LGC CLINICAL DIAGNOSTICS

Guide to Six Sigma

Automated Reports in IAMQC® Peer

TECHNOPATH
CLINICAL DIAGNOSTICS

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:

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

[all parameters expressed as %]

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

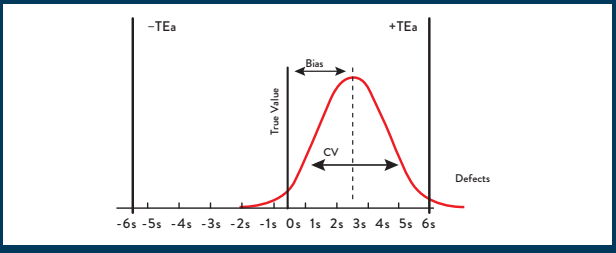
Total Error Allowable

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

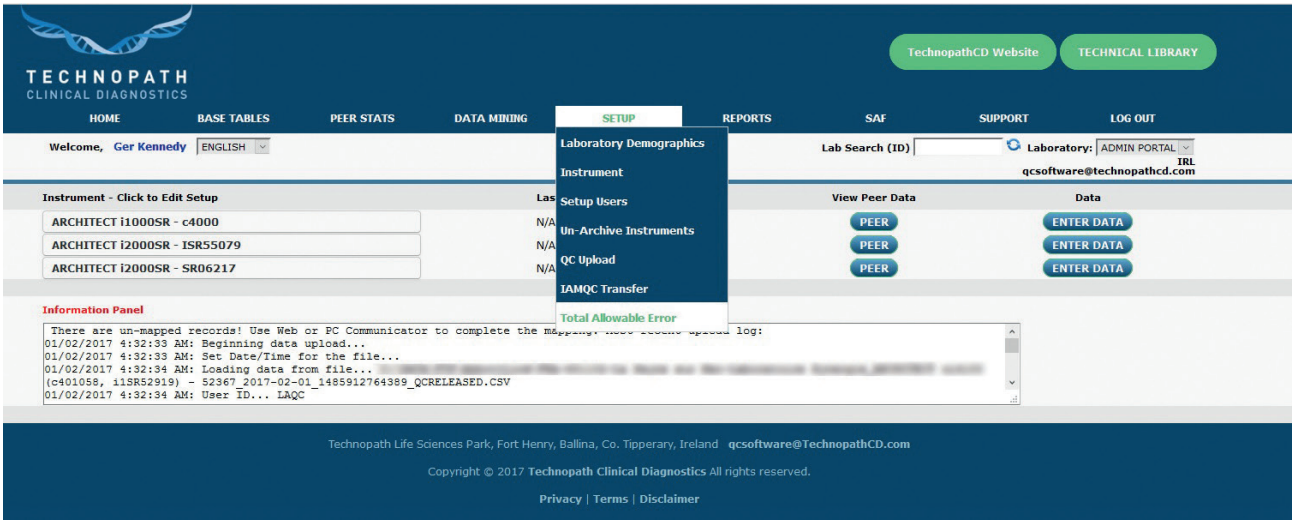
IAMQC® Peer now offers end-users the opportunity to automatically calculate and review their Sigma Metric performance. The system will automatically calculate imprecision and bias and once the end-user has defined their acceptability criteria (i.e. Total Allowable Error), the software will automatically 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 %]

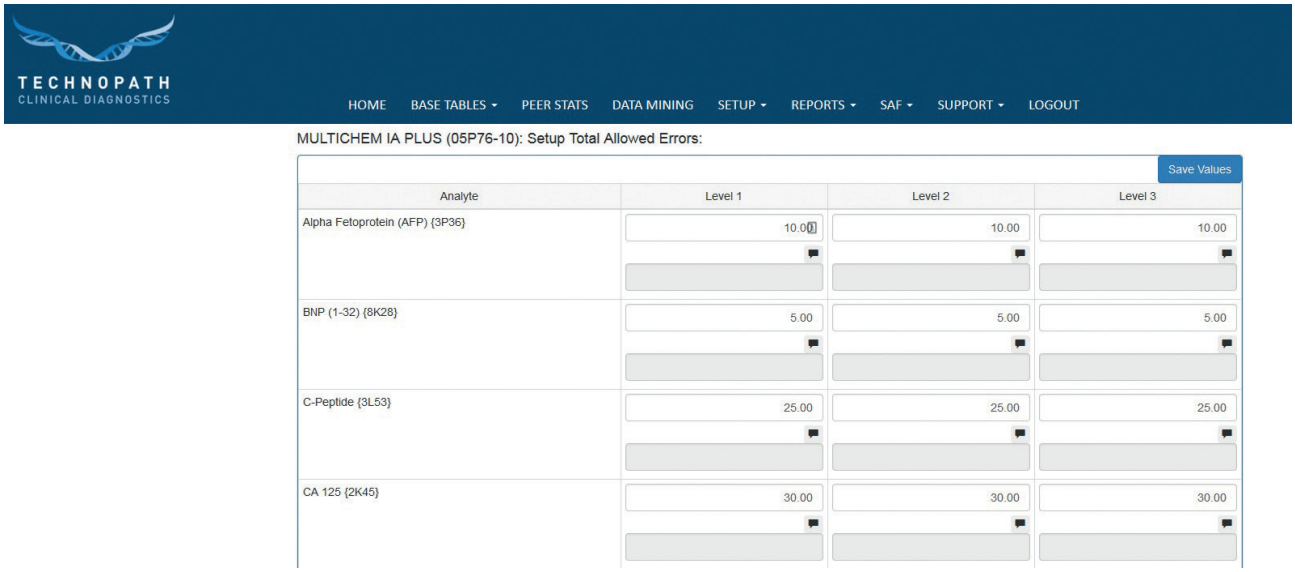
Step 1 - Select Total Allowable Error Tables:

