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Original Article

Quantitative Assessment of Analytical Phase Quality of Clinical Biochemistry Parameters Using Sigma Metrics

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ABSTRACT

Background and Aims: Six sigma is the latest version of total quality management. It is quantitative goal for process performance. With increasing demands for improved accuracy and reliability of the results, Six Sigma is gaining increased visibility in the clinical laboratory process outcomes. The aim of study was to evaluate the quality of analytical phase performance in a clinical biochemistry laboratory by calculating sigma metrics.

Materials and Methods: The study was conducted in a hospital laboratory of Bhatia Hospital, Mumbai. Mean, coefficient of variation, bias, and sigma values were calculated for 24 biochemistry parameters. The guidelines used for total error allowable (TEa) values were clinical laboratory improvement amendments (CLIA), RILIBAK and college of american pathologists (CAP). Four months' internal and external quality control data were extracted for the following parameters-albumin, alkaline phosphatase (ALP), alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), bilirubin direct, bilirubin total, Ca, cholesterol, creatine kinase (CK), creatinine, triglycerides (TG), Uric acid (UA), unsaturated iron binding capacity (UIBC), urea, gamma-glutamyl transferase (GGT), glucose, high-density lipoproteins (HDL), iron, lactate dehydrogenase (LDH), lipase, Mg, phosphorus and total protein.

Results: Albumin, ALP, AST, ALT, amylase, bilirubin total, Ca, cholesterol, CK, creatinine, TG, uric acid, GGT, glucose, iron, LDH, lipase, Mg, Phosphorus, total protein showed the performance of more than six Sigma for both level of controls. Bilirubin direct, Urea, for level 1; UIBC, urea, HDL for level 2 showed sigma from 3-6.

Conclusions: Based upon sigma metrics, laboratory quality control strategy can be planned and reevaluated for continuous monitoring and improvement of test methods.

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Introduction

One of the most important units of the healthcare sector, particularly in hospitals, is undoubtedly clinical laboratories. Obviously, without accurate test results, physicians cannot make diagnosis or provide effective treatment. That is why with respect to clinical laboratory, quality is not a supplementary value; it is an indispensible basic requirement [1]. The maintenance of a quality management system is crucial to a clinical laboratory for constantly generating the correct test results and providing them to the clinicians.

Internal and external quality control processes are the important aspects of quality assurance in the analytical phase of total testing processes in clinical laboratories. Both ensure that the data generated by the laboratory are consistent from one day to the next and that the results from one laboratory can be compared with those generated by others [2]. However, validation of quality control procedures is critical to maintain accurate laboratory results and its continuous improvement.

Six Sigma is the latest version of total quality management. it is quantitative goal for process performance. With increasing demands for improved accuracy and reliability of results, Six Sigma is gaining increased visibility in the clinical laboratory [3]. It began as a tool to minimize variation, improve manufacturing processes, and institutionalize quality. It is a means to identify errors or "defects" and reduce variability and to make processes more uniform and precise through the application of statistical methods [4]. The Sigma value indicates how often errors are likely to occur; the higher the sigma value, the less likely it is that the laboratory reports defects or false test results. This is quantified as defects per million. Quality is assessed on the sigma scale with a criterion of sigma 3 as the minimum allowable value for routine performance and a sigma of six being the goal for world-class quality [5]. The aim of present study was validate quality of analytical phase by evaluating the sigma metrics and total allowable error of biochemistry parameters for our laboratory method and instruments at a hospital laboratory in Mumbai.

Materials and Methods

The present observational study was conducted in department of clinical biochemistry, Bhatia Hospital, which is medium sized hospital has a modest 209 beds, situated in the central Mumbai. In this study, the internal quality control data for 24 routine biochemistry parameters was extracted from the COBAS-6000 Hitachi Modular 501 system (Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305, Mannheim, Germany) fully automated analyzer. The quality control data was analyzed retrospectively over a period of 4 months from August 2016 to November 2016.

The internal quality control check was performed everyday using two levels of control (PreciControl ClinChem Multi 1 (PCC1) and PreciControl ClinChem Multi 2 (PCC2). Control materials were obtained from Roche Diagnostics, D-68305, Mannheim, Germany.

