Journal Homepage: -www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/17860
DOI URL: http://dx.doi.org/10.21474/IJAR01/17860

*RESEARCH ARTICLE*

# IMPROVING QUALITY AND EFFICIENCY PERFORMANCE OF ANALYTICAL TESTING PROCESS USING SIGMA METRICS IN EMERGENCY LABORATORY OF KING FAHD ARMED FORCES HOSPITAL, JEDDAH, SAUDI ARABIA

**Amani MT Gusti[1], Malik S. Almuqati[1], Saleh A. Alkhilafi[1], Naif A. AlGhamdi[1], Elaf M. Gusti[2], Sahar H. Moamina[3], Glean Jamil Khoja[4], Aziz Jumaan Alsewaihy[1], Saja Mohammed llaqi[5], Mishal Olayan Alsulami[6], Bader Meshiel Alshelash[7], Abdulaziz Saad Alahmadi[7], Tariq Omar Algregri[8] and Badr Helal Almuafa[1]**

1. Department of Pathology and Laboratory Medicine, Emergency Laboratory, King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia.
2. Department of Nursing, Cardiac ward, King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia.
3. Department of Medical Laboratory, King Abdul-Aziz University Hospital, Jeddah, Saudi Arabia.
4. Department of Medical Laboratory, King Fahad General Hospital, Jeddah, Saudi Arabia.
5. Department of Pathology and Laboratory Medicine, Jeddah Regional Laboratory, Saudi Arabia.
6. Cytogenetics and Molecular Genetics Laboratory, central military laboratory and blood bank, Prince Sultan Military Medical City,Riyadh, Saudi Arabia.
7. Prince Sultan Military Medical City, Almadinah Almunawwarah, Saudi Arabia.
8. Department of Physiotherapy, King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia.

……………………………………………………………………………………………………....

## Manuscript Info

……………………….

***Manuscript History***
Received: 15 September 2023
Final Accepted: 17 October 2023
Published: November 2023

***Key words:-***
Quality Control, Quality Management, Bias, Internal Quality Control, Westgard Rule, Root Cause Analysis, Six Sigma, Sigma Metrics; Total Allowable Error

## Abstract

………………………………………………………………

**Background:** Six Sigma is a popular quality management system tool used for process improvement. Using that, the clinical technologist can directly intervene to improve the quality of test reporting during the analytical phase of the total testing process in the medical laboratory. The present study aimed to assess and continuously improve the performance of individual biochemical and hematological parameters on a Sigma Scale by calculating the Sigma metrics for individual parameters redesigning and customizing the internal quality control (IQC). A sigma metric is a simple measurement of assay quality that compares an assay's precision and bias performance to a total allowable error (TEa) goal. This analysis uses the Alinity-ci system, Alinityhq, and Stag for 47 assays from the Emergency Department of King Fahd Armed Forces Hospital.

**Methods:**The present study is retrospective-prospective conducted in a clinical Emergency laboratory of King Fahd Armed Forces Hospital (KFAFH) Medical Pathology, Jeddah, Saudi Arabia, from May 2021 to September 2022. A retrospective secondary data analysis of eight months duration was carried out in an ED laboratory with a follow-up prospective study for more than six months. During this period, 47 analyses were tabulated to analyze the Internal Quality Control (IQC) coefficient of variation percentage and external Quality Control (CAP). Bias %) and total error allowable for the same analytic were obtained monthly, and the sigma metrics were calculated for each analytic.

**Corresponding Author:- Malik S. Almuqati**
Address:- Department of Pathology and Laboratory Medicine, Emergency Laboratory, King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia.

Standardized QC sigma charts were established with these parameters.Root cause analysis (RCA) was used to discover potential problems for the analytes.For analytes with a sigma value <4, appropriate measures were taken to improve the quality of laboratory investigations.

**Results:** At critical decision levels, all data analyzed those parameters and identified the assays that were four Sigma or better. Those assays which meet these criteria are now considered to be verified. The method decision chart showed that out of 47 analyses, 57 % demonstrated a world-class performance of 6 sigma level, whereas 2 % showed an Excellence of 5 σ performance, and 12.0 % showed a good performance of 4 sigma level. In contrast, 30 % showed poor performance of less than four sigma at the QC levels. From root cause analysis, the source of error was detected and corrected. However, for all analyses of less than four sigma levels, indicating the area requiring improvement. In contrast, the SQC control rules have been redesigned for the improvement.

**Conclusions:**For the analyses listed in this report, under the circumstances detailed in the report, Westgard QC, Inc. is proud to re-verify that the Sigma performance of KFAFH, ED laboratory is achieving the appropriate goals of analytical quality performance. For QC procedure, sigma metric analysis is helpful to evaluate the performance and optimize the protocol for improvement and cost-effectiveness.



## Introduction:-

The present era of globalization has driven medical science into a newly established platform, which is of laboratory investigations with the highest sensitivity andspecificity.But ensuring the accuracy of the report has always been challenging for the clinical technologist, who steers the treating physician towards the next level of treatment for a patient's wellbeing

Around 70% of the patient-related decision isbased on the clinical laboratory (1). According to the statistics, the estimated error rates in the three phases of the total testing procedure, including pre-analytical, analytical and post-analytical phase are 30 - 75%, 4 - 30% and 9 - 55%, respectively (2).

Quality controlmeasures employed to assess the analytical phase in a clinical chemistry, Immunology and Hematology laboratory are internal quality control (IQC) and external quality control (External Quality Assurance Scheme [EQAS]).IQC is a sample material whose matrix is identical to the patients' sample and has an established concentration range available in two or three levels covering the medical decision points. The IQC is run as per CLIA guidelines, interpreted using control charts such as Levy Jennings' and application of Westgard rules. IQC ensures a continuous watch of the analytical system, so as to check whether the results are reliable enough to be released.

External quality (EQC)control involves analyzing and reporting of control samples supplied by an external agency, at a predefined time interval. The exact number of errors done by the laboratory in the analytical phase cannot be assessed by running internal and external QCs, but can be quantified using sigma metrics in the laboratory (3). Sigma in statistics is used to represent the standard deviation (SD) which is an indicator of the degree of variation in a set of processes. Sigma measures how far a given process deviates from perfection. Six-Sigma is one of the popular quality management system tools employed for process improvement. (4) A sigma value indicates the frequency of defects occurring in a process. Therefore, a higher sigma value translates in lower defects and a lower sigma value means a higher number of defects. A process is cited to be performing at 'world class' levels when it is functioning at levels of six-sigma.

The Six Sigma management method was proposed by Bill Smith (an engineer at Motorola), later introduced in China in the late 1990s and started to be applied in hospital management after 1999 (5).The main philosophy is based on a reduction of variation in a process, customer oriented and data driven decisions. In a 2013 review on improvements in quality and patient safety (6), Plebani emphasized the need for further improvements in analytical quality:

A better analytical quality should be achieved by setting and implementing evidence-based analytical quality specifications in everyday practice; if this will be done, rules for internal quality control and external quality assessment procedures would be more appropriate. Moreover, there is a compelling need for standardization programs aimed at improving metrological traceability and correcting biases and systematic errors. Finally, more stringent metrics, such as Six Sigma, should be largely introduced in clinical laboratories, to further improve current analytical quality.

Some studies have shown that sigma metrics can be applied to quantitatively evaluate errors or defects in testing projects in clinical laboratories, and the results are quantified as defects per million (DPMs) 3,4.

Six Sigma methodologies is an effective tool for evaluating the performanceof analytes and are conducive to quality assurance and improvement(7). It has been reported that Six Sigma methodology is an effective tool for evaluating the performanceof biochemical analytes and is conducive to quality assurance andimprovement(8). At the same time Actionsshould be taken to improve method performance for these parameters with sigma below 3sigma(9). Studies have been carried out to elicit the individual laboratory performance (10). Mao X et al.,in their study analysed 20 parameters over a period of five months and found “Six Sigma metrics can serve as a self-assessment method in guiding clinical laboratories to make QC strategy and plan QC frequency”.Similarly, Westgard JO and Westgard SA, in their study concluded that the EQC validation process will be greatly improved with the application of Six Sigma principal and metrics, and recommendations can be provide on the amount of QC scientifically which are needed for the laboratories (11).

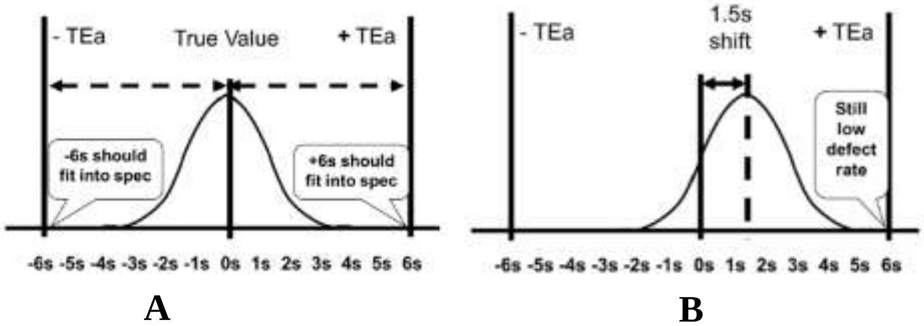



**Figure 2:-** A. How do you characterize the variation of an analytical testing process? B. How are defects predicted from the expected analytical variation?

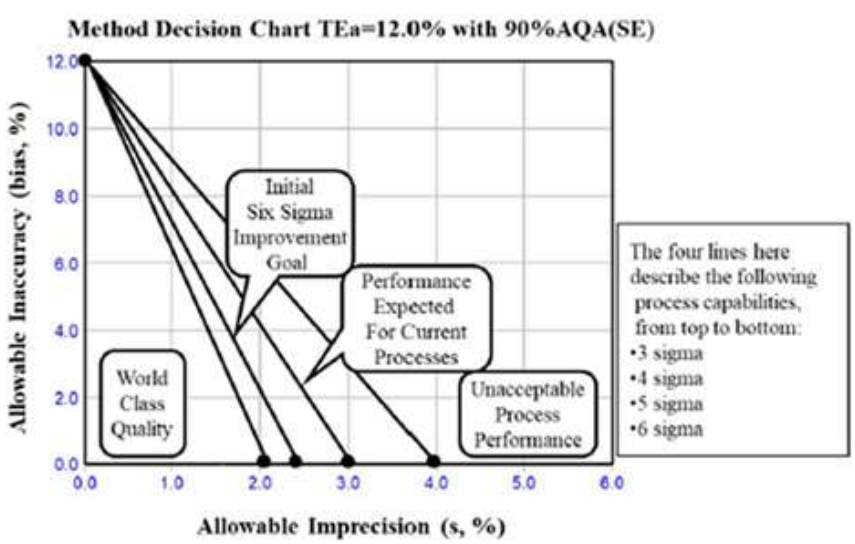



**Figure 3:-** Normalized Method Decision chart.

## Measurement:-

Six-Sigma metrics were measured and calculated using TEa as per the CLIA guideline from US and the biological variation database specification (12).

This was calculated by using formula, Sigma (σ)= (TEa-Bias %)CV%

Outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability and rationale:

The three purposes of QC measurements are monitoring the accuracy and precision of the analytical process and detection of immediate error. The standardized sigma values were categorized into six categories, i.e. world class ($\sigma \geq 6$), excellent ($5 \leq \sigma < 6$), good ($4 \leq \sigma < 5$), marginal ($3 \leq \sigma < 4$), poor ($2 \leq \sigma < 3$) and unacceptable ($\sigma < 2$) [4]. For each analyte, the sigma value was calculated and the quality of measurement was group according to sigma value.

The implementing QC is a continuous dynamic procedure, so that patient test results produced by the lab are reliable and contribute to patient care.

Operational definitions, and their validity and reliability-The performance of (47)analytes was evaluatedby calculating sigma values from the coefficient of variation (CV),bias, and total error allowable (TEa). In addition, root causeanalysis (RCA) were further performed to identify problems relatedto the measurement procedures for analytes with a sigmavalue below 4.