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



Step 2 - Enter TEa values in the table:

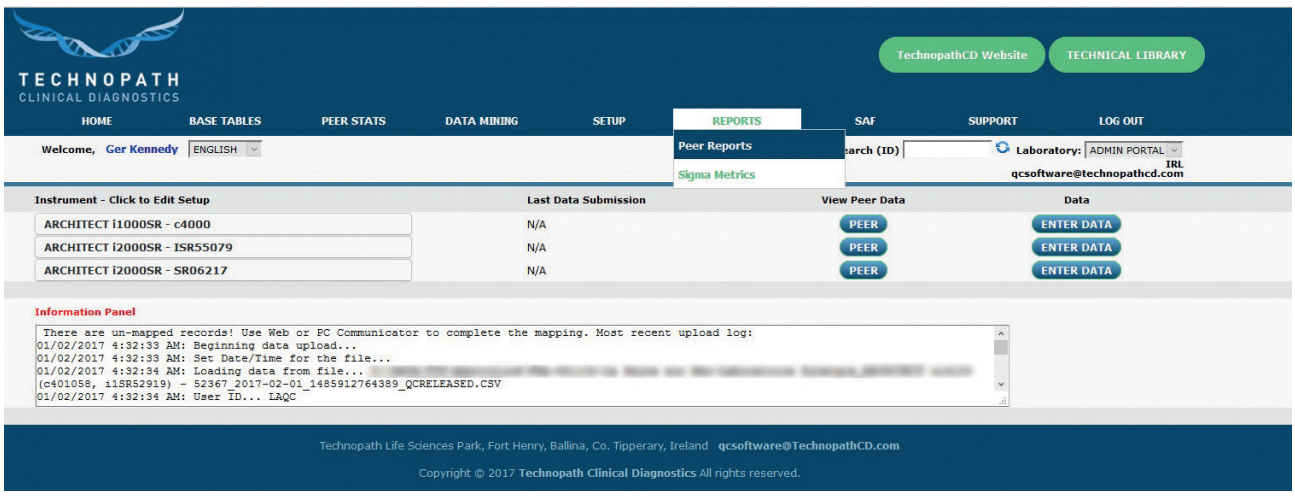
The system will display an entry table presenting the end-user with the opportunity to enter their Total Allowable Error (TEa) for each of the assays they test in their laboratory:



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.

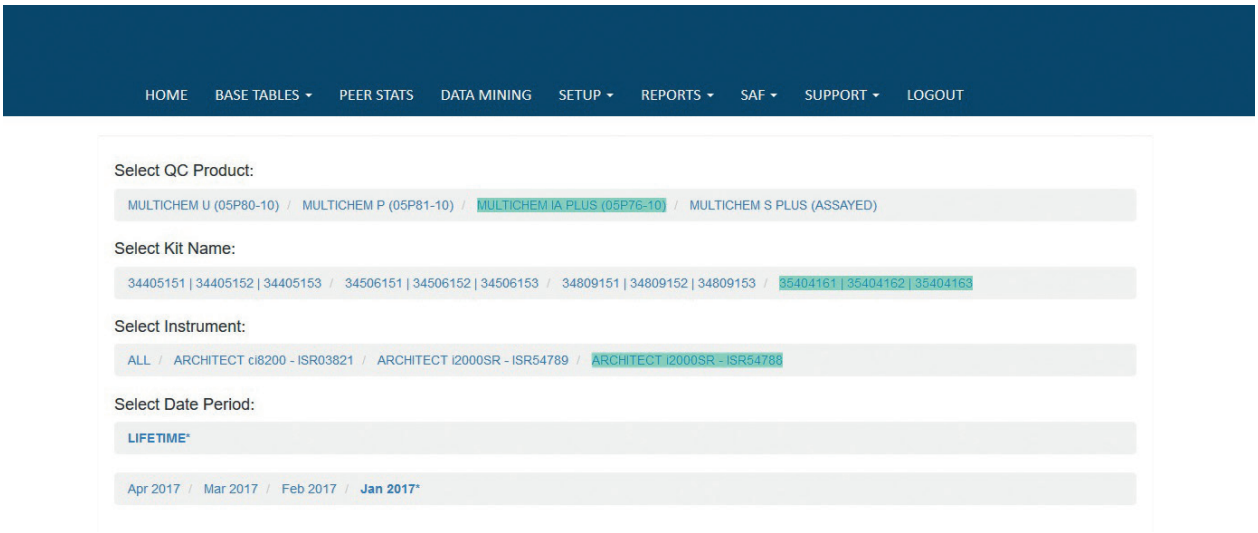
Step 3 - Select 'Sigma Metrics' from the IAMQC Reports Menu:

