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***Retrospective Study***

**Assessment of quality control system by sigma metrics and quality goal index ratio: A roadmap towards preparation for NABL**

Verma M *et al.* Roadmap towards NABL preparation

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**Abstract**

***AIM***

To study sigma metrics and quality goal index ratio (QGI).

***METHODS***

The present study is a retrospective one and was conducted at Clinical Biochemistry Laboratory (CBL), Department of Biochemistry, Pt B D Sharma, PGIMS, Rohtak, which is a National Accreditation Board for Testing and Calibration of Laboratories (NABL) accredited lab as per the International standard; International Organization for Standardization (ISO) 15189:2012 and provides service to a > 1700-bedded tertiary care hospital. Data of 16 analytes was extracted over a period of one year from January 2017 to December 2017 for calculation of precision, accuracy, sigma metrics, total error (TE) and QGI.

***RESULTS***

The average coefficient of variation (CV) ranged from 2.12% (Albumin) to 5.42% (Creatinine) for level 2 internal quality control (IQC) and 2% (Albumin) to 3.62% (high density lipoprotein-cholesterol) for level 3 IQC. Average CV of all the parameters is below 5%, reflecting very good precision. The sigma metrics for level 2 indicates that eleven (68.5%) of the 16 parameters fall short of meeting six sigma quality performance. Of these, 5 fail to meet minimum sigma quality performance with metrics less than three and another 6 just meet minimal acceptable performance with sigma metrics between three and six. For level 3, the data collected indicates eight (50%) of the parameters do not achieve six sigma quality performance, out of which 3 have metrics less than three and 5, between three and six. QGI ratio indicates that out of 5 and 3 parameters of level 2 and level 3, respectively which failed to meet six sigma quality performances, the main problem is inaccuracy in case of total cholesterol, aspartate transaminase (AST) and alanine transaminase (ALT) (QGI > 1.2), imprecision in case of urea (QGI < 0.8) and both imprecision and inaccuracy for glucose.

***CONCLUSION***

On the basis of sigma metrics and QGI, it may be concluded that CBL, PGIMS, Rohtak was able to achieve satisfactory results with world class performance for many analytes one year preceding to NABL as per ISO standard 15189:2012. AST and ALT required strict external quality assurance scheme monitoring and modification in quality control procedure as their QGI ratio is showing Inaccuracy.

**Key words:** Sigma; Quality goal index; Bias; Imprecision; Inaccuracy; Coefficient of variation

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**Core tip:** As majority of tests take place in biochemistry section, it plays a major role in patient care. So, it is necessary to follow a proper quality management system to provide accurate and precise reports to patients. National Accreditation Board for Testing and Calibration of Laboratories (NABL) accreditation is an important benchmark for “A” grade quality. Sigma metrics is also a well-known self-assessment tool to guide quality control strategy design. On the basis of sigma metrics and quality goal index ratio, it may be concluded that Clinical Biochemistry Laboratory, PGIMS, Rohtak was able to achieve satisfactory results with world class performance for many analytes one year preceding to NABL as per International Organization for Standardization standard 15189:2012.

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**INTRODUCTION**

Over 60% of tests are carried out under clinical biochemistry section; hence it plays a major role in diagnosing and managing the diseases. It is imperative to follow a proper quality management system (QMS) by this laboratory so as to provide accurate and reliable reports in an agreed upon time frame[1]. Clinical Biochemistry Laboratory (CBL), Pt BD Sharma, PGIMS, Rohtak, Haryana (CBL, Pt BDS PGIMS, Rohtak) is a National Accreditation Board for Testing and Calibration of Laboratories (NABL) accredited lab as per the International standard; International Organization for Standardization (ISO) 15189:2012. It has become the first laboratory in the government sector attached to a postgraduate institute to be accredited by NABL in the whole North India region.

