.6
Apolipoprotein B	11.6	ricos 2014		0.2 g/L or 10%	range			11.6	11.5
Aspartate Aminotransferase (AST)	16.69	ricos 2014	21	5 U/L or 12%	20	20	15	16.69	13.6
Beta -2 Microglobulin	9	ricos 2014		0.2 mg/L or 10%				9	6.4
Bile Acids				4 umol/L or 10%					
Bilirubin, Direct	44.5	ricos 2014		3 umol/L or 20%	0.4 mg/dL or 20%			44.5	
Bilirubin, Total	0.4 mg/dL or 20%	CLIA and CAP	24	3 umol/L or 12%	0.4 mg/dL or 20%	0.4 mg/dL or 20%	0.4 mg/dL or 20%	26.94	
Calcium	unit 1.0 mg/dL	CLIA and CAP	11	0.10 mmol/L or 4%	1.0 mg/dL	1.0 mg/dL	1.0 mg/dL	2.55	2.3
Carbamazepine	25	CLIA		0.5 mg/L or 10%	25	25	20		
Carbon Dioxide (Bicarbonate)	5 mm Hg or 8%	CLIA and CAP		2.0 mmol/L or 10%	5 mm Hg or 8%	5 mm Hg or 8%	20	4.86	4.9
Ceruloplasmin	8	EFLM 2021						7.9	8
Chloride	5	CLIA and CAP	9	3.0 mmol/L or 3%	5	5	5	1.5	1.3
Cholesterol HDL	20	CLIA 2019 prop	33	0.10 mmol/L or 12%	30	30	20	11.63	11.1
Cholesterol LDL	20	CLIA 2019 prop		0.20 mmol/L or 10%	30		20	11.9	13.7
Cholesterol Total	10	CLIA and CAP	11	0.30 mmol/L or 6%	10	10	10	9.01	8.7

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Multichem **S Plus** - Analytes, Value Assigned

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Cholinesterase	9.8	ricos 2014		500 U/L or 10%				9.8	
Creatine Kinase (CK)	20	CLIA 2019 prop	24	15 U/L or 12%	30	30	20	30.3	22.6
Complement C3	15	CLIA 2019 prop				range	15	8.4	7.8
Complement C4	16	ricos 2014				range	5 mg/dL or 30%	16	12.1
Cortisol	22.8	ricos 2014		15 nmol/L or 15%	25	25	20	22.8	32.5
Creatinine Enzymatic	0.3 mg/dL or 15%	CLIA and CAP	20	8.0 umol/L or 8%	0.3 mg/dL or 15%	0.3 mg/dL or 15%	0.3 mg/dL or 15%	8.87	7.4
Creatinine Picrate	0.3 mg/dL or 15%	CLIA and CAP	20	8.0 umol/L or 8%	0.3 mg/dL or 15%	0.3 mg/dL or 15%	0.3 mg/dL or 15%	8.87	7.4
C-Reactive Protein	50.7	EFLM 2021		0.8 mg/L or 20%			1 mg/dL or 30% (hs)	56.6	50.7
Digoxin			20	0.2 ug/L or 10%	0.2 ng/mL or 20%	0.2 ng/mL or 20%	0.2 ng/mL or 20%		
Gamma Glutamyl Transferase	22.11	ricos 2014	22	5 U/L or 12%	range		15	22.11	18.9
Gentamicin	25	CLIA and CAP		0.2 mg/L or 10%	25	25	25		
Glucose	mixed	CLIA and CAP	11	0.4 mmol/L or 8%	6 mg/dL or 10%	6 mg/dL or 10%	8	6.96	6.5
Haptoglobin	27.3	ricos 2014						27.3	17.1
Immunoglobulin A	15	CLIA 2019 prop	21			range	15	13.5	9.8
Immunoglobulin G	20	CLIA 2019 prop	16	0.02 g/L or 20%		range	20	8	7.3
Immunoglobulin M	20	CLIA 2019 prop	28			range	20	16.8	17.1
Iron	15	CLIA 2019 prop	24	3.0 umol/L or 12%	20	20	15	30.7	
Unsaturated Iron Binding Capacity (UIBC)					range				
Lactate	30.4	ricos 2014		0.5 mmol/L or 12%	0.4 mmol/L or 3 SD			30.4	
Lactate Dehydrogenase (LDH)	15	CLIA 2019 prop	26	20 U/L or 8%	20	20	15	11.4	7.7
Lipase	37.88	ricos 2014		12 U/L or 20%	30			37.88	14.2
Lithium	15	CLIA 2019 prop	18	0.2 mmol/L or 10%	0.3 mmol/L or 20%	0.3 mmol/L or 20%	15		
Magnesium	25	CLIA and CAP		0.1 mmol/L or 8%	25	25	15	4.8	4
Phenobarbital	20	CLIA and CAP	15	0.7 mg/L or 10%	20	20	15		
Phenytoin	25	CLIA and CAP	13	0.8 mg/L or 10%	25	25	2 mcg/dL or 15%		
Phosphorous	10.11	ricos 2014	17	0.06 mmol/L or 8%	0.3 mg/dL or 10.7%		0.3 mg/dL or 10%	10.11	9.7
Potassium	unit 0.3 mmol/L	CLIA 2019 prop	8	0.2 mmol/L or 5%	0.5 mmol/L	0.5 mmol/L	0.3 mmol/L	5.61	4.8
Prealbumin	14.5	ricos 2014			5.0 ng/mL or 25%			14.5	