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:



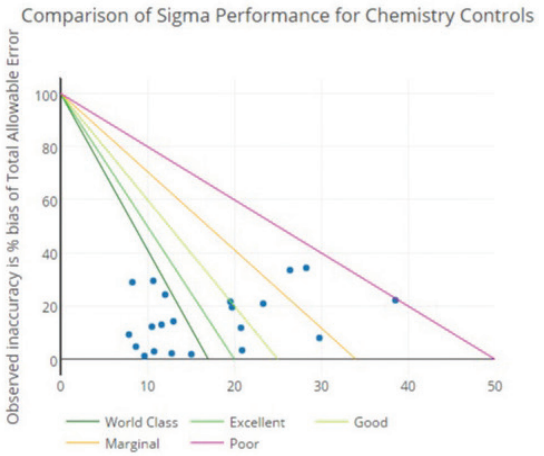
Step 4 - Select product, lot number and instrument of interest:

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:



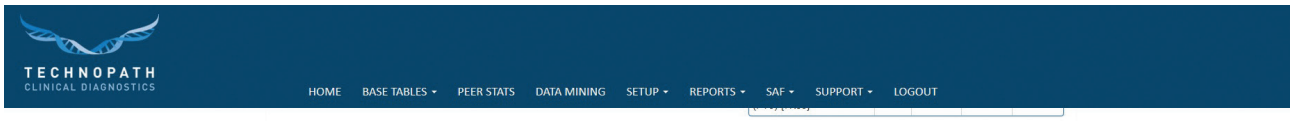
Sigma Metrics:

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:

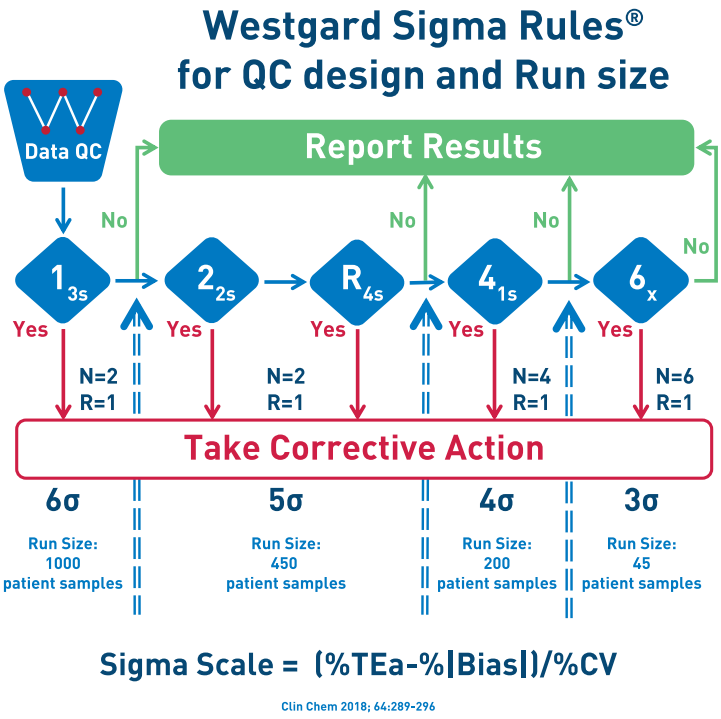
Reviewing Laboratory Quality Control frequency using Sigma Metrics.

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: technopath.iamqcsupport@lgcgroup.com

Sigma Verification Program services: technopath.info@lgcgroup.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.