In a CBL, total testing process consists mainly of 3 stages-pre-analytical phase, analytical phase and post-analytical phase. QMS includes strict compliance at all these phases as error can occur at any of these steps. In mid 1980s, a revolution came in QMS which reduced the cost of products, decreased variability in processing and hence, eliminated defects. This evolution was six sigma methodology which was developed by a Motorola Engineer named Bill Smith[2]. Sigma metrics is an important tool to evaluate the errors in quality control of laboratory system. Sigma is a metric that quantifies the performance of a process at a rate of Defects-Per-Million (DPM)[3]. The sigma value indicates how often errors are likely to occur. The higher is the sigma value, the less likely are the chances of false test results by the laboratory. It can easily quantify the exact number of errors by combining bias, precision and total allowable error (TEa). A sigma level < 3 is an indication of a poor performance procedure, whilst a good performance is indicated by a sigma level > 3. Sigma level of 6 or greater than 6 indicates world class performance[2].

To calculate precision and bias, internal quality control (IQC) and external quality assurance scheme (EQAS) are being carried out in our laboratory. IQC is run daily as per NABL guidelines and is interpreted by Levy Jennings’ charts and Westgard’s rules. The samples to be analyzed are run only when the IQC results are within control limits. EQAS sample is run monthly and is interpreted by Z score or Standard Deviation Index (SDI). Z-score is a calculated value that tells us how many standard deviations (SDs) a control result has shifted from the mean value which is expected for that material[2]. Quality goal index (QGI) is a comparatively newer parameter to represent the relative extent to which both bias and precision meet their respective quality goals.

The CBL, PGIMS, Rohtak is a large sized laboratory catering to 500 samples of outdoor patients (OPD) and 300 samples of indoor patients (IPD) per day on an average in the respective OPD and IPD sections of the laboratory. The laboratory is in a practice of running IQC and EQAS regularly for many years now. To aspire for NABL accreditation by such a large laboratory in government set-up appeared to be extremely daunting and almost a far-fetched dream. Once a system got established, which required not to compromise on quality at any aspect, the task in hand became achievable and motivated us to share our experience regarding EQAS data of the one year preceding the NABL accreditation.

The aim of the present study is to measure the sigma metrics and QGI for individual parameters in scope for NABL and to assess the errors associated with 1 year data of IQC and EQAS program of CBL, Pt BDS PGIMS, Rohtak.

**MATERIALS AND METHODS**

The present study is a retrospective one and was conducted at Department of Biochemistry, Pt B D Sharma, PGIMS, Rohtak, which provides service to a > 1700-bedded tertiary care hospital. Data was extracted over a period of one year from January 2017 to December 2017. A total of 16 analytes were included in the study which are: Glucose, urea, creatinine, total bilirubin, total protein, albumin, calcium, phosphorus, uric acid, total cholesterol, triglyceride, high density lipoprotein-cholesterol (HDL-C), aspartate transaminase (AST), Alanine Transaminase (ALT), alkaline phosphatase (ALP) and amylase. It, being a NABL accredited lab, all parameters were run along with IQC and EQAS. IQC data was analyzed for imprecision and EQAS data for inaccuracy. The parameters were done on Randox Suzuka autoanalyzer by using Randox kits obtained from manufacturer, following the standard operating procedures (SOPs) of the CBL.

As per laboratory policy, two levels of controls (level 2, normal and level 3, pathological, Randox Laboratories Limited) were run twice daily along with monthly EQAS lyophilized sample obtained from Christian Medical College, Vellore throughout the study period. The laboratory follows the Westgard’s rule to accept and reject the run. 13s, 22s, R4s, 41s and 10x were considered as rejection and 12s as a warning rule for each respective run. Mean, SD and coefficient of variance (CV) were calculated for each month for both the levels. The laboratory receives EQAS sample in 3 batches of 4 samples every year. Sample was reconstituted and analyzed same day. All the EQAS samples were handled as routine patient samples and were analyzed by senior lab technician on duty without his knowledge. Reports were uploaded before 20th of every month. On the 4th of next month SDI was checked. SDI within 0 ± 2 was considered as acceptable. Bias was also noted.

***Sigma metrics***

Mean of CV of both the levels and Bias was calculated and used for estimating sigma metrics by the following formula:

Sigma = (TEa − Bias)/CV[4]

Where, TEa is Total allowable error, Bias and CV are the indicators of systematic and random errors, respectively. The minimum acceptable performance of process was considered at 3 sigma level.