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The 4 month internal quality control (QC) (October 2012 to march 2013) and external quality assurance scheme (EQAS) data were scrutinized for the following 24 clinical biochemistry parameters- glucose, urea, creatinine, uric acid, cholesterol, total protein, albumin, amylase, lipase, creatine kinase (CK), magnesium (Mg), alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), Lactate dehydrogenase (LDH), iron, unsaturated iron binding capacity (UIBC), triglycerides (TG), bilirubin total, bilirubin direct, calcium (Ca) and phosphorus.

Internal quality control data was used for coefficient of variation (CV) estimation. CV was determined from the laboratory mean and standard deviation using following formula:

CV (%)=(Standard Deviation×100)/ Lab mean

for accuracy check by bias measurement, EQAS results of 4 months (August 2016 to November 2016) were used. Our laboratory used Bio Rad EQAS program. Bias was computed from the EQAS records using following formula:

Bias (%)=Mean of all laboratories using same instrument and method−our mean×100/mean of all laboratories using same instrument and method

Sigma metrics were calculated from CV, percentage bias and total allowable error (TEa) for the parameters by the following formula:

$$\Sigma\ (\sigma) = (TEa - bias) / CV\%$$

TEa values of various parameters were taken from clinical laboratories improvement amendments (CLIA) guidelines, RILIBAK (German quality guidelines), and CAPPT. For some parameters, no TEa value was available in the guidelines; so, we took TEa as 10% for those parameters (bilirubin direct and UIBC).

TE observed in our assay was calculated using the formula:

$$TE\ observed = bias\% + CV\% \times 2$$

Results

We have calculated mean, SD, CV%, bias, TE observed and sigma values. Results are given in the following tabulated columns. Tables 1 and 2 depict the 4 months''s internal quality control data (laboratory mean, target mean and SD) of level 1 and 2 controls, respectively. Table 3 shows the monthly bias and average of 4 months bias of all parameters. Tables 5 and 6 show the CV%, bias%, TE observed, TEa and sigma values for all 24 clinical biochemistry parameters in level 1 and level 2 controls.

Among the 24 analytes observed in Level 1 (normal) albumin, ALP, AST, ALT, amylase, bilirubin total, Ca, cholesterol, CK, creatinine, TG, uric acid, GGT, glucose, HDL, iron, LDH, lipase, Mg, phosphorus, total protein showed sigma value of more than 6. Bilirubin direct and urea showed Sigma value in the range of 3 to 6. UIBC showed Sigma value of less than 3.0 when TEa was taken as 10%.

In level 2 (High) albumin, ALP, AST,ALT, amylase, bilirubin total, Ca, cholesterol, CK, creatinine, TG, uric acid, GGT, glucose, iron, LDH, lipase, Mg, phosphorus, total protein showed the performance of more than six Sigma. Urea, UIBC and HDL sigma values were between the ranges of 3 to 6. No parameters showed Sigma value<3 in level 2 controls.

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Table 1. Comparison of designated mean and laboratory mean for various biochemistry parameters for level 1 control