Source Links

- **CLIA 2024: https://www.westgard.com/2024-clia-requirements.htm. https://www.federalregister.gov/documents/2022/11/17/2022-24990/clinical-laboratory-improvement-amendments-clia-proficiency-testing-related-to-analytes-and**
- CLIA 1992: **https://www.westgard.com/clia.htm** Federal Register February 28, 1992;57(40):7002-186
- CLIA 2019: **https://www.westgard.com/2019-clia-requirements.htm https://www.federalregister.gov/documents/2019/02/04/2018-28363/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to**
- Ricos 2014: **https://www.westgard.com/biodatabase1.htm** Ricos C, Alvarez V, Cava F, Garcia-Lario JV, Hernandez A, Jimenez CV, Minchinela J, Perich C, Simon M. "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500. Last updated in 2014.
- EFLM: **https://biologicalvariation.eu/meta_calculations**

For the most up-to-date compilation of performance requirements, visit:

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

MAU goals and other measurement uncertainty performance specifications:

- https://www.westgard.com/consolidated-uncertainty.htm

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	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	Ricos 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Alpha Fetoprotein (AFP)	20	CLIA 2024	20.0	range	20.0	21.9	17.6	26.5	6.9
Anti-Thyroglobulin	-	-	-	-	-	-	-	-	-
Anti-Thyroperoxidase	-	-	-	-	-	-	-	-	-
Human Chorionic Gonadotropin (BHCG)	3 mIU/mL or 18%	CLIA 2024	-	range	3 mIU/mL or 18%	-	-	-	-
BNP (1-32)	-	-	-	-	-	-	-	-	-
CA 125	20	CLIA 2024	-	-	20.0	35.4	13.9	20.9	13.0
CA 15-3	20.8	Ricos 2014	-	-	-	20.8			
CA 19-9	26.9	EFLM 2023 min	-	-	-	46.0	17.9	26.9	6.4
Carbamazepine	1.0 mcg/dL or 20%	CLIA 2024		25	10 mcg/dL or 20%				
Carcinogenic Embryonic Antigen (CEA)	1 ng/dL or 15%	CLIA 2024	16.0	-	1 ng/dL or 15%	24.7	20.5	30.8	10.2
Ck-Mb (STAT)	3 ng/mL or 25%	CLIA 2024	-	25	3 ng/mL or 25%	16.5	-	-	-
Cortisol	20.0	CLIA 2024	28.0	25	20.0	22.8	26.3	39.4	24.5
C-Peptide	20.8	Ricos 2014	-	-	-	20.8	-	-	-

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	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	Ricos 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
DHEA-Sulfate	15.6	EFLM 2023 min	-	-	-	10.4	10.4	15.6	9.0
Digoxin	0.2 ng/mL or 15%	CLIA 2024	20.0	-	0.2 ng/mL or 15%	-	-	-	-
Estradiol	30.0	CLIA 2024	26.0	-	30.0	26.9	17.3	26.0	22.5
Ferritin	20.0	CLIA 2024	21.0	-	20.0	16.9	13.8	20.6	19.2
Folate	1 ng/mL or 30%	CLIA 2024	-	-	1 ng/mL or 30%	39.0	-	-	-
Prostate Specific Antigen, Free	0.2 ng/dL or 20%	CLIA 2024	-	-	0.2 ng/dL or 20%	33.6	17.5	26.3	10.6
Follicle Stimulating Hormone (FSH)	2 IU/L or 18%	CLIA 2024	14.0	-	2 IU/L or 18%	21.2	21.2	31.8	18.6
Triiodothyronine, Free (FT3)	9.8	EFLM 2023 min	-	range	-	11.3	6.5	9.8	7.5
Thyroxine, Free (FT4)	0.3 ng/dL or 15%	CLIA 2024	16.0	-	0.3 ng/dL or 15%	8.8	6.3	9.5	7.4
Gentamicin	25.0	CLIA 2024	-	25.0	25.0	-	-	-	-
Homocysteine	15.4	Ricos 2014	-	-	-	15.4	-	-	-
IgE	20.0	CLIA 2024	-	range	20.0	-	-	-	-
Insulin	47.2	EFLM 2023 min	-	-	-	32.9	31.5	47.2	38.1
Luteinizing Hormone	20.0	CLIA 2024	-	-	20.0	27.9	28.4	42.6	34.2
Myoglobin (STAT)	19.6	Ricos 2014	-	-	-	19.6	-	-	-
Parathyroid Hormone (PTH) (1-84)	30.0	CLIA 2024	-	-	30.0	30.2	20.0	30.0	23.5
Parathyroid Hormone (PTH) (1-84) (STAT)	30.0	CLIA 2024	-	-	30.0	-	20.0	30.0	23.5
Phenobarbital	2 mcg/mL or 15%	CLIA 2024	15.0	20.0	2 mcg/dL or 15%	-	-	-	-
Phenytoin	2 mcg/dL or 15%	CLIA 2024	13.0	25.0	2 mcg/dL or 15%	-	-	-	-
Progesterone	25.0	CLIA 2024	26.0	-	25.0		26.2	39.3	27.8
Prolactin	20.0	CLIA 2024	22.0	-	20.0	29.4	37.4	56.1	44.3
Prostate Specific Antigen, Total	0.2 ng/dL or 20%	CLIA 2024	17.0	-	0.2 ng/dL or 20%	33.6	16.2	24.4	10.2