***QGI***

QGI represents the relative extent to which both bias and precision meet their respective quality goals. It was calculated using the following formula:

QGI = Bias/1.5 CV

QGI represents the reason behind lower sigma value i.e. imprecision or inaccuracy or both. For analytes which fall short of six sigma quality, a QGI score of < 0.8 indicates imprecision; QGI > 1.2 indicates inaccuracy while QGI score 0.8-1.2 indicates both imprecision and inaccuracy[4].

***Coefficient of variation***

The coefficient of variation(CV) is SD expressed as a percentage and is a measure of the variability of an assay and is expressed as a percentage[5].

CV = (SD/Mean) × (100)

### *Bias*

Bias is the systematic difference between the expected results obtained by the laboratory test method and the results that would be obtained from an accepted reference method[6].

### *TEa*

TEas were followed as per Clinical laboratory Improvement Amendments (CLIA) guidelines[1]. Total error (TE) of parameters was also calculated by the following formula[7]:

TE = Bias + 1.65CV

**RESULTS**

Tables 1 and 2 summarizes the CV% of level 2 and 3 IQC, respectively, for 16 biochemical parameters from January 2017 to December 2017 along with their average values. The average CV ranged from 2.12% (albumin) to 5.42% (creatinine) for level 2 IQC and 2% (albumin) to 3.62% (HDL-C) for level 3 IQC. Average CV of all the parameters is below 5% reflecting very good precision. Table 3 summarizes the Bias% obtained from EQAS from CMC Vellore for 16 parameters and their average for the same duration. Table 4 summarizes the average CV%, average Bias%, TEa (CLIA), calculated TE and sigma metrics of 16 parameters.

The sigma metrics for level 2 indicates that eleven (68.5%) of the 16 parameters fall short of meeting six sigma quality performance. Of these, 5 fail to meet minimum sigma quality performance with metrics less than three and another 6 just meet minimal acceptable performance with sigma metrics between three and six. For level 3, the data collected indicates eight (50%) of the parameters do not achieve six sigma quality performance, out of which 3 have metrics less than three and 5, between three and six. Calculated TEa of all the parameters is less than specified TEa (CLIA) except for AST and ALT. Table 5 summarizes the results of sigma metrics of various parameters. Table 6 summarizes the QGI ratio of analytes with lower sigma values (< 3). QGI ratio indicates that out of 5 and 3 parameters of level 2 and level 3 which failed to meet six sigma quality performances, the main problem is inaccuracy in case of total cholesterol, AST and ALT (QGI > 1.2), imprecision in case of Urea (QGI < 0.8) and both imprecision and inaccuracy for Glucose.

**DISCUSSION**

Now-a-days, it is a need of time to constantly verify the pre analytical, analytical and post-analytical processes of laboratory by internal or external audit. Sigma metrics is an important self-assessment tool to guide QC strategy design. It helps in improving the quality of process by removing defects. We have analyzed 16 parameters for sigma metrics over duration of 1 year (January-December, 2017). Similar studies have been conducted by Singh *et al*[8], Adiga *et al*[2], Iqbal *et al*[3] and Nanda*et al*[9] but none of these assessed the cause of low sigma, *i.e*., either imprecision or inaccuracy or both, to the best of our knowledge. Only a single study in literature could be found which carried out both sigma metrics and QGI[10].

The six sigma model is similar to Total Quality Management (TQM), which follows “Plan, Do, Check, Act” (PDCA) cycle. The basic scientific model in six sigma metrics is “Define, Measure, Analyze, Improve and Control” (DMAIC). So, the Six Sigma model has an extra step, control, which is important in modern quality management. This step helps in preventing the recurrence of defects, *i.e*., if an error is detected, we have to solve it and prevent it from affecting the process again. With this step, we continue to decrease the errors effectively until we obtain a desirable degree of quality[11]. The same is to be followed for the parameters with lower sigma values to attain desirable performance level, as continual improvement is necessary as per ISO standards for good laboratory practices.