Parameters	Lab Mean				Lab Mean±SD	Target Mean±SD
	(August)	(September)	(October)	(November)	(Cumulative)	Manufacturer
Albumin (g/dl)	3.37	3.32	3.32	3.39	3.35 + 0.036	3.32 + .20
ALP (U/L)	90.3	91	89	92.4	90.67 + 1.41	93.9 + 5.6
ALT (U/L)	45.77	45.22	44.02	44.71	44.93 + 0.745	47.5 + 2.8
Amylase (U/L)	79.8	81.1	79.4	79.5	79.95 + 0.77	79.9 + 4.8
AST (U/L)	46.8	47.05	46.88	46.65	46.84 + 0.168	46.1 + 2.8
Bili D (mg/dl)	0.958	0.978	0.962	0.981	0.969 + 0.011	0.98 + 0.07
Bili T (mg/dl)	1.007	1.037	0.98	1.009	1.008 + 0.02	1.03 + 0.06
Calcium (mg/dl)	8.98	9.01	8.92	9.02	8.98 + 0.04	8.98 + 0.36
Cholesterol (mg/dl)	103.26	105.58	104.73	104.76	104.58 + 0.96	101 + 5
CK (U/L)	157.1	150.1	146.2	146	149.85 + 5.17	153 + 9
Creatinine (mg/dl)	1.07	1.06	1.04	1.04	1.05 + 0.015	1.09 + 0.07
Triglycerides (mg/dl)	116.37	115.1	115.66	116.51	115.91 + 0.65	112 + 6
Uric acid (mg/dl)	4.72	4.76	4.66	4.61	4.68 + 0.06	4.77 + 0.24
UIBC (µg/dl)	209.6	207.45	214.34	222.8	213.54 + 6.8	220 + 15
Urea (mg/dl)	40.04	39.61	38.76	39.6	39.50 + 0.53	39.2 + 2.0
GGT (U/L)	47.5	48.9	48.1	48	48.1 + 0.61	48.8 + 2.9
Glucose (mg/dl)	101.77	101.49	101.06	103.18	101.87 + 0.91	100 + 5
HDL (mg/dl)	33.71	34.6	33.94	36.7	34.73 + 1.36	34.1 + 2.7
Iron (µg/dl)	110.02	112.53	109.81	110	110.59 + 1.29	106.0 + 6
LDH (U/L)	156	155.6	153.7	162.9	157.08 + 4.03	160 + 10
Lipase (U/L)	43.5	43.32	42.44	42.82	43.02 + 0.48	43.7 + 2.6
Magnesium (mg/dl)	1.89	1.87	1.85	1.85	1.86 + 0.02	1.93 + 0.08
Phosphorus (mg/dl)	3.95	3.91	3.85	3.88	3.90 + 0.045	3.94 + 0.20
Total protein (g/dl)	5.13	5.13	5.11	5.14	5.13 + 0.01	5.11 + 0.20

ALP= Alkaline phosphatase; ALT= Alanine aminotransferase; AST= Aspartate aminotransferase; Bili D=Bilirubin direct, Bili T= Bilirubin total; CK= Creatine kinase; UIBC= Unsaturated iron binding capacity; GGT= Gamma-glutamyl transferase; HDL= High-density lipoproteins; LDH= Lactate dehydrogenase

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Table 2. Comparison of designated mean and laboratory mean for various biochemistry parameters for level 2 control

Parameters	Lab Mean				Lab Mean+SD	Target Mean+SD
	(August)	(September)	(October)	(November)	(Cumulative)	Manufacturer
Albumin (g/dl)	4.94	4.96	4.93	5.06	4.97 + 0.060	4.96 + .30
ALP (U/L)	215.9	216.7	215.8	215.3	215.9 + 0.59	219 + 13
ALT (U/L)	117.32	116.52	114.34	113.03	115.30 + 1.96	123 + 7
Amylase (U/L)	185.9	187.6	186.3	185	186.2 + 1.07	186 + 11
AST (U/L)	141.28	142.02	141.65	140.34	141.32 + 0.72	138 + 8
Bili D (mg/dl)	2.61	2.65	2.64	2.66	2.64 + 0.023	2.56 + 0.20
Bili T (mg/dl)	3.939	4	3.849	3.89	3.919 + 0.0651	3.97 + 0.24
Calcium (mg/dl)	13.99	14.07	13.98	13.91	13.98 + 0.064	13.8 + 0.6
Cholesterol (mg/dl)	171.31	175.22	173.81	172.88	173.30 + 1.64	170 + 9
CK (U/L)	309.5	300	292.2	290	297.92 + 8.81	303 + 18
Creatinine (mg/dl)	4.03	4.06	4.03	4.03	4.038 + 0.016	4.1 + 0.25
Triglycerides (mg/dl)	210.51	209.33	209.86	210.02	209.93 + 0.48	205 + 10
Uric acid (mg/dl)	9.9	9.94	9.72	9.63	9.79 + 0.15	9.89 + 0.5
UIBC (µg/dl)	259.2	255.57	262.32	263.73	260.20 + 3.62	268 + 19
Urea (mg/dl)	117.58	116.56	113.16	116.04	115.83 + 1.89	118.0 + 6.0
GGT (U/L)	208.9	212	210.2	209.2	210.08 + 1.38	213 + 13
Glucose (mg/dl)	235.62	235.76	234.86	237.91	236.04 + 1.31	234 + 12
HDL (mg/dl)	59.18	62.24	60.46	65.633	61.87 + 2.79	59.1 + 4.7
Iron (µg/dl)	241.91	244.82	243.01	239.72	242.36 + 2.13	240.0 + 14
LDH (U/L)	286.7	289.7	287.8	300.1	291.08 + 6.16	298.0 + 18
Lipase (U/L)	95.77	95.91	95.56	95.77	95.75 + 0.14	98.3 + 5.9
Magnesium (mg/dl)	3.21	3.23	3.2	3.17	3.20 + 0.027	3.33 + 0.13
Phosphorus (mg/dl)	8.35	8.3	8.24	8.16	8.26 + 0.08	8.40 + 0.42
Total protein (g/dl)	7.97	7.96	7.95	7.85	7.93 + 0.05	7.90 + 0.32