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	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	Ricos 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Sex Hormone Binding Globulin	26.1	EFLM 2023 min	-	-	-	20.4	17.4	26.1	14.5
T-Uptake	18.0	CLIA 2024	-	range	18.0	-	-	-	-
Testosterone, Free	20 ng/dL or 30% (not free)	CLIA 2024	-	-	20 ng/dL or 30% (not free)	-	27.3	40.9	33.0
Theophylline	20.0	CLIA 2024	-	25.0	20.0	-	-	-	-
Troponin I	0.9 ng/mL or 30%	CLIA 2024	-	-	0.9 ng/mL or 30%	27.9	-	-	-
Troponin T	0.2 ng/mL or 30%	CLIA 2024	-	-	0.2 ng/mL or 30%	48.9	-	-	-
High Sensitive Troponin I	0.9 ng/mL or 30%	CLIA 2024	-	-	0.9 ng/mL or 30% (not free)	-	19.4	29.0	18.0
High Sensitivity Troponin T	0.2 ng/mL or 30%	CLIA 2024	-	-	0.2 ng/mL or 30% (not free)	-	17.6	26.5	17.1
Thyroid Stimulating Hormone (TSH)	2 mIU/L or 20%	CLIA 2024	15.0	range	2 mIU/L or 20%	23.7	24.6	36.9	26.5
Triiodothyronine, Total (TT3)	30.0	CLIA 2024	-	range	30.0	9.2	11.6	17.4	14.1
Thyroxine, Total (TT4)	1.0 mcg/dL or 20%	CLIA 2024	24.0	1.0 mcg/dL or 20%	1.0 mcg/dL or 20%	7.0	8.6	13.0	9.6
Valproic Acid	20	CLIA 2024	-	25.0	20	-	-	-	-
Vancomycin	2.0 mcg/dL or 15%	CLIA 2024	-	-	2.0 mcg/dL or 15%	-	-	-	-
Vitamin B12	30 pg/mL or 25%	CLIA 2024	-	30.0	30 pg/mL or 25%	30.0	-	-	-
25-OH Vitamin D	18.7	EFLM 2023 min	-	-	-	-	12.4	18.7	10.4

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[1]

ANALYTES	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
17-Hydroxyprogesterone	53.0	EFLM 2023 min	-	-	-	29.7	35.3	53.0	42.5
Acetaminophen	3 mcg/dL or 15%	CLIA 2024	-	-	3 mcg/dL or 15%	-	-	-	-
Adrenocorticotrophic Hormone (ACTH)	-	-	-	-	-	-	-	-	-
Aldosterone	42.8	EFLM 2023 des	-	-	-	36.7	42.8	64.2	54.9
Amikacin	-	-	-	-	-	-	-	-	-
Androstenedione	23.5	RICOS 2014	-	-	-	23.5	-	-	-
Angiotensin	-	-	-	-	-	-	-	-	-
Caffeine	-	-	-	-	-	-	-	-	-
Calcitonin	27.5	EFLM 2023 des	-	-	-	-	27.5	41.2	19.5
Carbamazepine, Free	1.0 mcg/dL or 20% (not free)	CLIA 2024	-	25.0	1.0 mcg/dL or 20% (not free)	-	-	-	-
Chloramphenicol	-	-	-	-	-	-	-	-	-
Cyclosporine	-	-	-	-	-	-	-	-	-
Disopyramide	-	-	-	-	-	-	-	-	-
EPO	-	-	-	-	-	-	-	-	-
Ethosuximide	-	-	-	-	-	-	-	-	-
Estriol, Free	-	-	-	-	-	-	-	-	-
Estriol, Total	-	-	-	-	-	-	-	-	-
Estrogen, Total	-	-	-	-	-	-	-	-	-
Human Growth Hormone	-	-	-	-	-	-	-	-	-
Ibuprofen	-	-	-	-	-	-	-	-	-
Insulin Like Growth Factor (IgF-1)	22.4	EFLM 2023 min	-	-	-	24	14.9	22.4	14.1
Lidocaine	-	-	-	-	-	-	-	-	-
Lithium	0.3 mmol/L or 15%	CLIA 2024	18.0	0.3 mmol/L or 20%	0.3 mmol/L or 15%	-	-	-	-

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Multichem **IA Plus** - Analytes, No Value Claimed[1]