In this study, 4 parameters (Albumin, Uric acid, HDL-cholesterol and ALP) showed a sigma of > 6 for both the levels of IQC showing excellent performance, while Creatinine, Total Bilirubin and Amylase showed > 6 for level 3 IQC only. Total cholesterol, AST and ALT were short of sigma metrics with value < 3 for both the levels with Glucose and urea showing < 3 sigma for level 2 only. Nanda *et al*[9] and Kumar *et al*[10] have reported 4 parameters with < 3 sigma metrics. The lowest value for sigma was found for total cholesterol (1.72) at level 2 and the highest value for HDL-cholesterol (13.09) at level 3. For parameters showing lower sigma values, root cause analysis is to be done. Strict monitoring as well as increased frequency of IQC run is required. QGI ratio for parameters with sigma < 3 depicts inaccuracy in case of TC, AST and ALT (QGI > 1.2), imprecision in case of Blood Urea (QGI < 0.8) and both imprecision and inaccuracy for Glucose. But we have found certain limitations in sigma metrics system as when we see separately there is no problem in CV% and bias% of Glucose (level 2), Urea (level 2) and TC (level 2 and level 3) but sigma is showing lesser value. In case of AST and ALT, calculated TE is more as compared to allowable error as per CLIA, which is rightly reflected in QGI and sigma metrics. So, in our opinion, if TE of an analyte is within allowable error limits specific for that analyte, bias% and CV% might be more reliable than sigma metrics though the claim needs to be supported by further studies.

On the basis of sigma metrics and QGI, it may be concluded that CBL, PGIMS, Rohtak was able to achieve a quality of results which proved to be phenomenal in getting NABL accreditation to the laboratory as per ISO standard 15189:2012. AST and ALT required strict EQAS monitoring and modification in quality control procedure as their QGI ratio is showing Inaccuracy. Although sigma metrics is a well-known industrial standard, it might not be applied universally for all the analytes.

**ARTICLE HIGHLIGHTS**

***Research background***

Accreditation is a formal recognition from a third party body which demonstrates the capability, competence and capability to carry out a certain task which it is claiming to do.

***Research motivation***

Over 60% of tests are carried out under clinical biochemistry section; hence it plays a major role in diagnosing and managing the diseases. So, It is imperative to follow a proper quality management system (QMS) by the laboratory so as to provide accurate and reliable reports in an agreed upon time frame.

***Research objectives***

Assessment of the analytical phase of quality control system by sigma metrics and quality goal index ratio (QGI).

***Research methods***

The present study is a retrospective one and was conducted at Clinical Biochemistry Laboratory (CBL), Pt B D Sharma, PGIMS, Rohtak, which is a National Accreditation Board for Testing and Calibration of Laboratories (NABL) accredited lab as per the International standard; International Organization for Standardization (ISO) 15189:2012 and provides service to a > 1700-bedded tertiary care hospital. Data of 16 analytes was extracted over a period of one year from January 2017 to December 2017 for calculation of precision, accuracy, sigma metrics, total error and QGI.

***Research results***

Average CV of all the parameters is below 5% reflecting very good precision. The sigma metrics for level 2 indicates that 5 of the 16 parameters fall short of meeting minimal six sigma quality performance. For level 3, the data collected indicates 3 of the parameters do not achieve minimal six sigma quality performance. QGI ratio indicates that out of 5 and 3 parameters of level 2 and level 3 which failed to meet six sigma quality performances, the main problem is inaccuracy in case of total cholesterol, AST and ALT (QGI > 1.2), imprecision in case of Urea (QGI < 0.8) and both imprecision and inaccuracy for Glucose.

***Research conclusions***

On the basis of sigma metrics and QGI, it may be concluded that CBL, PGIMS, Rohtak were able to achieve satisfactory results with world class performance for many analytes one year preceding to NABL as per ISO standard 15189:2012.

***Research perspectives***

Although sigma metrics is a well-known industrial standard, it might not be applied universally for all the analytes.