ALP= Alkaline phosphatase; ALT= Alanine aminotransferase; AST= Aspartate aminotransferase; Bili D=Bilirubin direct, Bili T= Bilirubin total; CK= Creatine kinase; UIBC= Unsaturated iron binding capacity; GGT= Gamma-glutamyl transferase; HDL= High-density lipoproteins; LDH= Lactate dehydrogenase

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Table 3. Average percentage bias calculated from EQAS results for a period of 4 months

Parameters	Month 1	Month 2	Month 3	Month 4	Average
	August	September	October	November	Cumulative
Albumin (g/dl)	1.2	0.29	0.01	1.32	0.71
ALP (U/L)	1.98	0.44	1.98	1.86	1.57
ALT (U/L)	1.95	0.25	3.44	6.14	2.95
Amylase (U/L)	0.13	0.74	0.16	*	0.34
AST (U/L)	0.51	2.62	0.42	0.42	0.99
Bili D (mg/dl)	4.58	6.21	4.21	2.44	4.36
Bili T (mg/dl)	2.04	3.1	4.93	0.39	2.62
Calcium (mg/dl)	1.15	1.32	0.09	1.14	0.93
Cholesterol (mg/dl)	1.31	1.7	0.57	0.27	0.96
CK (U/L)	2.34	4.27	5.86	5.35	4.46
Creatinine (mg/dl)	9.5	4.73	0.1	9.43	5.94
Triglycerides (mg/dl)	0.68	1.14	5.29	1.62	2.18
Uric acid (mg/dl)	0.17	0.19	5.33	4.29	2.50
UIBC (µg/dl)	2.9	0.41	5.28	1.77	2.59
Urea (mg/dl)	2.58	1.63	2.41	3.84	2.62
GGT (U/L)	3.8	7.62	5.82	5.47	5.68
Glucose (mg/dl)	1.44	0.2	0.64	2.37	1.16
HDL (mg/dl)	4.19	0.57	0.57	6.56	2.97
Iron (µg/dl)	1.07	3.17	3.53	0.31	2.02
LDH (U/L)	1.45	1.35	3.84	2.23	2.22
Lipase (U/L)	5.29	5.57	6.13	4.17	5.29
Magnesium (mg/dl)	1.72	2.44	0.88	*	1.68
Phosphorus (mg/dl)	0.06	1.16	0.84	3.44	1.38
Total Protein (g/dl)	0.26	1.07	0.12	0.17	0.41

ALP= Alkaline phosphatase; ALT= Alanine aminotransferase; AST= Aspartate aminotransferase; Bili D=Bilirubin direct, Bili T= Bilirubin total; CK= Creatine kinase; UIBC= Unsaturated iron binding capacity; GGT= Gamma-glutamyl transferase; HDL= High-density lipoproteins; LDH= Lactate dehydrogenase

* Value not available

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Table 4. Average calculated bias %, CV, Tea and Sigma values for a period of 4 months for level-1 control