Describe how you planned to collect this data throughout your project and how frequently:

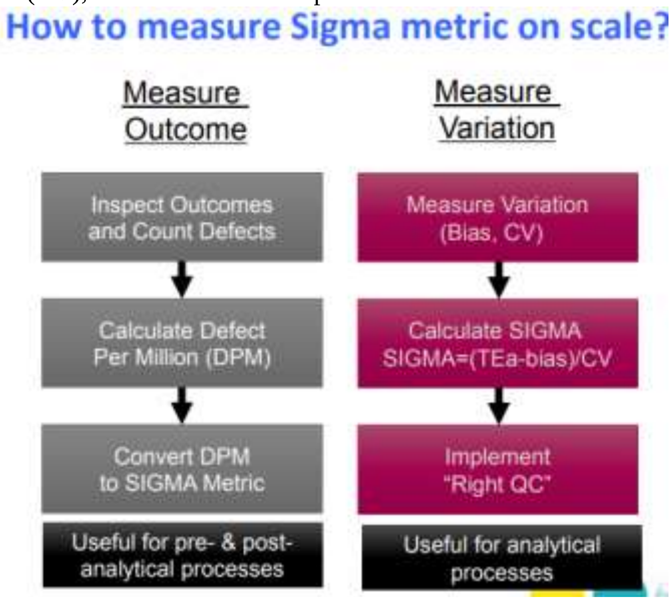
The present retrospective-prospective study was conducted at the Emergency Laboratory of King Fahd Armed Forces Hospital, Jeddah. A retrospective secondary data analysis of eight- month's duration (May to December 2021) was carried out in a clinical ED laboratory with a follow-up prospectively for eight months (January to August 2022).Based on real working conditions in routine performance measures were monitored daily, weekly, monthly, and quarterly followed by interventions and action plans accordingly The collected information for each analyte were tabulated in Microsoft (Unity Real-time control software tool, Bio-Rad QC-Net and EQA/CAP reports) on daily basis for the eight months period which performed on Alinity-ci system for Chemistry immunoassay analyzer(Abbott) andAlinity-hq for Hematology (Abbott) and Compact Max Stago for coagulation at our Emergency laboratory and advance analysis (QC sigma chart and RCA) were done in (http://www.westgard.com) The mean and Standard Deviation (SD) was calculated for each analyte.

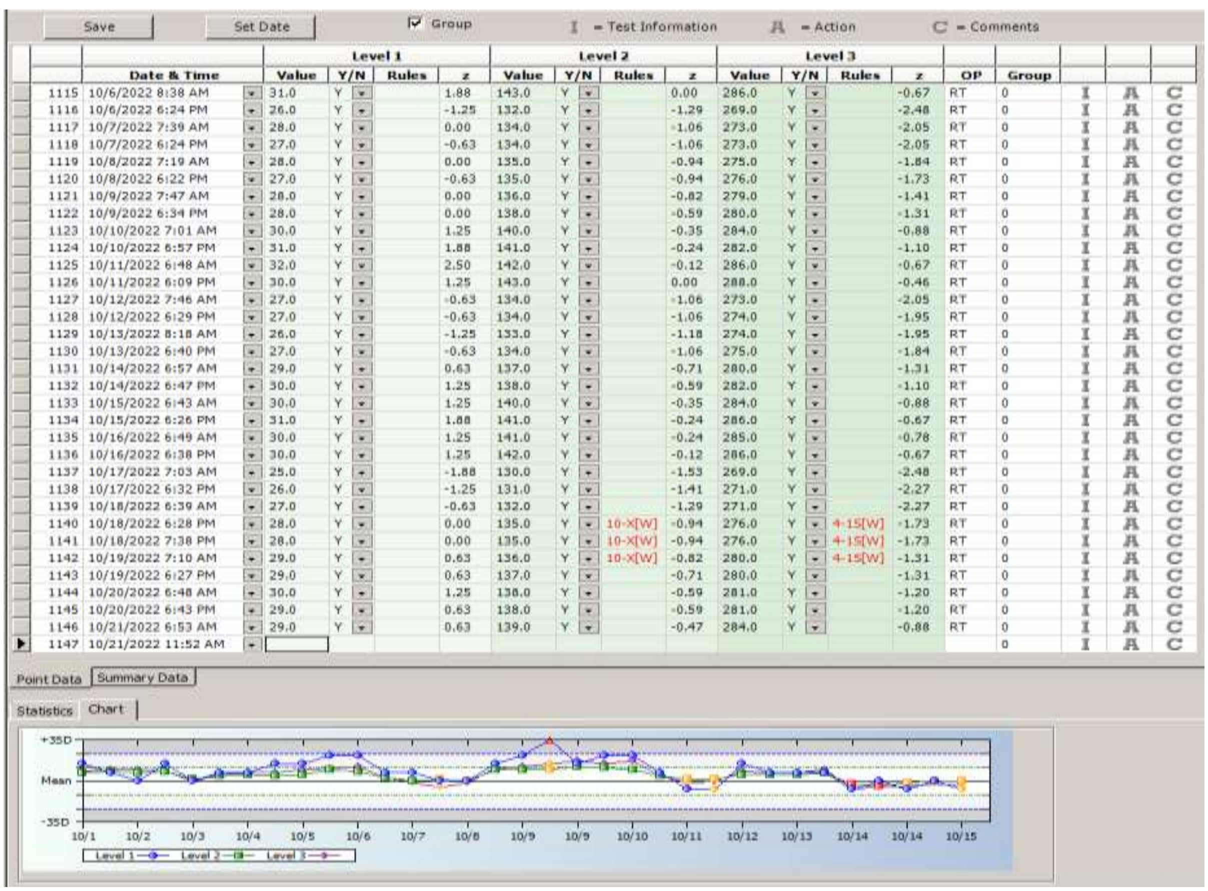
The following 47 analytes were tested using all analysis modules (27) chemistry, (2) immunoassay and (18) Hematology: albumin (ALB), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), Amylase (AMY), albumin (ALB), total bilirubin (TBIL), direct bilirubin (CBIL), Calcium (CA), carbon dioxide (CO2), C-Reactive Protein (CRP), Chloride (CL), Creatinine Kinase (CK), γ-glutamyl transferase (γ-GT), glucose (GLU), Iron (FE), lactate dehydrogenase (LDH), Lipase (LIP), lactate (LA), Magnesium (MG), Phosphorous (PO4), Potassium (K), Protein, Total (TP), blood urea (BUN), uric acid (UA), Ammonia (NH4), Ferritin (FERR), Hi sensitive Troponin (HSTI) and In addition, sodium (Na), potassium (K), and chlorine (Cl) were analyzed using the Integrated-chip technology (ICT) module andHemoglobin, MCV, MCH, Platelets, RBC, Eosinophil's and Neutrophils, HCT, WBC, RDW, Lymph, MONO, BASO, RETIC, APTT, FIB and PT.The daily internal quality control IQC material tested twice a day at 6:00 am and 6:00 pm. 3 Levels were purchased from Bio-Rad Laboratories Inc. Chemistry was [Bio-Rad: Multiqual (45870), Cardiac (67630), Immunoassay plus (85210), Ammonia (54320), while Haematology manufacture Abbott controls three level (11379), Latex coagulation (2186)]. External quality EQA/PT program data were collected from external quality assurance schemes of the collage of American pathology (CAP) for 2021. According to the requirements of external quality assessment (EQA) for clinical laboratories, CAP activities were implemented three times per year in the emergency laboratory routine projects conducted in our laboratory.

Outline how you planned to establish if the observed outcomes were due to your interventions:

Thus accumulative bias values data were obtained to calculate the average value, which was used to evaluate the system error in terms of accuracy for every analyte. In addition, it is worth noting that once the nonconformity of an

EQA/CAP activity (score < 80%) for an analyte was observed, the bias data for the corresponding analyte in the EQA/CAP activity would not be included in the analysis. All data must be submitted to Bio-Rad QC.net before 7th of each month and report will deliver after 15th monthly. Quality control data shall be reviewed at regular intervals to detect trends in examination performance; by Unity Real Time(URT) software provides a variety of charts of QC results and the Summary Data Report shows all monthly and cumulative statistics; (Level, Mean, Standard deviation (SD), Coefficient of variation (CV), and Number of data points for each test in the selected data set.




| | | Level 1 | | | | Level 2 | | | | Level 3 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Date & Time | Value | Y/N | Rules | z | Value | Y/N | Rules | z | Value | Y/N | Rules | z | OP | Group | | | |
| 1115 | 10/6/2022 8:38 AM | 31.0 | Y | | 1.88 | 143.0 | Y | | 0.00 | 286.0 | Y | | -0.67 | RT | 0 | I | A | C |
| 1116 | 10/6/2022 6:24 PM | 26.0 | Y | | -1.25 | 132.0 | Y | | -1.29 | 269.0 | Y | | -2.48 | RT | 0 | I | A | C |
| 1117 | 10/7/2022 7:39 AM | 28.0 | Y | | 0.00 | 134.0 | Y | | -1.06 | 273.0 | Y | | -2.05 | RT | 0 | I | A | C |
| 1118 | 10/7/2022 6:24 PM | 27.0 | Y | | -0.63 | 134.0 | Y | | -1.06 | 273.0 | Y | | -2.05 | RT | 0 | I | A | C |
| 1119 | 10/8/2022 7:19 AM | 28.0 | Y | | 0.00 | 135.0 | Y | | -0.94 | 275.0 | Y | | -1.84 | RT | 0 | I | A | C |
| 1120 | 10/8/2022 6:22 PM | 27.0 | Y | | -0.63 | 135.0 | Y | | -0.94 | 276.0 | Y | | -1.73 | RT | 0 | I | A | C |
| 1121 | 10/9/2022 7:47 AM | 28.0 | Y | | 0.00 | 136.0 | Y | | -0.82 | 279.0 | Y | | -1.41 | RT | 0 | I | A | C |
| 1122 | 10/9/2022 6:34 PM | 28.0 | Y | | 0.00 | 138.0 | Y | | -0.59 | 280.0 | Y | | -1.31 | RT | 0 | I | A | C |
| 1123 | 10/10/2022 7:01 AM | 30.0 | Y | | 1.25 | 140.0 | Y | | -0.35 | 284.0 | Y | | -0.88 | RT | 0 | I | A | C |
| 1124 | 10/10/2022 6:57 PM | 31.0 | Y | | 1.88 | 141.0 | Y | | -0.24 | 282.0 | Y | | -1.10 | RT | 0 | I | A | C |
| 1125 | 10/11/2022 6:48 AM | 32.0 | Y | | 2.50 | 142.0 | Y | | -0.12 | 286.0 | Y | | -0.67 | RT | 0 | I | A | C |
| 1126 | 10/11/2022 6:09 PM | 30.0 | Y | | 1.25 | 143.0 | Y | | 0.00 | 288.0 | Y | | -0.46 | RT | 0 | I | A | C |
| 1127 | 10/12/2022 7:46 AM | 27.0 | Y | | -0.63 | 134.0 | Y | | -1.06 | 273.0 | Y | | -2.05 | RT | 0 | I | A | C |
| 1128 | 10/12/2022 6:29 PM | 27.0 | Y | | -0.63 | 134.0 | Y | | -1.06 | 274.0 | Y | | -1.95 | RT | 0 | I | A | C |
| 1129 | 10/13/2022 8:18 AM | 26.0 | Y | | -1.25 | 133.0 | Y | | -1.18 | 274.0 | Y | | -1.95 | RT | 0 | I | A | C |
| 1130 | 10/13/2022 6:40 PM | 27.0 | Y | | -0.63 | 134.0 | Y | | -1.06 | 275.0 | Y | | -1.84 | RT | 0 | I | A | C |
| 1131 | 10/14/2022 6:57 AM | 29.0 | Y | | 0.63 | 137.0 | Y | | -0.71 | 280.0 | Y | | -1.31 | RT | 0 | I | A | C |
| 1132 | 10/14/2022 6:47 PM | 30.0 | Y | | 1.25 | 138.0 | Y | | -0.59 | 282.0 | Y | | -1.10 | RT | 0 | I | A | C |
| 1133 | 10/15/2022 6:43 AM | 30.0 | Y | | 1.25 | 140.0 | Y | | -0.35 | 284.0 | Y | | -0.88 | RT | 0 | I | A | C |
| 1134 | 10/15/2022 6:26 PM | 31.0 | Y | | 1.88 | 141.0 | Y | | -0.24 | 286.0 | Y | | -0.67 | RT | 0 | I | A | C |
| 1135 | 10/16/2022 6:49 AM | 30.0 | Y | | 1.25 | 141.0 | Y | | -0.24 | 285.0 | Y | | -0.78 | RT | 0 | I | A | C |
| 1136 | 10/16/2022 6:38 PM | 30.0 | Y | | 1.25 | 142.0 | Y | | -0.12 | 286.0 | Y | | -0.67 | RT | 0 | I | A | C |
| 1137 | 10/17/2022 7:03 AM | 25.0 | Y | | -1.88 | 130.0 | Y | | -1.53 | 269.0 | Y | | -2.48 | RT | 0 | I | A | C |
| 1138 | 10/17/2022 6:32 PM | 26.0 | Y | | -1.25 | 131.0 | Y | | -1.41 | 271.0 | Y | | -2.27 | RT | 0 | I | A | C |
| 1139 | 10/18/2022 6:39 AM | 27.0 | Y | | -0.63 | 132.0 | Y | | -1.29 | 271.0 | Y | | -2.27 | RT | 0 | I | A | C |
| 1140 | 10/18/2022 6:28 PM | 28.0 | Y | | 0.00 | 135.0 | Y | 10-X[W] | -0.94 | 276.0 | Y | 4-1S[W] | -1.73 | RT | 0 | I | A | C |
| 1141 | 10/18/2022 7:38 PM | 28.0 | Y | | 0.00 | 135.0 | Y | 10-X[W] | -0.94 | 276.0 | Y | 4-1S[W] | -1.73 | RT | 0 | I | A | C |
| 1142 | 10/19/2022 7:10 AM | 29.0 | Y | | 0.63 | 136.0 | Y | 10-X[W] | -0.82 | 280.0 | Y | 4-1S[W] | -1.31 | RT | 0 | I | A | C |
| 1143 | 10/19/2022 6:27 PM | 29.0 | Y | | 0.63 | 137.0 | Y | | -0.71 | 280.0 | Y | | -1.31 | RT | 0 | I | A | C |
| 1144 | 10/20/2022 6:48 AM | 30.0 | Y | | 1.25 | 138.0 | Y | | -0.59 | 281.0 | Y | | -1.20 | RT | 0 | I | A | C |
| 1145 | 10/20/2022 6:43 PM | 29.0 | Y | | 0.63 | 138.0 | Y | | -0.59 | 281.0 | Y | | -1.20 | RT | 0 | I | A | C |
| 1146 | 10/21/2022 6:53 AM | 29.0 | Y | | 0.63 | 139.0 | Y | | -0.47 | 284.0 | Y | | -0.88 | RT | 0 | I | A | C |
| 1147 | 10/21/2022 11:52 AM | | | | | | | | | | | | | | 0 | I | A | C |