ANALYTES	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
N-Acetyl procainamide	-	-	-	-	-	-	-	-	-
NT Pro-BNP	13.0	Ricos 2014	-	-	-	13.0	-	-	-
Ostase	-	-	-	-	-	-	-	-	-
Phenytoin	2 mcg/dL or 15%	CLIA 2024	13.0	25.0	2 mcg/dL or 15%	-	-	-	-
Primidone	25.0	CLIA 1992	-	25.0	-	-	-	-	-
Procainamide	25.0	CLIA 1992	-	25.0	-	-	-	-	-
Procollagen NP Type 1	24.5	EFLM 2023 min	-	-	-	-	16.3	24.5	13.2
Quinidine	25.0	CLIA 1992	-	25.0	-	-	-	-	-
Renin	56.5	EFLM 2023 min	-	-	-	-	37.7	56.5	45.2
Salicylate	2 mcg/dL or 15%	CLIA 2024	-	-	2 mcg/dL or 15%	-	-	-	-
Testosterone, Free	20 ng/dL or 30% (not free)	CLIA 2024	-	-	20 ng/dL or 30% (not free)	-	27.3	40.9	33.0
Thyroglobulin	28.2	EFLM 2023 des	-	-	-	-	28.2	42.3	15.9
Thyroxine Binding Globulin	0.1	Ricos 2014	-	-	-	0.1	-	-	-
Tobramycin	20.0	CLIA 2024	-	25.0	20.0	-	-	-	-
Troponin T	0.2 ng/mL or 30%	CLIA 2024	-	-	0.2 ng/mL or 30%	48.9	17.6	26.5	17.1
C-Reactive Protein (hs)	1 mg/dL or 30%	CLIA 2024	-	-	1 mg/dL or 30%	56.6	72.9	109.4	88.3
Valproic Acid, Free	20.0 (not free)	CLIA 2024	-	25.0	20.0 (not free)	-	-	-	-

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

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Alpha-1 Acidglycoprotein	-	-	-	-	-	16.2	-	-	-
Alpha-1 Antitrypsin	20.0	CLIA 2024	-	range	20.0	9.2	6.2	9.3	15.1
Acetaminophen	3 mcg/mL or 15%	CLIA 2024	-	-	3 mcg/mL or 15%	-	-	-	-
Acid Phosphatase	10.3	Ricos 2014	-	-	-	10.3	-	-	-
Activated Alanine Aminotransferase (AALT)	-	-	-	-	-	-	-	-	-
Activated Aspartate Aminotransferase (AAST)	-	-	-	-	-	-	-	-	-
Albumin BCG	10.0	CLIA 2024	14.0	10.0	10.0	4.1	3.4	5.2	3.8
Albumin BCP	10.0	CLIA 2024	14.0	10.0	10.0	4.1	3,4	5.2	3.8
Alkaline Phosphatase (ALP)	20.0	CLIA 2024	31.0	30.0	20.0	12.0	14.5	21.7	9.9
Alanine Aminotransferase (ALT)	6 U/L or 15%	CLIA 2024	23.0	20.0	6 U/L or 15%	27.5	16.1	24.1	15.1
Amikacin	-	-	-	-	-	-	-	-	-
Amylase	20.0	CLIA 2024	35.0	30.0	20.0	14.6	13.2	19.8	9.9
Amylase Pancreatic, see above	-	-	-	-	-	17.7	12.2	18.3	10.1
Apolipoprotein A1	11.3	EFLM 2023 min	-	-	-	9.1	7.6	11.3	8.1
Apolipoprotein B	17.2	EFLM 2023 min	-	-	-	11.6	11.5	17.2	11.1
Aspartate Aminotransferase (AST)	6 U/L or 15%	CLIA 2024	21.0	20.0	6 U/L or 15%	16.7	13.6	20.5	14.4
Beta -2 Microglobulin	9.7	EFLM 2023 min	-	-	-	9.0	6.4	9.7	6.1
Bile Acids	-	-	-	-	-	-	-	-	-
Bilirubin, Direct	44.5	Ricos 2014	-	-	-	44.5	-	-	-
Bilirubin, Total	0.4 mg/dL or 20%	CLIA 2024	24.0	0.4 mg/dL or 20%	0.4 mg/dL or 20%	27.0	24.8	37.3	30.0
Calcium	1.0 mg/dL	CLIA and CAP	11.0	1.0 mg/dL	1.0 mg/dL	2.6	2.3	3.4	2.7
Carbamazepine	1.0 mcg/mL or 20%	CLIA 2024	-	25.0	1.0 mcg/dL or 20%	2.5	-	-	-