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**Table 1 The CV% of 16 parameters of level 2 internal quality control for a period of 1 year (Jan-Dec, 2017) and their average**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CV% of level 2 (2017)** | | | | | | | | | | | | | |
| **Parameter** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Average** |
| **Glucose** | **2.04** | **1.81** | **2.12** | **1.98** | **2.99** | **2.07** | **4.74** | **2.96** | **3.07** | **4.01** | **2.94** | **2.17** | **2.74** |
| **Urea** | **3.13** | **4.27** | **3.87** | **5.84** | **4.08** | **5.30** | **4.43** | **4.08** | **3.89** | **3.70** | **3.61** | **4.39** | **4.21** |
| **Creatinine** | **7.02** | **8.30** | **8.02** | **7.15** | **4.47** | **3.38** | **6.28** | **4.13** | **3.45** | **4.02** | **4.26** | **4.66** | **5.42** |
| **Total Bilirubin** | **2.88** | **3.89** | **3.27** | **2.93** | **2.52** | **4.60** | **4.75** | **4.62** | **2.99** | **2.54** | **4.07** | **4.86** | **3.66** |
| **Total Protein** | **1.95** | **2.18** | **2.67** | **2.94** | **3.81** | **2.99** | **3.03** | **3.00** | **3.83** | **3.99** | **2.34** | **3.27** | **3** |
| **Albumin** | **0.99** | **2.55** | **2.04** | **0.96** | **3.40** | **2.18** | **1.86** | **1.86** | **2.27** | **1.94** | **3.00** | **2.47** | **2.12** |
| **Calcium** | **2.09** | **2.90** | **2.76** | **2.70** | **2.75** | **2.38** | **2.57** | **2.55** | **2.06** | **3.24** | **2.74** | **1.85** | **2.54** |
| **Phosphorus** | **5.48** | **6.83** | **6.70** | **4.47** | **5.40** | **6.72** | **4.52** | **3.58** | **3.87** | **3.68** | **4.22** | **3.54** | **4.91** |
| **Uric acid** | **3.63** | **4.17** | **2.73** | **3.59** | **3.64** | **3.81** | **2.80** | **3.21** | **3.36** | **2.53** | **2.66** | **2.60** | **3.22** |
| **Total Cholesterol** | **2.26** | **1.86** | **3.42** | **2.17** | **2.53** | **4.16** | **3.64** | **2.62** | **2.38** | **2.87** | **3.00** | **3.49** | **2.86** |
| **Triglyceride** | **3.74** | **4.95** | **5.07** | **5.30** | **7.17** | **5.07** | **5.36** | **3.96** | **3.62** | **4.23** | **5.13** | **3.29** | **4.74** |
| **HDL cholesterol** | **5.08** | **3.43** | **5.68** | **1.74** | **4.56** | **2.85** | **4.57** | **3.89** | **3.14** | **2.90** | **2.94** | **3.56** | **3.69** |
| **AST** | **5.74** | **6.18** | **6.79** | **4.22** | **4.59** | **4.97** | **5.72** | **4.31** | **3.49** | **3.40** | **4.38** | **3.56** | **4.77** |
| **ALT** | **5.82** | **6.10** | **4.80** | **5.09** | **5.25** | **5.39** | **5.56** | **5.64** | **1.99** | **3.05** | **4.90** | **3.46** | **4.75** |
| **ALP** | **2.98** | **3.59** | **2.81** | **2.56** | **2.51** | **2.87** | **3.02** | **3.77** | **2.26** | **5.97** | **4.17** | **2.84** | **3.27** |
| **Amylase** | **4.03** | **5.70** | **4.71** | **4.24** | **4.00** | **3.14** | **5.47** | **4.72** | **4.10** | **3.30** | **3.07** | **3.87** | **4.19** |

CV: Coefficient of variation; IQC: Internal quality control; HDL: High density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