**Figure 4:-** Daily monitoring (Pre-Improvement).

Review the data of IQC using a Levey-Jennings Chart by Technologists, such as an example below; ALP period from 1st to 30th of October 2021 have been reviewed and managed by westgard rules.

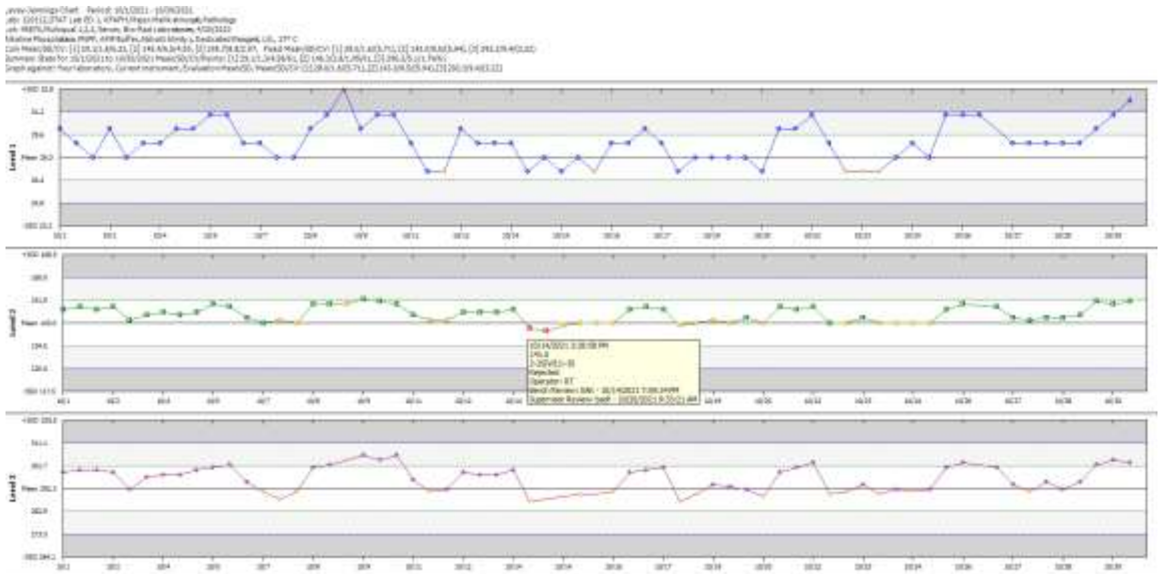


**Figure 5:-** Levey Jennings Chart showing three levels mean as grey line, at ±3 SD (daily monitoring,(Pre-Improvement).

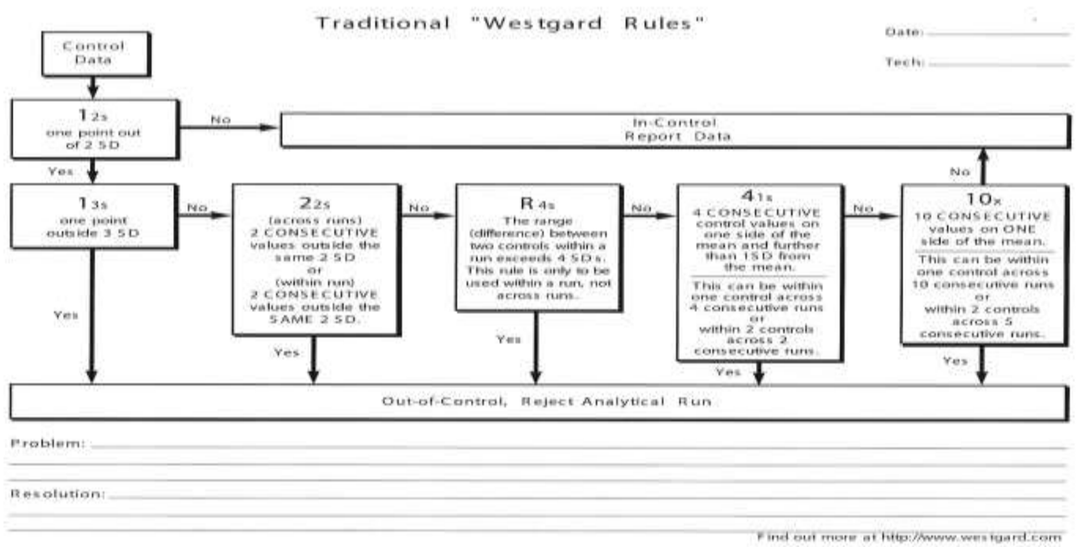
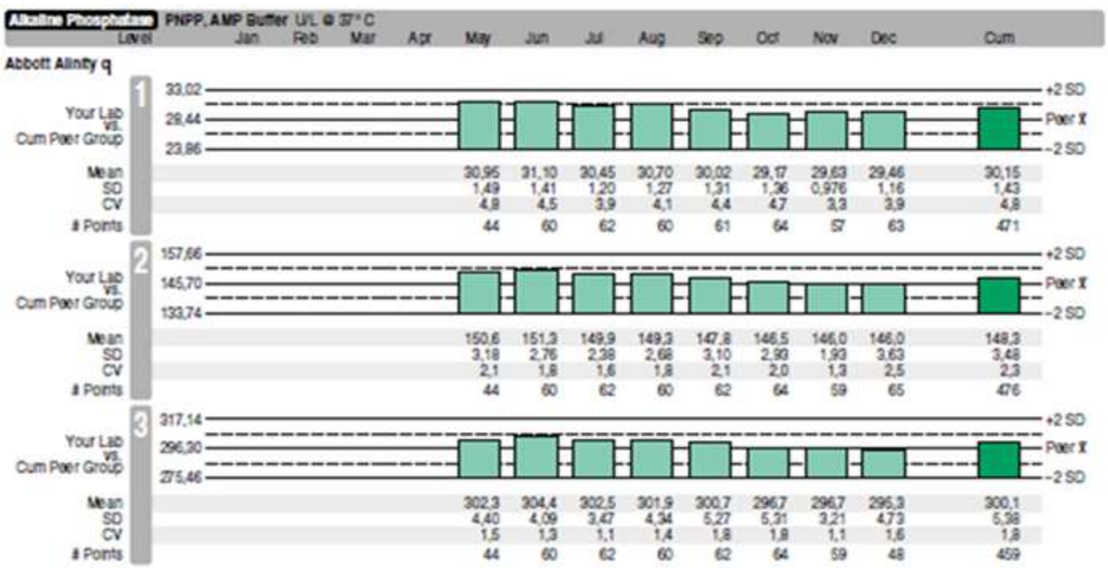



**Table 2:-** Showing different Westgard rules and their implications. These rules to monitor test performance, to evaluate data points against the active SPC rules to determine whether to accept or reject the data.

| **Rule Violation** | What does it mean | Type of Error ( Systematic or Random) | Alarm produced (Accepted/ Reject) |
|---|---|---|---|
| **1 2S** | One level of control is outside the ±2SD limits | random or systematic | Accept/warning rule |
| **1 3S** | One level of control is outside the ±3SD limits | random error or / beginning of a large systematic error | Reject rule |
| **2 2S** | • Two consecutive QC results<br>• Greater than 2SD | systematic error | Rejection rule |

| | | | |
|---|---|---|---|
| | • On the same side of the mean | | |
| **R 4S** | Two levels of control show a difference of 4 SD.<br>There is at least a 4SD difference of value between two control levels within a single run. | random error | Rejection rule |
| **10X** | rules are violated when there are 10 control results on the same side of the mean regardless of the specific standard deviation that they are located in. | systematic error | Rejection rule<br>(this rule can be applied within a control level or across control levels indicating systematic bias over a particular range or over broader analytical range respectively)<br>Indicates the need to perform instrument maintenance or reagent calibration**.** |




| Analyte | TEa% | Source | Bias % | CV % | Sigma | QC Level | Existing Rules | False Rejection |
|---|---|---|---|---|---|---|---|---|
| ALB | 10% | CLIA | 5.03 | 2.59 | 3. 7 | 3 | 1-2s/13s/ 2-2s/ 4S/41S/10X | 3.18% |
| ALP | 30% | CLIA | 5.66 | 4.64 | 5.24 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.11% |
| ALT | 20% | CLIA | -2.36 | 2.88 | 6.12 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.02% |
| AMY | 30% | CLIA | 2.97 | 3.49 | 7 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| AST | 20% | CLIA | 0.931 | 2.32 | 8.22 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| CBIL | 44.50% | CLIA | 2.04 | 4.37 | 14 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| TBIL | 22% | BV | 6.1 | 6.35 | 9.58 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| CA | 0.2495 mmol/l | CLIA | -2.31 | 0.853 | 6.35 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.02% |
| CO2 | 20% | CLIA | 2.81 | 9.79 | 3.8 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| CK | 30% | CLIA | 1.9 | 1.39 | 10.3 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| CRE | 15% | CLIA | -2.82 | 3.02 | 12 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| NA | 4 mmol/l | CLIA | 0.715 | 0.713 | 3.93 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 2.78% |
| K | 0.5 mmol/l | CLIA | -0.577 | 0.81 | 23.1 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| CL | 5% | CLIA | 1.07 | 0.854 | 4.6 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 1.08% |
| GGT | 25% | CLIA | -8.95 | 1.67 | 10 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| GLU | 10% | CLIA | 0.146 | 20.7 | 0.476 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| Iron | 20% | CLIA | -2.53 | 1.29 | 13.5 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.00% |
| LDH | 20% | CLIA | 4.96 | 3.05 | 4.93 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.83% |
| LA | 30.40% | BV | 1 | 2.94 | 5 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 9.00% |
| MG | 25% | CLIA | 0.227 | 16 | 1.55 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 6.49% |
| PO4 | 10.0% | CLIA | -1.27 | 3.38 | 4.12 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 2.68% |
| TP | 10% | CLIA | 2 | 2 | 4 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.03% |
| UREA | 9% | CLIA | -2.9 | 2.47 | 4.15 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 2.68% |
| UA | 17% | CLIA | -1.63 | 3.13 | 4.92 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.83% |
| LIP | 29.1% | CLIA | 10.16 | 6.63 | 1.33 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 8.09% |
| NH4 | 10% | RCPA | 9.07 | 4.75 | 0.42 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 5.4 % |
| **C-RP** | 56% | CRP | 4.77 | 13.21 | 5.12 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 0.01 |
| **FERR** | 16.9% | BV | 8.93 | 6.26 | 0.14 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 4.6 % |
| **HSTI** | 41.90% | BV | 5.6 | 7.1 | 7.2 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X | 4.8 % |