Parameters	CV %	Bias % (Average of 4 months from EQAS)	Total error allowable (%)	Guideline followed for TEa	Observed total error (bias+CV*2)	Sigma
Albumin (g/dl)	1.07	0.71	10	CLIA	2.85	8.76
ALP (U/L)	1.56	1.57	30	CLIA	4.69	18.22
ALT (U/L)	1.66	2.95	20	CLIA	6.27	10.27
Amylase (U/L)	0.96	0.34	30	CLIA	2.26	30.89
AST (U/L)	0.36	0.99	20	CLIA	1.71	52.80
Bili D (mg/dl)	1.18	4.36	10	……..	6.72	4.77
Bili T (mg/dl)	1	2.62	20	CLIA	4.62	14.72
Calcium (mg/dl)	0.52	0.93	25	CLIA	1.97	46.28
Cholesterol (mg/dl)	0.92	0.96	10	CLIA	2.80	9.82
CK (U/L)	3.45	4.46	30	CLIA	11.36	7.40
Creatinine (mg/dl)	1.04	5.94	15	CLIA	8.02	8.70
Triglycerides (mg/dl)	0.56	2.18	25	CLIA	3.30	40.75
Uric acid (mg/dl)	1.39	2.50	17	CLIA	5.28	25.89
UIBC (µg/dl)	3.19	2.59	10	……..	8.97	2.30
Urea (mg/dl)	1.36	2.62	9	CLIA	5.34	4.60
GGT (U/L)	1.27	5.68	21	RILIBAK	8.22	12.00
Glucose (mg/dl)	0.9	1.16	10	CLIA	2.96	9.80
HDL (mg/dl)	3.92	2.97	30	CLIA	10.81	6.96
Iron (µg/dl)	1.17	2.02	20	CLIA	4.36	15.36
LDH (U/L)	2.57	2.22	20	CLIA	7.36	6.91
Lipase (U/L)	0.48	5.29	29.1	RICOS	6.25	49.6
Magnesium (mg/dl)	1.1	1.68	25	CAP PT	3.88	21.20
Phosphorus (mg/dl)	1.17	1.38	16	RILIBAK	3.72	12.49
Total protein (g/dl)	0.29	0.41	10	CLIA	0.99	33.00

ALP= Alkaline phosphatase; ALT= Alanine aminotransferase; AST= Aspartate aminotransferase; Bili D=Bilirubin direct, Bili T= Bilirubin total; CK= Creatine kinase; UIBC= Unsaturated iron binding capacity; GGT= Gamma-glutamyl transferase; HDL= High-density lipoproteins; LDH= Lactate dehydrogenase

Discussion

Quality control in the clinical laboratory refers to the process of detecting analytical errors within the laboratory, evaluate and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported to ensure both the reliability and accuracy of test results in order to provide the best possible patient care [6].

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Table 5. Average calculated bias %, CV, Tea and Sigma values for a period of 4 months for level-2 control

Parameters	CV %	Bias % (Average of 4 months from EQAS)	Total error allowable (%)	Guideline followed for TEa	Observed total error (bias+CV*2)	Sigma
Albumin (g/dl)	1.21	0.71	10	CLIA	3.13	7.67
ALP (U/L)	0.27	1.57	30	CLIA	2.11	105.29
ALT (U/L)	1.71	2.95	20	CLIA	6.37	9.97
Amylase (U/L)	0.57	0.34	30	CLIA	1.48	52.00
AST (U/L)	0.51	0.99	20	CLIA	2.01	37.20
Bili D (mg/dl)	0.89	4.36	10	……..	6.14	6.33
Bili T (mg/dl)	1.66	2.62	20	CLIA	5.94	10.46
Calcium (mg/dl)	0.46	0.93	25	CLIA	1.85	52.30
Cholesterol (mg/dl)	0.95	0.96	10	CLIA	2.86	19.60
CK (U/L)	2.96	4.46	30	CLIA	10.38	8.60
Creatinine (mg/dl)	0.4	5.94	15	CLIA	6.74	22.60
Triglycerides (mg/dl)	0.23	2.18	25	CLIA	2.64	99.20
Uric acid (mg/dl)	1.53	2.50	17	CLIA	5.56	9.40
UIBC (µg/dl)	1.39	2.59	10	……..	5.37	5.33
Urea (mg/dl)	1.64	2.62	9	CLIA	5.90	3.89
GGT (U/L)	0.66	5.68	21	RILIBAK	7.00	23.20
Glucose (mg/dl)	0.56	1.16	10	CLIA	2.28	15.70
HDL (mg/dl)	4.52	2.97	30	CLIA	12.01	5.98
Iron (µg/dl)	0.88	2.02	20	CLIA	3.78	20.40
LDH (U/L)	2.12	2.22	20	CLIA	6.46	8.30
Lipase (U/L)	0.15	5.29	29.1	RICOS	5.59	158.70
Magnesium (mg/dl)	0.86	1.68	25	CAP PT	3.40	27.10
Phosphorus (mg/dl)	0.99	1.38	16	RILIBAK	3.36	14.76
Total protein (g/dl)	0.74	0.41	10	CLIA	1.89	12.90