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

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Carbon Dioxide (Bicarbonate)	20.0	CLIA 2024	-	5 mm Hg or 8%	20.0	4.9	4.9	7.3	6.0
Ceruloplasmin	12.1	EFLM 2023 min	-	-	-	7.9	8.0	12.1	7.4
Chloride	5.0	CLIA 2024	9.0	5.0	5.0	1.5	1.3	2.0	1.7
Cholesterol HDL	6 mg/dL or 20%	CLIA 2024	33.0	30.0	6 mg/dL or 20%	11.6	11.1	16.6	8.7
Cholesterol LDL	20.0	CLIA 2024	-	-	20.0	11.9	13.7	20.5	12.5
Cholesterol Total	10.0	CLIA 2024	11.0	10.0	10.0	9.0	8.7	13.0	7.9
Cholinesterase	9.8	Ricos 2014	-	-	-	9.8	-	-	-
Creatine Kinase (CK)	20.0	CLIA 2024	24.0	30.0	20.0	30.3	22.6	33.8	22.5
Complement C3	15.0	CLIA 2024	-	range	15.0	8.4	7.8	11.6	6.9
Complement C4	5.0 mg/dL or 20%	CLIA 2024	-	range	5 mg/dL or 20%	16.0	12.1	18.1	10.4
Cortisol	20.0	CLIA 2024	28.0	25.0	20.0	22.8	26.3	39.4	24.5
Creatinine Enzymatic	0.2 mg/dL or 10%	CLIA 2024	20.0	0.3 mg/dL or 15%	0.3 mg/dL or 15%	8.9	7.4	11.1	22.5
Creatinine Picrate	0.2 mg/dL or 10%	CLIA 2024	20.0	0.3 mg/dL or 15%	0.2 mg/dL or 10%	8.9	7.4	11.1	22.5
C-Reactive Protein (hs)	1 mg/dL or 30%	CLIA 2024	-	-	1 mg/dL or 30%	56.6	72.9	109.4	88.3
Digoxin	0.2 ng/mL or 15%	CLIA 2024	20.0	0.2 ng/mL or 20%	0.2 ng/mL or 15%	-	-	-	-
Ethanol	-	-	-	-	-	-	-	-	-
Gamma Glutamyl Transferase	5 U/L or 15%	CLIA 2024	22.0	-	5 U/L or 15%	22.1	18.9	28.3	13.6
Gentamicin	25.0	CLIA 2024	-	25.0	25.0	-	-	-	-
Glucose	6 mg/dL or 8%	CLIA 2024	11.0	6 mg/dL or 10%	6 mg/dL or 8%	7	6.5	9.8	7.5
Haptoglobin	25.6	EFLM 2023 min	-	-	-	27.3	17.1	25.6	12.9
Immunoglobulin A	20.0	CLIA 2024	21.0	range	20.0	13.5	9.8	14.7	8.6
Immunoglobulin G	20.0	CLIA 2024	16.0	range	20.0	8	7.3	10.9	5.3
Immunoglobulin M	20.0	CLIA 2024	28.0	range	20.0	16.8	17.1	25.6	8.9

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Multichem S Plus - Analytes, Value Assigned

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Iron	15.0	CLIA 2024	24.0	20.0	15.0	30.7	26.7	40.0	31.0
Unsaturated Iron Binding Capacity (UIBC)	-	-	-	-	-	-	-	-	-
Lactate	30.4	Ricos 2014	-	-	-	30.4	-	-	-
Lactate Dehydrogenase (LDH)	15.0	CLIA 2024	26.0	20.0	15.0	11.4	7.7	11.5	7.8
Lipase	21.3	EFLM 2023 min	-	-	-	37.9	14.2	21.3	13.8
Lithium	0.3 mmol/L or 15%	CLIA 2024	18.0	0.3 mmol/L or 20%	0.3 mmol/L or 15%	-	-	-	-
Magnesium	15.0	CLIA 2024	-	25.0	15.0	4.8	4.0	6.0	4.3
Phenobarbital	2 mcg/mL or 15%	CLIA 2024	15.0	20.0	2 mcg/dL or 15%	-	-	-	-
Phenytoin	2 mcg/mL or 15%	CLIA 2024	13.0	25.0	2 mcg/dL or 15%	-	-	-	-
Phosphorous	0.3 mg/dL or 10%	CLIA 2024	17.0	-	0.3 mg/dL or 10%	10.1	9.7	14.6	11.7
Potassium	0.3 mmol/L	CLIA 2024	8.0	0.5 mmol/L	0.3 mmol/L	5.6	4.8	7.3	6.1
Prealbumin	14.5	Ricos 2014	-	-	-	14.5	-	-	-
Protein, Total	8.0	CLIA 2024	12.0	10.0	8.0	3.6	3.5	5.2	3.9
Rheumatoid Factor	13.5	Ricos 2014	-	range	range	13.5	-	-	-
Salicylate	2 mcg/dL or 15%	CLIA 2024	-	-	2 mcg/dL or 15%	-	-	-	-
Sodium	4 mmol/L	CLIA 2024	5.0	4 mmol/L	4 mmol/L	0.7	0.7	1.0	0.8
Theophylline	20.0	CLIA 2024	-	25.0	20.0	-	-	-	-
Thyroxine, Total (TT4)	1.0 mcg.dL or 20%	CLIA 2024	24.0	1.0 mcg.dL or 20%	1.0 mcg.dL or 20%	7.0	8.6	13.0	9.6
Tobramycin	20.0	CLIA 2024	-	25.0	20.0	-	-	-	-
Transferrin	10.2	EFLM 2023 min	-	-	-	3.8	6.8	10.2	5.8
Triglycerides	15.0	CLIA 2024	18.0	25.0	15.0	26	27	40.6	30.0
Urea Nitrogen	2 mg/dL or 9%	CLIA 2024	19.0	2 mg/dL or 9%	2 mg/dL or 9%	15.5	17.8	26.6	20.9