**Table 3**:- Summarizing the Total allowable error (TEa), precision (CV %), bias % and sigma metrics values (degree of variation in a set of processes) for the controls tested (Pre-Sigma procedure); Chemistry Assays on Alinity-ci analyzer.
*Bias %=( Measured value-Target value)*100/Target value, Bias% value obtained from external quality evaluation

| **Analyte** | **TEA** | **Source** | **Bias* %** | **CV %** | **Sigma**** | **QC Level** | **Existing Rules** |
|---|---|---|---|---|---|---|---|
| HGB | 7.0% | CLIA | 4.25 | 3.36 | 2.69 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| HCT | 6% | CLIA | 2.0 | 2.44 | 3.20 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| **MCV** | 10% | ESFEQA | 1.90 | 3.02 | 8.30 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| MCH | 9% | ESFEQA | 2.57 | 2.18 | 3.03 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| MCHC | 7% | ESFEQA | 2.25 | 2.93 | 4.01 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| **PLT** | 25% | CLIA | 1.26 | 1.22 | 6.03 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| **RBC** | 6% | CLIA | 1.20 | 1.24 | 5.0 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| WBC | 15% | CLIA | 1.5 | 1.48 | 2.36 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| RDW | 1% | ESFEQA | 4.18 | 2.60 | 2.24 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| APTT | 15% | CLIA | 1.67 | 2.79 | 2. 64 | 2 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| FIB | 20% | CLIA | 2.57 | 2.18 | 3.41 | 2 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| PT | 15% | CLIA | 4.25 | 2.69 | 4.0 | 2 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| Lymph | 17.60% | BV | 2.25 | 2.93 | 4.01 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| MONO | 27.90% | BV | 2.57 | 2 | 3.72 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| EOS | 37.10% | BV | 2.91 | 2.03 | 3.49 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| BASO | 38.50% | BV | 1.67 | 2.78 | 2.64 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| RETIC | 16.50% | BV | 2.25 | 3.54 | 2.19 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |
| NEUT | 23.35 | BV | 4.18 | 3.30 | 1.76 | 3 | 1-2s/13s/ 2-2s/R4S/41S/10X |

for eight months (May to December 2021) **Sigma= (TEa%-Bias %) /CV%

**Table 4**:- Summarizing the Total allowable error (TEa), precision (CV %), bias % and sigma metrics values (degree of variation in a set of processes) for the controls tested (Pre-Sigma procedure); Hematology Assays on Alinityhq and Stago.
*Bias %=( Measured value-Target value)*100/Target value, Bias% value obtained from external quality evaluation for **eight months (May to December 2021)** **Sigma= (TEa%-Bias %) /CV%

**Design:**
It was clear that the practice had to make a decision of using a quick and reliable validated tool to assess patient's results and reliability. Most of the practitioners were amenable to the change.

K.F.A.F.H, King Fahd Armed Forces Hospital, Emergency laboratory has submitted an update of the performance data for chemistry and Hematology assays. It also has provided technical and managerial data, as well as designating four Quality Managers of the ED lab who have assumed the responsibility of assuring quality and implementing

Sigma metric and QC design for the laboratory. Those Quality Managers were given an access to competency exams on the Westgard course portal **(Figure.8)**

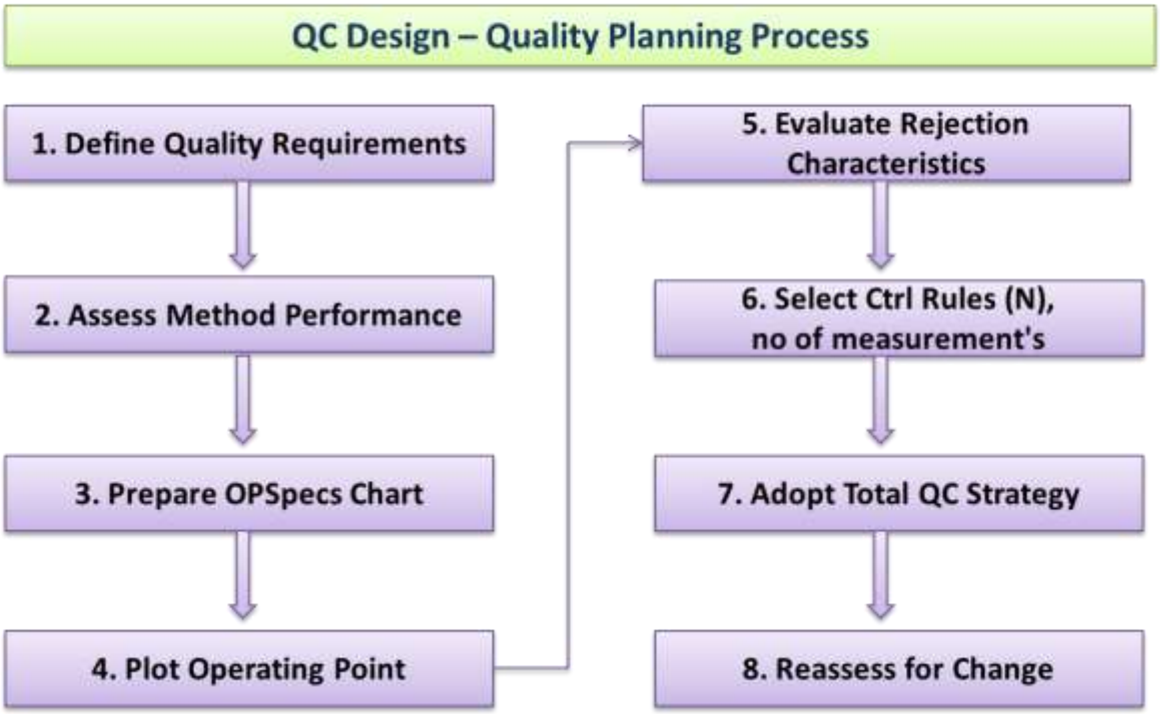



**Figure 8:-** Six-Sigma Quality Management System.

**Construction of the standardized QC sigma charts:**

1. The frame of the standardized QC sigma charts was constructed by registering An ED laboratory in Westgard sigma VP account in (http://www.westgard.com) for one year and inputting parameters such as TEa, bias, and CV in the interface of the Six Sigma management menu.
2. The construction of the standardized QC sigma charts obeyed the concept of previously reported studies.
3. This approach allows a laboratory to obtain an audiovisual and comprehensive view of the performance of all the analytes in a single graph at every control measurement level and with every instrument module.
4. Westgard QC assessed those metrics and determined which assays were 4 Sigma and better at critical decision levels. Those assays which meet these criteria are now considered to be verified.

| **Plan for Verification of Sigma Quality** | |
|---|---|
| **1** | • Operate instrument and methods with **all manufacturers recommended** service, maintenance, calibrators, reagents, etc.<br>• **Third-party reagent** is **not** eligible for Sigma Verification.<br>• In contrast, the use of **independent controls** is required. |
| **2** | • Identify **personnel** who will be **responsible** for defining quality requirements, evaluating method performance, and establishing SQC procedures.<br>• The lab must designate a **minimum of 2 and up to 4** Quality Managers who are responsible for assessing and implementing Sigma-metric analysis of method performance.<br>• The laboratory Quality Managers must **pass online exams** covering **Basic QC Practices** and **Six Sigma QC Design and Control**. |
| **3** | • Define quality goals and requirements for intended use for ED –STAT laboratory examination. |
| **4** | • Evaluate **analytical performance of examination procedures** against the defined **quality requirements** following **standard method evaluation** and **quality control principles** and practices. [A **minimum of 100 data** points or approximately **3 months** of **routine operational** data is required |

| | |
|---|---|
| | to evaluate performance.]<br>• Quality Controls must be from a third-party source. Manufacturer controls are **not acceptable** as an indicator of method imprecision. |
| **5** | • Assess quality on the **sigma-scale** using a **Sigma Method Decision Chart** to determine the **sigma metric** from the performance data collected in ED-STAT laboratory and judge acceptability. |
| **6** | • Select SQC procedures for a test and the **precision** and **bias** observed for the **examination procedure**.<br>• Utilize a Chart of Operating Specifications or other QC Design tool to select appropriate control rules and the total number of control measurements needed to detect medically important errors.<br>**[Laboratories will submit the charts or Sigma metrics and appropriate rule choices, as well as evidence that these rules have been implemented on the instrument to Westgard QC]** |
| **7** | • Submit a **request** to **Westgard QC** to **verify** the laboratory's claim for quality on the **sigma scale** and its application of appropriate SQC procedures.<br>• Laboratories should submit a list of at least **20 assays** that can achieve verification. These assays must be from manufacturer's intended reagent – no third-party reagent is considered acceptable for verification |
| **8** | • Include and implement **specified Quality Policies** in the **ED-STAT laboratory's Quality Manual.** |
| **9** | • Provide Westgard QC with updated information on Sigma performance if major changes occur.(i.e. instrument malfunctions, changes in instrumentation or methodology, etc.)<br>• The Verification will **not be** considered active if Westgard QC is **not informed** of such changes. |

**Describe any reasons or assumptions that were used to develop the intervention(s) and reasons why you expected them to work:**
Statistical analysis: for Evaluating test performance in terms of method precision and bias are done as per the following equations as shown below:

| Test performance | formula | Source collection | Function |
|---|---|---|---|
| **Bias** | **Bias** = (mean of peer group −lab's mean) /mean of peer group) X 100 % | calculated from the EQC data | |
| **CV** | **CV%** = (Standard deviation /Laboratory mean) X 100 % | calculated from the calculated laboratory mean and calculated standard deviation procured from the internal quality control data over preceding months | Used to compare precision, to check manufacturer's claims, peer group QC report and as a part of internal quality control. A test with high standard deviation means poor precision, greater instability and high random error in the laboratory. |
| **EQA activity** | **Bias (%)** = (∣measurement value−target value∣∕target value) ×100. | The median of the EQA results reported by clinical laboratories that used the same type of instrument and method was used as the target value for every analyte. | |
| **Prediction of performance of QC procedure** | Using operational process specifications (OPSpecs) charts.<br>Using the TEa, precision and accuracy of an analyte, optimal Westgard rule can be selected using OPSpecs charts. | Available in the Westgard website at: www.westgard.com. | These charts describe operational limits for imprecision and inaccuracy for specific QC procedure. |
| **TEa** | The TEa was determined according to the proficiency testing criteria | | |

| | | | |
|---|---|---|---|
| | of American Clinical Laboratory Improvement Amendment 88 (CLIA88). | | |
| **Selecting an appropriate QC procedure** | The appropriate IQC procedure is one having a 90% chance of detecting medically important errors (Ped≥0.90) and a 5% chance of false rejection (Pfr≤0.05), preferably 1 % or less. | is done with sigma metrics | |
| **Sigma metrics** | Sigma=_TEa−Bias_⁄CV. | Westgard VP QC.Co | to reduce the variation in analytical process |

| | **Key concepts and principles that must be adopted include the following:** |
|---|---|
| 1 | **Six Sigma** concept of measuring variation processon **sigma scale** |
| 2 | **Define** of **"tolerance limits"** for analytical specifications in the form of an **Allowable Total Error (TEa)** |
| 3 | **Calculation** of a **"sigma-metric"** from the **"tolerance limits" (TEa)** for the process (bias) and (SD) observed:<br>**Sigma = [(TEa – bias)/SD]** where all terms are in concentration units, or<br>**Sigma = [(%TEa-%Bias)/%CV]** |
| 4 | **Utilization** of **the sigma-metric** in the assessment of the performance of **examination procedures** and the **selection** and **design of SQC** procedures (control rules, number of control measurements) |

The exactnumber of defects or errors done by the laboratory canbe quantified using sigma metrics in the laboratory. Thelevel of sigma metrics and the corresponding defects permillion tests is shown in Table 5.