**Table 2 The CV% of 16 parameters of level 3 internal quality control for a period of 1 year (Jan-Dec, 2017) and their average**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CV% of level 3 (2017)** | | | | | | | | | | | | | |
| **Parameter** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Average** |
| **Glucose** | **1.20** | **1.31** | **1.59** | **1.50** | **1.96** | **1.65** | **2.80** | **2.05** | **4.32** | **2.45** | **1.76** | **1.90** | **2.04** |
| **Urea** | **2.60** | **2.91** | **3.50** | **4.40** | **3.23** | **3.84** | **3.41** | **3.36** | **3.65** | **4.02** | **3.28** | **2.60** | **3.4** |
| **Creatinine** | **3.34** | **3.49** | **5.29** | **4.77** | **2.75** | **1.97** | **3.10** | **3.03** | **2.98** | **2.95** | **2.92** | **2.16** | **3.22** |
| **Total Bilirubin** | **2.50** | **2.35** | **2.52** | **2.05** | **2.35** | **3.34** | **2.86** | **3.99** | **2.12** | **3.91** | **2.66** | **2.71** | **2.78** |
| **Total Protein** | **2.36** | **2.41** | **1.96** | **2.36** | **3.84** | **2.90** | **2.75** | **4.24** | **3.50** | **3.82** | **3.25** | **3.34** | **3.06** |
| **Albumin** | **2.25** | **1.95** | **3.29** | **1.73** | **1.69** | **1.84** | **1.99** | **1.69** | **1.86** | **1.74** | **1.96** | **2.02** | **2** |
| **Calcium** | **1.37** | **2.95** | **2.57** | **2.54** | **2.00** | **2.21** | **2.92** | **2.93** | **2.14** | **2.22** | **2.34** | **2.20** | **2.36** |
| **Phosphorus** | **3.50** | **4.85** | **4.77** | **4.78** | **3.85** | **4.02** | **2.22** | **1.88** | **1.62** | **2.78** | **2.41** | **2.61** | **3.27** |
| **Uric acid** | **2.90** | **3.03** | **2.33** | **2.12** | **2.66** | **2.42** | **3.56** | **2.51** | **2.54** | **1.97** | **3.11** | **2.23** | **2.61** |
| **Total Cholesterol** | **2.09** | **1.30** | **2.86** | **2.35** | **2.61** | **4.61** | **2.30** | **3.91** | **2.03** | **2.57** | **2.60** | **2.79** | **2.66** |
| **Triglyceride** | **2.50** | **2.26** | **3.61** | **2.85** | **3.18** | **4.22** | **3.80** | **2.70** | **1.98** | **2.72** | **3.49** | **2.83** | **3.01** |
| **HDL cholesterol** | **3.03** | **3.72** | **4.19** | **1.95** | **5.17** | **4.54** | **5.22** | **2.91** | **1.97** | **4.35** | **4.10** | **2.35** | **3.62** |
| **AST** | **2.12** | **3.40** | **2.65** | **2.75** | **3.45** | **2.55** | **3.48** | **3.76** | **3.95** | **2.92** | **3.62** | **2.70** | **3.11** |
| **ALT** | **3.19** | **2.81** | **3.09** | **2.89** | **4.45** | **2.66** | **4.22** | **4.32** | **2.89** | **2.67** | **2.56** | **3.11** | **3.23** |
| **ALP** | **2.93** | **2.61** | **2.67** | **2.74** | **2.59** | **2.53** | **2.53** | **2.30** | **2.30** | **4.08** | **2.82** | **2.90** | **2.75** |
| **Amylase** | **3.10** | **3.51** | **3.57** | **3.47** | **3.30** | **2.84** | **5.30** | **2.25** | **3.03** | **3.42** | **2.73** | **3.33** | **3.32** |

CV: Coefficient of variation; IQC: Internal quality control; HDL: High density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