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Multichem **S Plus** - Analytes, Value Assigned

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Protein, Total	10	CLIA and CAP	12	3 g/L or 5%	10	10	8	3.63	3.5
Rheumatoid Factor	13.5	ricos 2014			range	range	range	13.5	
Salicylate				14 mg/L or 10%	10% or 3 SD		15		
Sodium	4 mmol/L	CLIA and CAP	5	3 mmol/L or 2%	4 mmol/L	4 mmol/L	4 mmol/L	0.73	0.7
Theophylline	25	CLIA and CAP		0.5 mg/L or 10%	25	25	20		
Thyroxine, Total (TT4)	1.0 mcg.dL or 20%	CLIA and CAP	24	12 nmol/L or 10%	1.0 mcg.dL or 20%	1.0 mcg.dL or 20%	1.0 mcg.dL or 20%	7	8.7
Tobramycin	25	CLIA and CAP		0.2 mg/L or 10%	25	25	20		
Transferrin	20	CAP		0.2 g/L or 8%	20			3.8	6.8
Triglycerides	25	CLIA and CAP	18	0.2 mmol/L or 12%	25	25	15	25.99	27
Urea Nitrogen	2 mg/dL or 9%	CLIA and CAP	19	0.5 mmol/L or 12%	2 mg/dL or 9%	2 mg/dL or 9%	2 mg/dL or 9%	15.55	17.8
Uric Acid	17	CLIA and CAP	17	0.03 mmol/L or 8%	17	17	10	11.97	10.6
Valproic Acid	25	CLIA and CAP		4.0 mg/L or 10%	25	25	20		
Vancomycin	2 mcg/dL or 15%	CLIA 2019 prop		2.0 mg/L or 10%	10% or 3 SD		2 mcg/dL or 15%		

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Multichem **S Plus** - Analytes, No Value Claimed

ANALYTES (No Value Claimed)	Recommended Default	Source Of Recommendation	Spanish Minimum	RCPA	CAP 2021	CLIA 1992	CLIA 2019	RICOS 2014	EFLM 2021
Alpha-2-Macroglobulin	7.56	ricos 2014						7.56	
Anti-streptolysin O (ASO)						range	range		
Antithrombin III	8,3	ricos 2014						8.3	
Caffeine					10% or 3 SD				
Calcium Ionized	2	Ricos 2014		0.04 mmol/L or 4%	range			2	
Cystatin C	6.5	ricos 2014						6.5	6.5
Copper	7.47	ricos 2014		1.6 umol/L or 8%				7.47	
Fructosamine	3.6	ricos 2014		15 umol/L or 6%				3.6	3.6
Ferritin	16.9	ricos 2014	21	4 ug/L or 15%	range			16.9	
Kappa Light Chain	8	ricos 2014						8	8
Lambda Light Chain	8.6	ricos 2014						8.6	8.4
Lipoprotein (a)	24.1	ricos 2014		0.06 g/L or 20%	range			24.1	39.9
Osmolality	1.5	ricos 2014		8 mmol/kg or 3%				1.5	
Properdin Factor B	11.5	ricos 2014						11.5	
Prostatic Acid Phosphatase					range				
Retinol Binding Protein	17.1	ricos 2014						17.1	
sTfR (Soluble Transferrin Receptor)	10.2	EFLM 2021							10.2
Triiodothyronine, Total (TT3)	30	CLIA 2019 prop		0.2 nmol/L or 15%	range	range	30	12.94	11.6
Total Iron Binding Capacity				4.0 umol/L or 8%					
Zinc	11	ricos 2014		2.0 umol/L or 10%				11	

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