Table 5: Level of Sigma metrics by percentage.

| Sigma metric | Percent defects | Percentage yield |
|---|---|---|
| **1** | 69 % | 31 % |
| **2** | 31 % | 69 % |
| **3** | 6.7 % | 93.3 % |
| **4** | 0.62 % | 99.38 % |
| **5** | 0.023 % | 99.977 5 |
| **6** | 0.00034 % | 99.99966 % |

**Project Timeline:**

The implementation teem met every month during the cycles to monitor the implementation of the project. Also the providers and the staff were educated about the tool, its validity and questions about the clinical flow were answered. New quality team and staff got orientation from the Westgard QC, Inc and Bio-Rad team and laboratory director was also included in the monthly meeting.

..\SIGMA (2021-2022)\PROJECT ACTION PLAN ED STAT sigma(2021-2022).docx

https://docs.google.com/document/d/1OuXgKS92kw0a7aTGGDeoUABXLIOp5cKc

**Did you anticipate/predict any problems at this stage?**RCA was performed with plotting ofcause-effect diagram of the various process performed at clinicallaboratory i.e. from beginning of sample collection to report deliveryto the patient. Following the analysis, corrective measures weretaken as per problem identifiedReasons for the potential cause and effect for the low sigma value (<3) of some analytes are illustrated in cause-effect chart (Fish-bone diagram) **fig.9**

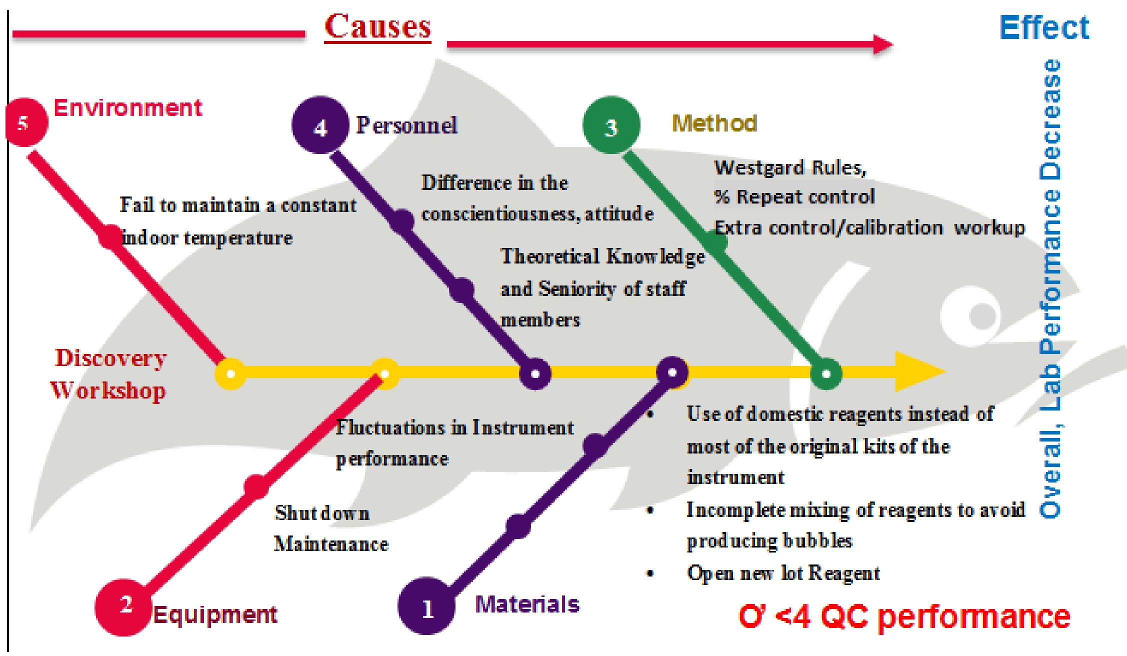



**Figure 9:-** Cause-effect chart (Fish-bone diagram) for the potential cause and effect for the low sigma value of some analysis.