**Table 3 The Bias % obtained from external quality assurance scheme from CMC Vellore for 16 parameters for a period of 1 year (Jan-Dec, 2017) and their average**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Bias % (2017)** | | | | | | | | | | | | | |
| **Parameter** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Average** |
| **Glucose** | **10.8** | **-9.7** | **6.1** | **1.2** | **1.2** | **6** | **3.8** | **3.2** | **0.9** | **7.5** | **8.5** | **4.5** | **3.66** |
| **Urea** | **-3.8** | **-7.2** | **-2.5** | **-2.2** | **2.2** | **-12.2** | **-1.8** | **-5.4** | **4** | **-10.1** | **-1.6** | **5.3** | **-2.94** |
| **Creatinine** | **-8.3** | **-13.6** | **-18.8** | **-7.7** | **-10.9** | **-9.1** | **-9.9** | **14.3** | **-7.5** | **-14** | **0** | **-10.7** | **-8.01** |
| **Total Bilirubin** | **0.0** | **-20** | **-4.8** | **5.4** | **5.9** | **-5.9** | **-4.0** | **-10** | **3.3** | **-3.8** | **6.2** | **10.9** | **-1.4** |
| **Total Protein** | **-4.2** | **-14** | **-2** | **-6.0** | **-2** | **-9.6** | **-5.8** | **-8.3** | **-6.2** | **-10** | **-8.2** | **-4.1** | **-6.7** |
| **Albumin** | **-3.3** | **-16.1** | **-6.5** | **-9.4** | **-12.9** | **-15.6** | **-6.3** | **-10** | **-10** | **-6.5** | **0** | **-3.3** | **-8.32** |
| **Calcium** | **1.2** | **-0.8** | **4.1** | **-4.3** | **3.1** | **-1.6** | **2.2** | **3.4** | **1.1** | **2.1** | **15.7** | **12.6** | **3.23** |
| **Phosphorus** | **-12.8** | **-37.5** | **-20.6** | **-15.8** | **-12.5** | **-9.3** | **-25.9** | **-4.4** | **-20** | **1.9** | **-18.8** | **7.3** | **-14** |
| **Uric acid** | **-14.5** | **-20.4** | **-16.2** | **-11.6** | **-22.9** | **-3.3** | **-4.8** | **-26.7** | **-5.7** | **-7.1** | **-8.3** | **-5.5** | **-12.2** |
| **Total cholesterol** | **-0.6** | **-6.4** | **1.8** | **2** | **-1.9** | **-3.5** | **3.3** | **6** | **26.9** | **8.9** | **15.8** | **8.7** | **5.08** |
| **Triglyceride** | **9.1** | **-1.3** | **4** | **5.9** | **-2.8** | **6.5** | **12.2** | **1.5** | **15.5** | **17.5** | **11.5** | **9.4** | **7.41** |
| **HDL cholesterol** | **-12.1** | **-23.6** | **-19.4** | **-14.7** | **-18** | **-27.7** | **-13** | **-15** | **-17.4** | **-18** | **-15.3** | **-14.6** | **-17.4** |
| **AST** | **20.0** | **2.4** | **20.7** | **7.6** | **0.8** | **5.8** | **13.7** | **17.8** | **20.1** | **11** | **14.8** | **24.3** | **13.2** |
| **ALT** | **33.5** | **12.3** | **22** | **-3.6** | **6.7** | **-4.3** | **13.2** | **-11.9** | **18.3** | **7.6** | **29** | **29.6** | **12.7** |
| **ALP** | **-5.6** | **-5** | **4.3** | **-8.3** | **-6.0** | **-18.2** | **-6.1** | **-4.5** | **1.5** | **6.6** | **7.3** | **3.2** | **-2.56** |
| **Amylase** | **12.4** | **-0.7** | **17.9** | **4.8** | **8.2** | **4.8** | **15.1** | **15.3** | **17.6** | **5.9** | **-1.6** | **16.4** | **9.67** |

CV: Coefficient of variation; EQAS: External quality assurance scheme; HDL: High density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