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

ANALYTES (Value Assigned)	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Uric Acid	10.0	CLIA 2024	17.0	17.0	10.0	12.0	12.8	19.2	12.5
Valproic Acid	20.0	CLIA 2024	-	25.0	20.0	-	-	-	-
Vancomycin	2 mcg/dL or 15%	CLIA 2024	-	-	2 mcg/dL or 15%	-	-	-	-

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Multichem S Plus - Analytes, No Value Claimed[1]

ANALYTES (No Value Claimed)	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Alpha Hydroxybutyrate Dehydrogenase	-	-	-	-	-	-	-	-	-
Alpha-2-Macroglobulin	7.6	Ricos 2014	-	-	-	7.6	-	-	-
ADNase B (Anti-Streptococcal DNase B)	-	-	-	-	-	-	-	-	-
Angiotensin Converting Enzyme	-	-	-	-	-	-	-	-	-
Anti-streptolysin O (ASO)	-	-	-	range	range	-	-	-	-
Antithrombin III	8.3	Ricos 2014	-	-	-	8.3	-	-	-
Beta Hydroxybutyrate Dehydrogenase	-	-	-	-	-	-	-	-	-
Bilirubin Indirect	-	-	-	-	-	-	-	-	-
Caffeine	-	-	-	-	-	-	-	-	-
Calcium Ionized	2.0	Ricos 2014	-	-	-	2.0	-	-	-
C1 Inhibitor	-	-	-	-	-	-	-	-	-
CH50 (Total hemolytic Complement)	-	-	-	-	-	-	-	-	-
Cystatin C	9.7	EFLM 2023 min	-	-	-	7.6	6.5	9.7	6.0
Copper	15.0	EFLM 2023 min	-	-	-	7.5	10.0	15.0	11.3
Fructosamine	5.4	EFLM 2023 min	-	-	-	4.5	3.6	5.4	3.4
Ferritin	20.0	CLIA 2024	21.0	-	20.0	16.9	13.8	20.6	19.2
Hemopexin	-	-	-	-	-	-	-	-	-
IgG1, Subclass	-	-	-	-	-	-	-	-	-
IgG2, Subclass	-	-	-	-	-	-	-	-	-
IgG3, Subclass	-	-	-	-	-	-	-	-	-
IgG4, Subclass	-	-	-	-	-	-	-	-	-
IgE	20.0	CLIA 2024	-	range	20.0	-	-	-	-
Kappa Light Chain	12.0	EFLM 2023 min	-	-	-	8.0	8.0	12.0	7.2

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Multichem S Plus - Analytes, No Value Claimed[1]

ANALYTES (No Value Claimed)	Recommended Default	Source Of Recommendation	Spanish Minimum	CLIA 1992	CLIA 2024	RICOS 2014	EFLM 2023 des	EFLM 2023 min	EFLM 2023 MAU
Lambda Light Chain	12.7	EFLM 2023 min	-	-	-	8.6	8.4	12.7	7.2
Lipoprotein (a)	14.4	EFLM 2023 min	-	-	-	24.1	9.6	14.4	13.4
Osmolality	1.5	Ricos 2014	-	-	-	1.5	-	-	-
Properdin Factor B	11.5	Ricos 2014	-	-	-	11.5	-	-	-
Protein Electrophoresis	-	-	-	-	-	-	-	-	-
Prostatic Acid Phosphatase	-	-	-	-	-	-	-	-	-
Retinol Binding Protein	-	-	-	-	-	-	-	-	-
sTfR (Soluble Transferrin Receptor)	16.2	EFLM 2023 min	-	-	-		10.8	16.2	10.4
Triiodothyronine, Total (TT3)	30.0	CLIA 2024		range	30.0	9.2	11.6	17.4	14.1
Total Iron Binding Capacity	20.0	CLIA 2024	-	-	20.0	-	-	-	-
Zinc	15.1	EFLM 2023 min	-	-	-	11.0	10.1	15.1	12.8

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