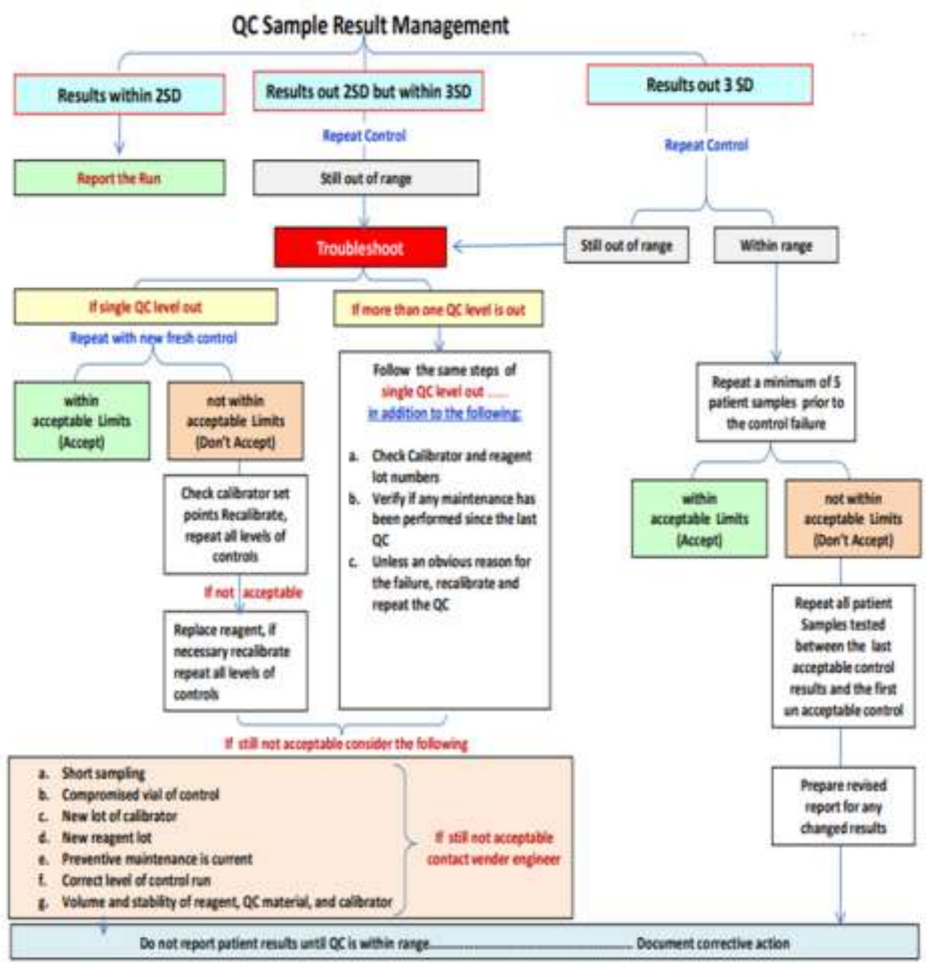



**Figure 10:-** Plane for Quality Control validation intervention sustainable (QC results management).

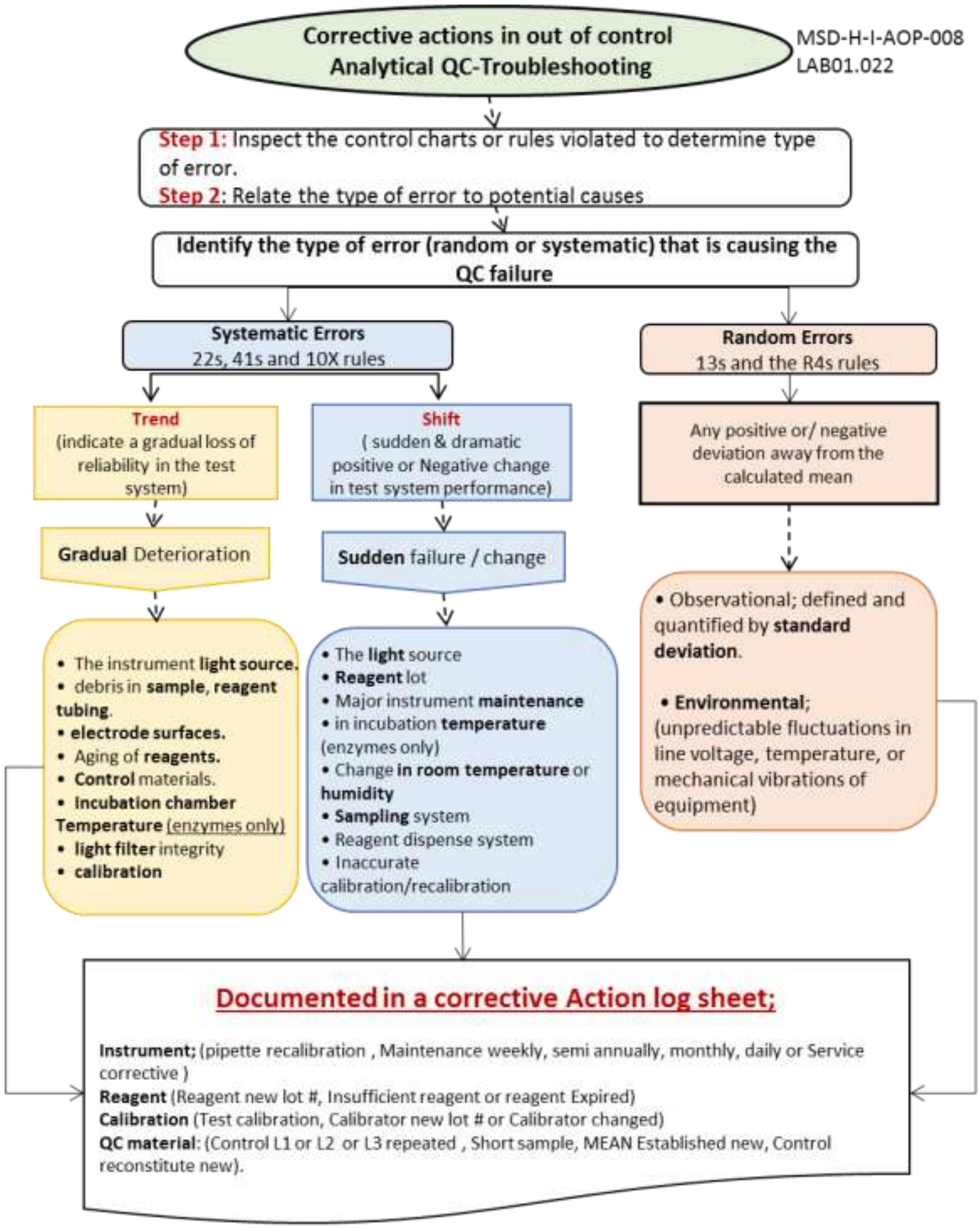



**Figure 11:-** Plan for Quality Control validation intervention sustainable (Corrective action of out of QC).

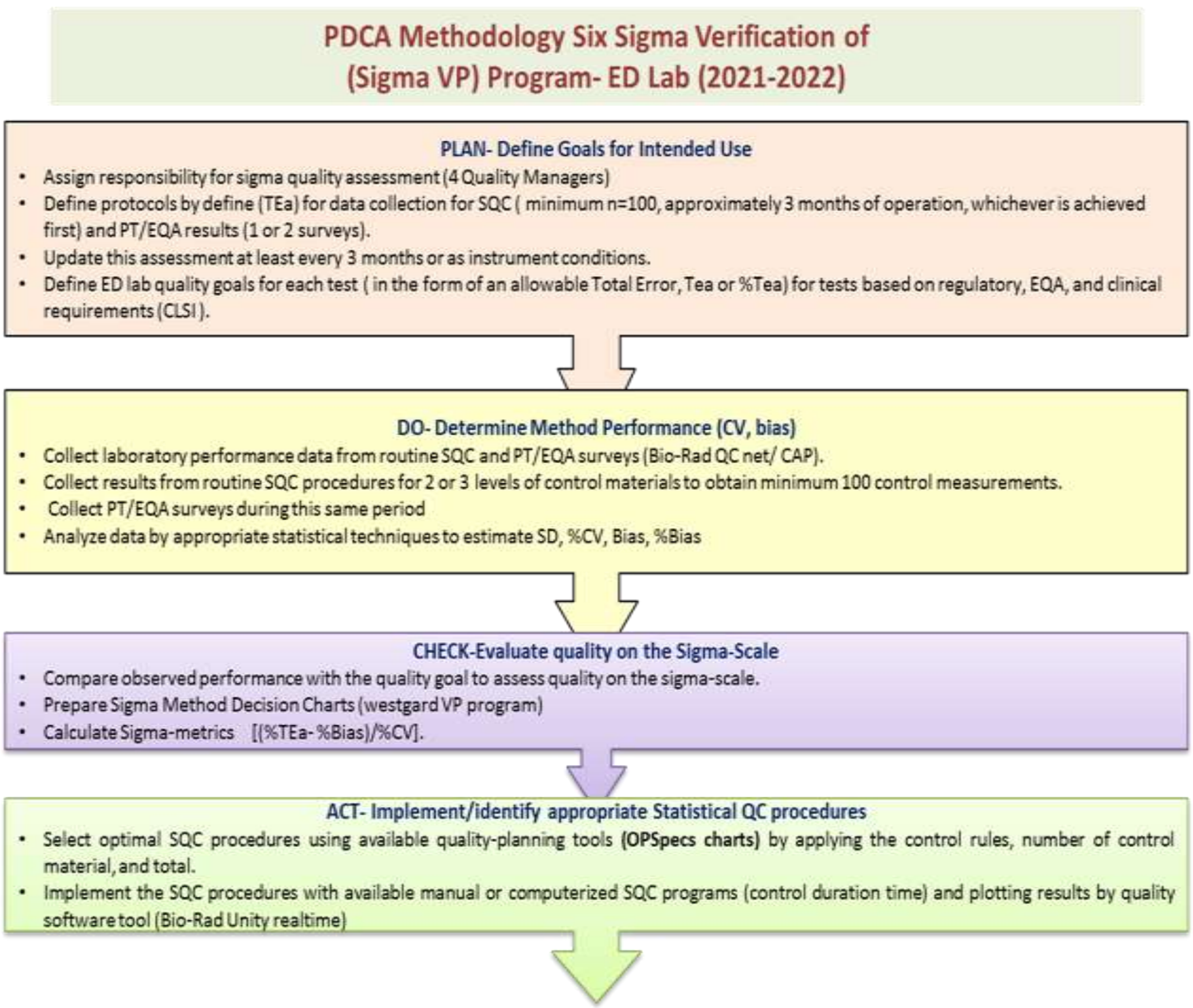
**Strategy:**

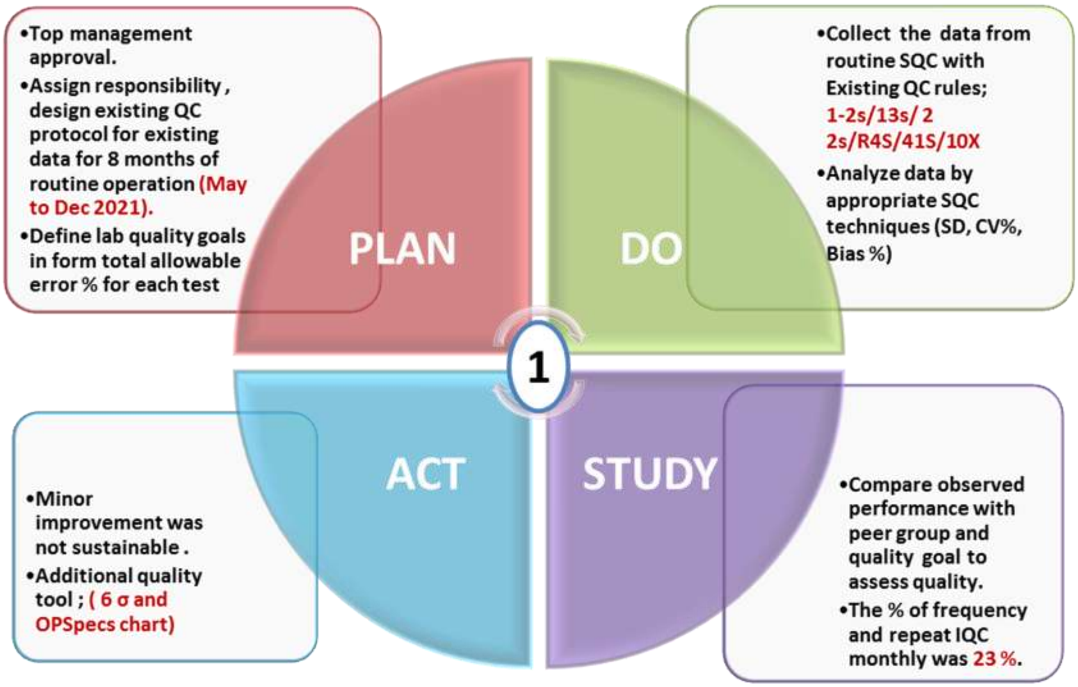
**The PDCA cycles Quality improvement method was used for this project:**

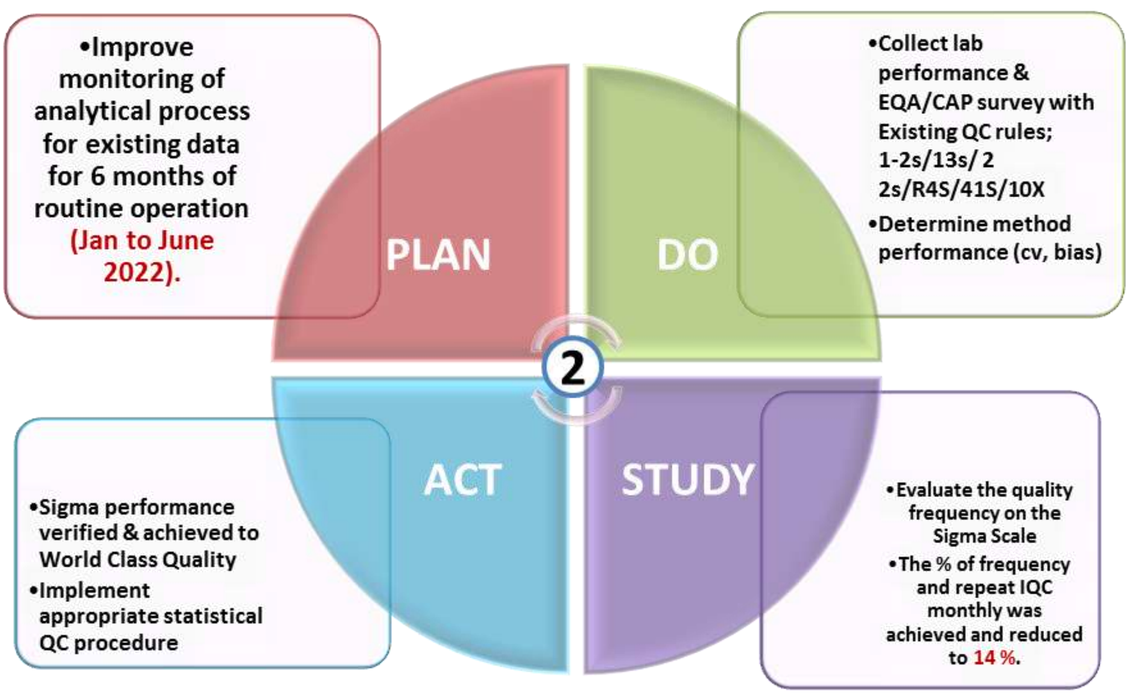
**PDCA cycle 1**: our initial intervention or any efforts to improve quality was to reduce Patient result TAT after monitoring the Internal quality control to achieved from (60 minutes) to be less and that require the commitment of top management and must assess current management testing analytical practices to identify the need for improvement of examination procedures. Top management approval and assign responsibility , design existing QC protocol for existing data for 8 months of routine operation (May to Dec 2021).. Define lab quality goals in form total allowable error % for each test.Collect the data from routine SQC with Existing QC rules; (1-2s/13s/ 2 2s/R4S/41S/10X) Analyze data by appropriate SQC techniques (SD, CV%, Bias %).Compare observed performance with peer group and quality goal to assess quality. The % of frequency and repeat IQC monthly was 23 %. Minor improvement was not sustainable. Additional quality tool; (6 σ and OPSpecs chart).

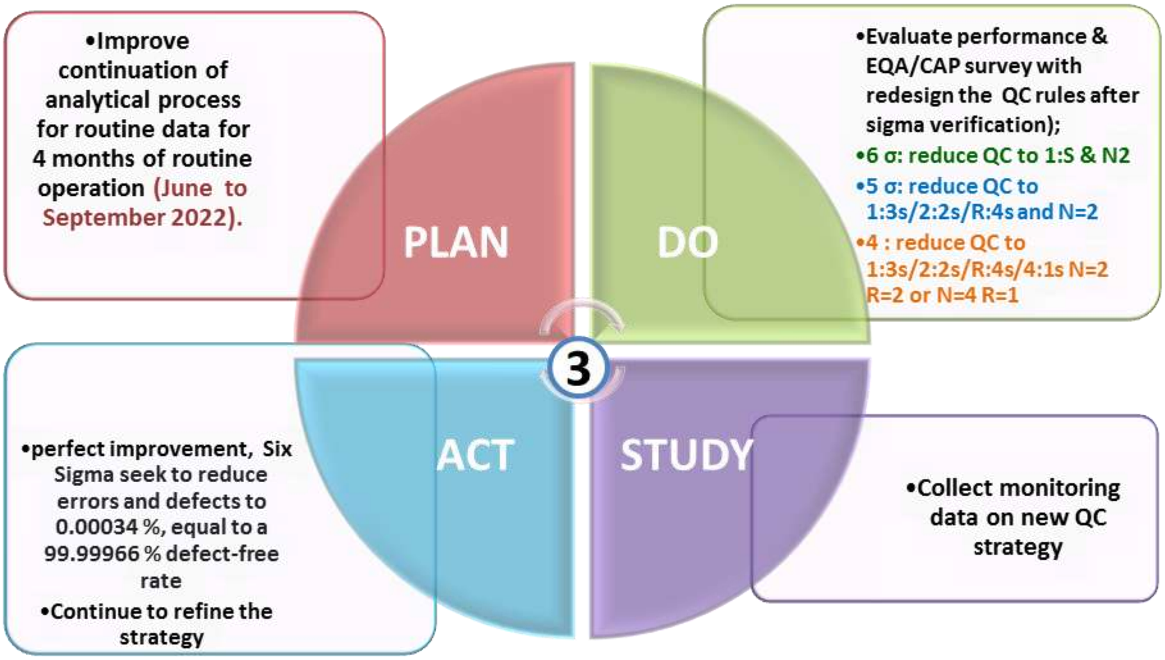
**PDCA cycle 2**: Improve monitoring of analytical process for existing data for 6 months of routine operation (Jan to June 2022). Collect lab performance & EQA/CAP survey with Existing QC rules; 1-2s/13s/ 2 2s/R4S/41S/10X. Determine method performance (cv, bias). Evaluate the quality frequency on the Sigma Scale. The % of frequency and repeat IQC monthly was achieved and reduced to 14 %. Sigma performance verified & achieved to World Class Quality. Implement appropriate statistical QC procedure

**PDCA cycle 3**Improve continuation of analytical process for routine data for 4 months of routine operation (June to September 2022). Evaluate performance & EQA/CAP survey with redesign the QC rules after sigma verification);
6 σ: reduce QC to 1:S & N2
5 σ: reduce QC to 1:3s/2:2s/R:4s and N=2
4 σ: reduce QC to 1:3s/2:2s/R: 4s/4:1s N=2 R=2 or N=4 R=1.
Collect data on new QC strategy. Perfect improvement, Six Sigma seeks to reduce errors and defects to 0.00034 %, equal to a 99.99966 % defect-free rate. Continue to refine the strategy.