**Table 4 Sigma metrics (Level 1 and 2) and quality goal index ratio (Level 1 and 2) of 16 parameters calculated from coefficient of variation (Level 1 and 2), total allowable error (Clinical Laboratory Improvement Act), and Bias %, for a period of 1 year (Jan-Dec, 2017)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameter** | **CV%** | | **Bias %** | **TEa (CLIA)** | **TE (calculated)** | | **Sigma** | |
| **Level 2** | **Level 3** | **Level 2** | **Level 3** | **Level 2** | **Level 3** |
| **Glucose** | **2.74** | **2.04** | **3.66** | **10** | **8.18** | **7.03** | **2.31** | **3.11** |
| **Urea** | **4.21** | **3.4** | **-2.94** | **9** | **4.01** | **2.67** | **2.84** | **3.51** |
| **Creatinine** | **5.42** | **3.22** | **-8.01** | **15** | **0.93** | **-2.70** | **4.25** | **7.15** |
| **Total Bilirubin** | **3.66** | **2.78** | **-1.4** | **20** | **4.64** | **3.19** | **5.85** | **7.70** |
| **Total Protein** | **3** | **3.06** | **-6.7** | **10** | **-1.75** | **-1.65** | **5.57** | **5.46** |
| **Albumin** | **2.12** | **2** | **-8.32** | **10** | **-4.82** | **-5.02** | **8.64** | **9.16** |
| **Calcium** | **2.54** | **2.36** | **3.23** | **11** | **7.42** | **7.12** | **3.06** | **3.29** |
| **Phosphorus** | **4.91** | **3.27** | **-14** | **10** | **-5.90** | **-8.60** | **4.89** | **7.34** |
| **Uric acid** | **3.22** | **2.61** | **-12.2** | **17** | **-6.89** | **-7.89** | **9.07** | **11.19** |
| **Total Cholesterol** | **2.86** | **2.66** | **5.08** | **10** | **9.80** | **9.47** | **1.72** | **1.85** |
| **Triglyceride** | **4.74** | **3.01** | **7.41** | **25** | **15.23** | **12.38** | **3.71** | **5.84** |
| **HDL cholesterol** | **3.69** | **3.62** | **-17.4** | **30** | **-11.31** | **-11.43** | **12.85** | **13.09** |
| **AST** | **4.77** | **3.11** | **13.2** | **20** | **21.07** | **18.33** | **1.43** | **2.19** |
| **ALT** | **4.75** | **3.23** | **12.7** | **20** | **20.54** | **18.03** | **1.54** | **2.26** |
| **ALP** | **3.27** | **2.75** | **-2.56** | **30** | **2.84** | **1.98** | **9.96** | **11.84** |
| **Amylase** | **4.19** | **3.32** | **9.67** | **30** | **16.58** | **15.15** | **4.85** | **6.12** |

CV: Coefficient of variation; TE: Total error; CLIA: Clinical Laboratory Improvement Act; HDL: High density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

**Table 5 Sigma metrics of various parameters**

|  |  |  |
| --- | --- | --- |
| **Sigma metrics** | **Level 2** | **Level 3** |
| **< 3** | **Glucose, urea, total cholesterol, AST, ALT** | **Total cholesterol, AST, ALT** |
| **3-6** | **Creatinine, total bilirubin, total protein, calcium, phosphorus, triglyceride** | **Glucose, urea, total protein, calcium, triglyceride** |
| **> 6** | **Albumin, uric acid, HDL-cholesterol, ALP** | **Creatinine, total bilirubin, albumin, uric acid, HDL-cholesterol, ALP, amylase** |

HDL: High density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

**Table 6 Quality goal index ratio of analytes performed low for sigma for accuracy and precision problem**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Analytes** | **Qc levels** | **Bias%** | **CV%** | **Sigma** | **QGI** | **Problem** |
| **Glucose** | **Level 2** | **3.66** | **2.74** | **2.31** | **0.89** | **Imprecision and Inaccuracy** |
| **Urea** | **Level 2** | **-2.94** | **4.21** | **2.84** | **0.47** | **Imprecision** |
| **TC** | **Level 2** | **5.08** | **2.86** | **1.72** | **1.18** | **Inaccuracy** |
| **Level 3** | **5.08** | **2.66** | **1.85** | **1.27** | **Inaccuracy** |
| **AST** | **Level 2** | **13.2** | **4.77** | **1.43** | **1.84** | **Inaccuracy** |
| **Level 3** | **13.2** | **3.11** | **2.19** | **2.83** | **Inaccuracy** |
| **ALT** | **Level 2** | **12.7** | **4.75** | **1.54** | **1.78** | **Inaccuracy** |
| **Level 3** | **12.7** | **3.23** | **2.26** | **2.62** | **Inaccuracy** |

QGI: Quality goal index ratio; AST: Aspartate transaminase; ALT: Alanine transaminase; TC: Total cholesterol.