ALP= Alkaline phosphatase; ALT= Alanine aminotransferase; AST= Aspartate aminotransferase; Bili D=Bilirubin direct, Bili T= Bilirubin total; CK= Creatine kinase; UIBC= Unsaturated iron binding capacity; GGT= Gamma-glutamyl transferase; HDL= High-density lipoproteins; LDH= Lactate dehydrogenase

A good laboratory practice requires that laboratories design their QC procedures to assure that reported patient results meet the quality required for their intended use [7]. The important elements of quality assurance are documentation, standard operating procedures (SOP's), internal quality control and external quality assessment [8].

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The Sigma metrics is an objective tool based on the statistical concept and is used as quality indicator of quantitative assays in modern era. It provides an intuitive, encompassing, snapshot of method performance suitable for using in quality management plan.

Sigma values are valuable for managing QC strategy design. For a high Sigma process, it is relatively easy for the laboratory to design a QC procedure, and detect any out-of-control conditions that could pose a significant risk of producing unreliable results. A relatively large out-of-control condition would have to occur before there would be much chances of producing results that contained errors that exceeded the TEa specification and it is easy to design QC procedures that can detect large out-of-control conditions. The Sigma metrics values are useful in setting the internal QC acceptability criteria. For Sigma value of 5.8 to 6.0, 1- 3.5S rule with 2 levels of controls once in a day has to be used. For Sigma value of 5.2-5.4, 1-3S rule with 2 levels of controls once in a day have to be used. For Sigma value of 4.1-5.0, 1-2.5S rule with 2 levels of controls once in a day have to be used. For Sigma value of 3.4-4.0, 13S, 2-2S, R-4S and 4-1S with 2 levels of control twice in a day have to be used. For Sigma value of 3.0-3.2, 13S, 2-2S, R-4S and 4-1S with 3 levels of control twice in a day have to be used. For Sigma value of <3, method performance must be improved before the method can be used for routine production [9].

Before calculating Sigma metrics, in our lab we followed 1-3S, 2-2S and R-4S rules for all the parameters. The 2 levels of controls used to be run once in a day for all biochemistry parameters given above.

The results indicated that among the 24 analytes observed; albumin, ALP, AST,ALT, amylase, bilirubin total, Ca, cholesterol, CK, creatinine, TG, uric acid, GGT, glucose, iron, LDH, lipase, Magnesium, phosphorus, total protein showed Sigma value of more than 6 for both levels (level 1 and 2) of control. So, for these parameters, the QC protocol can be relaxed from 1-3S to 1-3.5S.

Sigma value of bilirubin direct for level 1 was 4.77 and for level 2 it was 6.33. The rule needs to be shifted from 1-3S, 2-2S to 1-2.5S. HDL showed Sigma value of 6.96 for level 1 and 5.98 for level 2. For HDL, we can follow the same rule, which we are presently using i.e. (1-3S and 2-2S) in the laboratory.

Urea showed Sigma value of 4.6 for level 1 and 3.89 for level 2. So, for urea, the rules need to be followed are-13S, 2-2S, R-4S and 4-1S with 2 levels of control twice in a day.

UIBC showed Sigma value of less than 3.0 for level 1 and 5.33 for level 2 when TEa was taken as 10% is not defined TEa was available in the guidelines. So, for UIBC we need to follow the maximum Westgard rules-13S, 2-2S, R-4S and 4-1S with 3 levels of control twice in a day, but need not to evaluate method performance as the TEa we chose was very low, which caused the decrease in Sigma value and for level-2 the Sigma value is above 5.

Conclusion

Sigma metrics is a modern tool to evaluate analytical methodologies in order to improve laboratory performance. Based upon Sigma

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metrics, laboratory quality control strategy can be planned and reevaluated for continuous monitoring and improvement of test methods. In our laboratory, out of 24 analytes, 20 parameters showed very good Sigma metrics and for remaining 4 parameters (bilirubin direct, HDL, UIBC and urea) the quality control protocols need to be modified and then monitor and reevaluated after few months.

Conflict of Interest

The authors declare no conflict of interest.

Acknowledgement

There is no acknowledgment to declare.

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