•Top management approval.
•Assign responsibility, design existing QC protocol for existing data for 8 months of routine operation (May to Dec 2021).
•Define lab quality goals in form total allowable error % for each test
PLAN
DO
•Collect the data from routine SQC with Existing QC rules; 1-2s/13s/2 2s/R4S/41S/10X
•Analyze data by appropriate SQC techniques (SD, CV%, Bias %)
1
ACT
STUDY
•Minor improvement was not sustainable.
•Additional quality tool; ( 6 σ and OPSpecs chart)
•Compare observed performance with peer group and quality goal to assess quality.
•The % of frequency and repeat IQC monthly was 23 %.


•Improve monitoring of analytical process for existing data for 6 months of routine operation (Jan to June 2022).
PLAN
DO
•Collect lab performance & EQA/CAP survey with Existing QC rules; 1-2s/13s/2 2s/R4S/41S/10X
•Determine method performance (cv, bias)
2
ACT
STUDY
•Sigma performance verified & achieved to World Class Quality
•Implement appropriate statistical QC procedure
•Evaluate the quality frequency on the Sigma Scale
•The % of frequency and repeat IQC monthly was achieved and reduced to 14 %.




Six Sigma methodology also encompass robust techniques Requires Five Steps for Quality Improvement such as, Define-Measure-Analyze- Improve-Control **(DMAIC)** to reduce the variation during the processes as shown below.

**Table 6:-** Summary of the ED Laboratory project DMAIC phases.

| phase | Description | outputs | Tools & techniques |
|---|---|---|---|
| **Define** | - IQC Frequency and repeat the QC measurements according the rules, that led to delay TAT of patient results.<br>- The main goal to reduce the variation, cost effective and frequency of IQC.<br>- Training to all (user & quality managers) | - Action plan (2021-2022)<br>- Six Sigma committee<br>- project charters (goals)<br>- flow charts<br>- Sigma metrics: initial estimate | brainstorming |
| **Measure** | - data gathering regarding the current situation<br>- Identification of possible causes of frequent repeat (IQC, calibration reagent). | - Data collected for eight month<br>- Sigma metrics: initial assessment (next nine months) | - Bio-Rad Unity real-time, control charts |
| **Analyze** | - collect & analyze the data<br>- identification of relationships among variables | - brainstorming sessions<br>- Ishikawa diagram | - logical analysis<br>- Ishikawa diagram |
| **Improve** | - prioritization of causes through RCA<br>- definition of improved process<br>- Implement the sigma scale tool | corrective actions plan<br>process standardization | OPSpecs chart, Decision limit chart&RCA |
| **Control** | - Validate& verify the improvement by monitoring and transfer the impact of reducing the cost to the team and management.<br>- project closure | - metric assessment of improved process<br>- monitoring plan of implemented corrective actions | Optima SQC procedure using OPSpecs chart and available computerized SQC program |

## Results:-

According to the sigma level, the performance of the analytes was divided into six grades, namely world class ($\sigma \geq 6$), excellent ($5 \leq \sigma < 6$), good ($4 \leq \sigma < 5$), marginal ($3 \leq \sigma < 4$), poor ($2 \leq \sigma < 3$), and unacceptable ($\sigma < 2$), as shown **in (Figures 1&2).**

**Table 7 summarizes** that the **Chemistry Alinity-ci** module, 21 of the 29 analytes showed a performance of 6 to at least 4σ at QC material Levels, and six of these analytes (ALP, ALT, AMY, AST, DBIL, CA, CRP, GGT, CK, GLU, FE, LIP, MG, PO4, K and TP) presented**6σ(world-class)** performance. In addition, One of the 21 analytes showed a performance of at least **5σ(Excellent**). While 4 of 21 analytes showed a performance of at least **4σ (good**) at QC material Levels. Moreover, 7 of 18 **hematology**analytes showed a performance of at least **4σ (good)** at QC material Levels, and four of these 7 analytes (MCV, PLT, RBC and Eos) presented **world-class** performance. In addition 3 of 7 analytes (HB, MCH and Neutrophils) presented **4σ (good**) a performance. **(Table 9 &10 and Figure …) summarizes** The data demonstrated that the performance of 20 chemistry and Hematology analytes reached the Six Sigma level in all analysis modules and at all QC material levels and that 18 analytes exhibited σ < 4 (poor performance ) at one or all QC material levels.

To further detect the root causes of the problems with theseanalytes, a cause-effect chart was used as a technical tool As shown in Figure 3, five aspects of potential root causes, including aspects related to methodology, materials, personnel, equipment, and working conditions, were investigated.

The same staff members worked under the same conditions using the same QC material level, the same domestic brand of reagents (with the exception of the Hematology and Coagulation using the manufacture control material). Therefore, reevaluating and improving the methodology used for the analytes would improve the quality.

**Table 7:-** QC procedures selected for Sigma matrix of chemistry analytes for all levels (3 Levels) calculated by westgard verification program.

| Analyte | Existing Rules | Sigma Verified | suggested rules | Problem |
|---|---|---|---|---|
| ALB | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| ALP | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| ALT | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| AMY | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| AST | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| CBIL | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| TBIL | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Imprecision |
| CA | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| CO2 | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Inaccuracy |
| CK | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| CRE | 1-2s/13s/ 2-2s/R4S/41S/10X | **five sigma** | 1:3S/2:2S/R:4Sand N=2 | Imprecision & inaccuracy |
| NA | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| K | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| CL | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Imprecision |
| GGT | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| GLU | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| Iron | 1-2s/13s/ 2- | **six sigma** | 1:3s and N=2 | None |

| | | | | |
|---|---|---|---|---|
| | 2s/R4S/41S/10X | | | |
| LDH | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Imprecision & inaccuracy |
| LA | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Inaccuracy |
| MG | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| PO4 | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| TP | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| UREA | 1-2s/13s/ 2-2s/R4S/41S/10X | **five sigma** | 1:3S/2:2S/R:4Sand N=2 | Imprecision |
| UA | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Inaccuracy |
| LIP | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| NH4 | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Inaccuracy |
| **C-RP** | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| **FERR** | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision & inaccuracy |
| **HSTI** | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Inaccuracy |

**Table 8:-** QC procedures selected for hematology analytes Sigma matrix for all levels (3 Levels) calculated by westgard verification program.

| Analyte | Existing Rules | Sigma Verified | suggested rules | Problem |
|---|---|---|---|---|
| HGB | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Imprecision |
| HCT | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| MCV | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| MCH | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Imprecision |
| MCHC | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| PLT | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| RBC | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| WBC | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| RDW | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| APTT | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| FIB | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| PT | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| Lymph | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| MONO | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2- | Imprecision |

| | | | | |
|---|---|---|---|---|
| | | | 2s/R4S/41S/10X | |
| EOS | 1-2s/13s/ 2-2s/R4S/41S/10X | **six sigma** | 1:3s and N=2 | None |
| BASO | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| RETIC | 1-2s/13s/ 2-2s/R4S/41S/10X | < 4 sigma | 1-2s/13s/ 2-2s/R4S/41S/10X | Imprecision |
| NEUT | 1-2s/13s/ 2-2s/R4S/41S/10X | **four sigma** | 1:3S/2:2S/R:4S/4:1Sand N=2 | Imprecision |

Six Sigma: World Class Quality, possible to reduce QC to 1:3s and N=2
Five Sigma: Excellent Quality, possible to reduce QC to 1:3s/2:2s/R:4s and N=2
Four Sigma: Good Quality, possible to reduce QC to 1:3s/2:2s/R:4s/4:1s N=2 R=2 or N=4 R=1

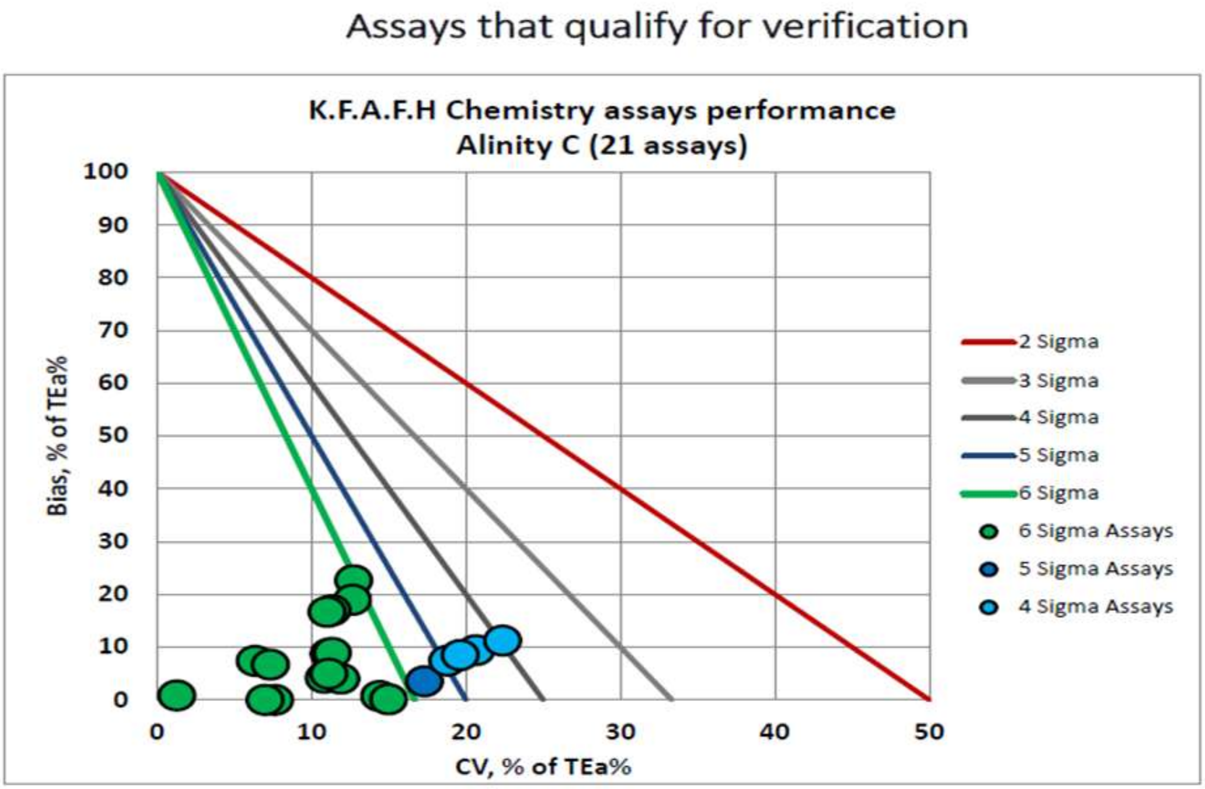



**Figure 12:-** Standardized QC sigma charts for chemistry analytes (3 Levels) analyzed with the Alinity-ci module of Abbott.

The slope of the five lines is the negative value of sigma. The circles with different colors represent different sigma grades. X-axis is the percentage of CV normalized to TEa and show imprecision and the y-axis is the percentage of bias normalized to TEa and shows inaccuracy

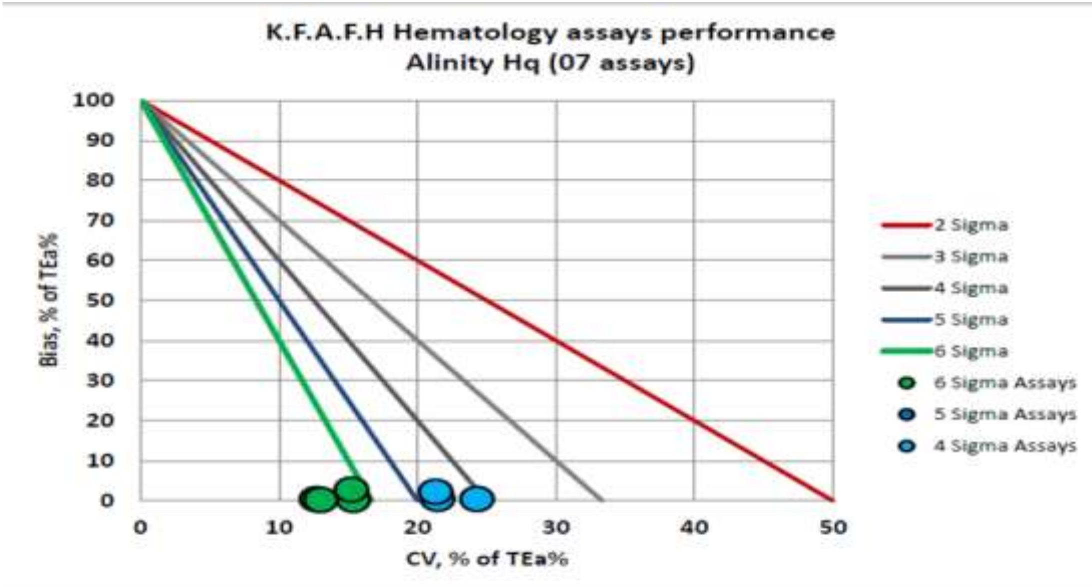
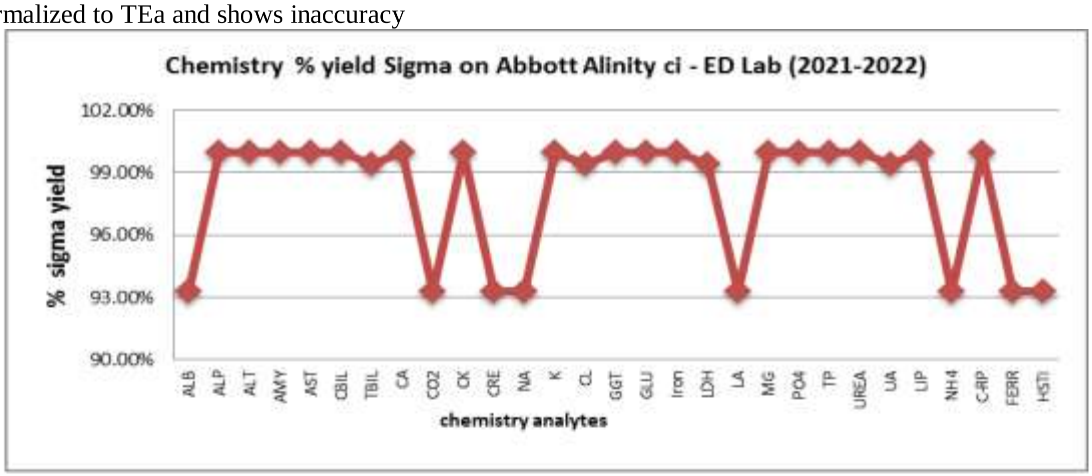
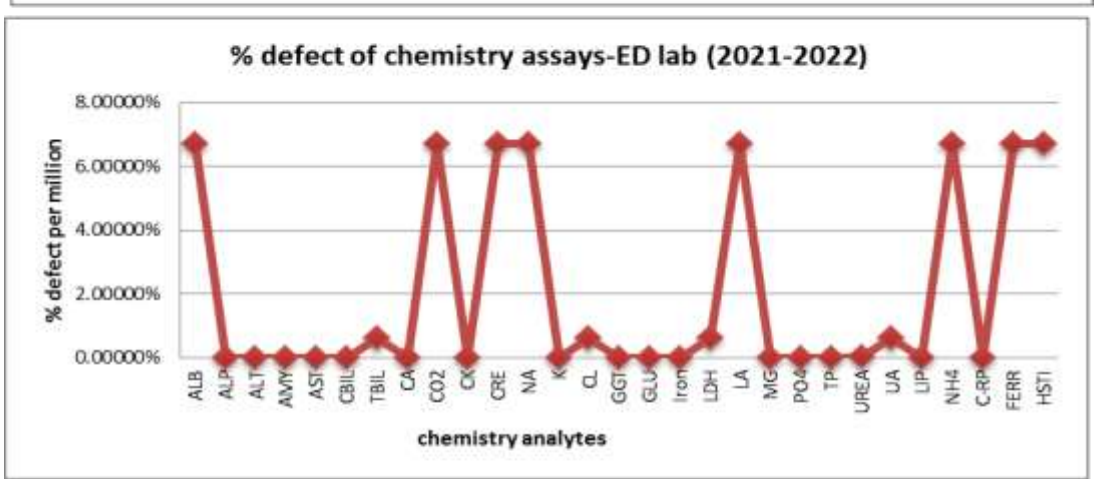
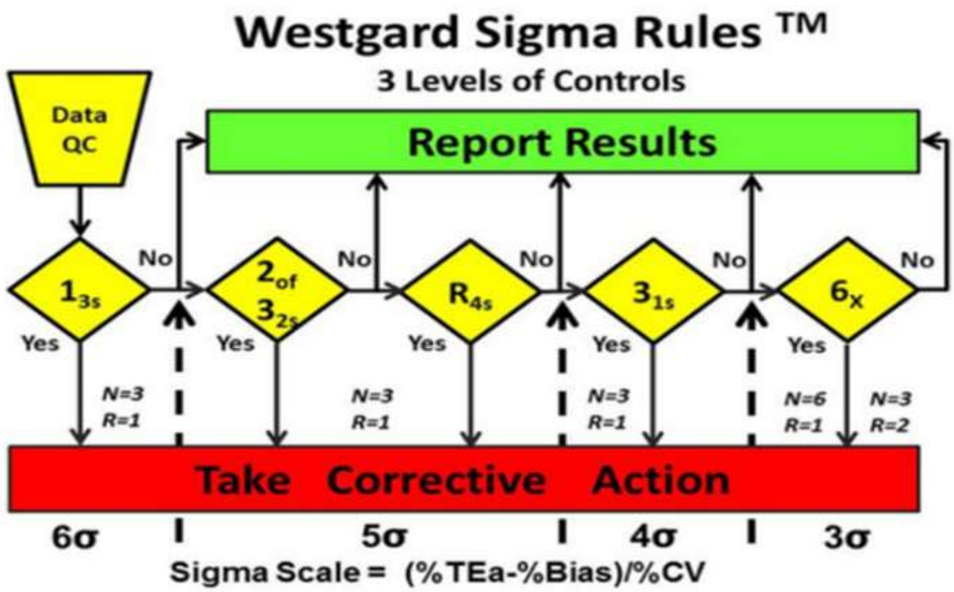



**Figure 12:-** Standardized QC sigma charts for hematology analytes (3 Levels) analyzed with the Alinity-hq module of Abbott.

The slope of the five lines is the negative value of sigma. The circles with different colors represent different sigma grades. X-axis is the percentage of CV normalized to TEa and show imprecision and the y-axis is the percentage of bias normalized to TEa and shows inaccuracy






## Conclusion and Limitations:-

The project aim was to improve and assess the analytical performance of a clinical Emergency laboratory and reveals that the sigma metrics methodology is a reliable quality tool, with the key focus of implementing sustainable solution rather than a short term intervention and **reveal errors or defects in precision and accuracy that can be used to evaluate quantitative projects,** it make sense to implement six sigma metrics into our daily analytical processes and can serve as a self-assessment method in guiding clinical laboratory to make QC strategy and plan QC frequency. It's very helpful to implement this metrics into our laboratory daily analytical processes in order to produce accurate test results.

Even though, the result of proficiency testing material values were within statistical limit, there were some poor performances detected (by 18 parameters) by using of Six Sigma metrics.

**This phenomenon could be attributed to two points: One was the detection system, including the different types of analyzers, reagents, and QC materials used, as well as other pre-analytical and analytical conditions; and the other was the source selection of** the TEa targets used to evaluate the bias and CV, which might affect the sigma values. The two analysis modules could be considered three separate analyzers, and differences in performance could not be avoidable. Various corrective actions were performed in this study for these analytes, as shown in **Table 7 & 8**.

Building on previous ideas, we also wanted a system that offered more appropriate QC procedures might not only decrease the false rejection but also avoid economic costs and improve efficiency. For example, compared with the previous procedures adopted in our laboratory, only one QC rule, 13s, needed to be used for analytes, which decreased economic costs and increased the working efficiency. However, for the analytes with $\sigma < 6$, more difficult QC procedures were implemented in this study compared with those used current study: Obviously, methodology improvements (reagent substitution) and personnel training can improve the quality of analytes. So, selecting QC Procedures; mean Higher Sigma associated with: lower reagent supply, lower labor costs, and fewer QC failures and between laboratory reproducibility. Therefore, addressing the method and personnel factors could improve the quality of some analytes with low sigma values.

The problems associated with working conditions and instrument proficiency could also affect measurement quality, and these problems cannot be ignored. For example, the analyzer sometimes emits a high-temperature alarm once in summer, which is inevitably linked to the environmental temperature due to the lack of a constant indoor temperature. This situation would impact not only the instrument proficiency but also the enzymatic methods used for the analytes. Thus, designing a constant-temperature system for use in a laboratory would help resolve this problem. To address fluctuations in instrument proficiency and thus improve quality, the frequency of calibrating these analytes could be increased from once a week to every 2 days in our laboratory. **The degree of improvement** in the quality of these analytes will be investigated in our future work. Certainly, if the performance of an analyte cannot be improved by implementation of all the proposed actions, nonstatistical QC procedures, including repeated tests for a patient and comparability testing, could be adopted for QA.

**There are certain limitations** in clinical application of sigma metrics for few analytes. The rest of Hematology and Coagulation parameters, other than routine clinical testing were not perform 6 sigma which got detected under below 4 sigma value and not included in the study due to fluctuation different lot numbers of internal quality control and low sample size for each lot. While NH4& LA due to small sample size and reagent stability onboard.A key lesson learnt during the process was the importance of PDSA cycles, which helped to ensure that at each stage the model was optimized before full distribution across the core laboratory for outpatient.

Indeed,the next effort suggested that the further apply the sigma metrics to all phases of laboratory process and to assess their performance on a Sigma Scale are needed to keep standards up.

For **low sigma values** showing wide variation, the methodology should be re-evaluated along with a strict compliance of Westgard multirule and number of QC run should be increased to avoid the discrepancy. Like the Total Quality Management, the sigma model pursues a Plan, Do, Check, Act cycle (PDCA). The salient features of Six Sigma metrics are Define, Measure, Analyze, Improve and Control (DMAIC) which are dominant in current quality management ensuring superior patient care by ruling out the recurrence of defects.

The corrective action was taken for those parameters following the Westgard rules [6]. The RCA was carried out with considering 5 factors as shown in cause-effect chart (Fish-bone diagram) for the determination of potential cause and effect on the low sigma values of some analytes.

## Conclusion:-

Overall, the Six Sigma methodology provides a useful evaluation system for the Emergency Laboratory projects considered in this study, optimizes the QC procedures for every item, and supplies a problem- solving strategy for analytes with $\sigma < 4$. This method has great practical value in clinical biochemical laboratories.

For the analyses listed in this report, under the circumstances detailed in the report, Westgard QC, Inc. is proud to re-verify that the Sigma-performance of K.F.A.F.H King Fahd Armed Forces Hospital is achieving the appropriate goals of analytical quality performance.

Sigma metric analysis, Method Decision charts, and OPSpecs charts provide easy tools for laboratories to determine the performance of their current methods and QC design, and to compare competing instruments on the markets. Both quantitative calculations and visual assessment can be made with this approach. These techniques give the laboratory a practical way to select the right method and then select the right QC for that method. This would help save precious time, effort, unnecessary runs the redundancy of control measurement's, calibration, reagents waste per day which effect on the ultimate outcome of turnaround time of Emergency lab analytical testing and improve efficiency with better focus on quality control, where required. That defines our processes as trustworthy which lessens the redundancy of control measurements, calibration and change the reagent waste per day which effect on the ultimate outcome of turnaround time of Emergency lab analytical testing.

## References:-

1. Forsman RW. Why is the laboratory an afterthought for managed care organizations? Clinchem 1996;42:813-6.
2. Shah S, Saini R, Singh SB, Aggarwal O, Goel AK. Six Sigma Metrics and Quality Control in Clinical Laboratory. Int J Med Res Rev 2014;2:140-9.
3. Aggarwal K, Patra S, Acharya V, Agrawal M, Mahapatra SK. Application of six sigma metrics and method decision charts in improvising clinical Chemistry laboratory performance enhancement. Int J Adv Med. 2019 Sep;6(5):1524-30.
4. Westgard JO. Internal quality control: planning and implementation strategies. Annals of clinical biochemistry. 2003 Nov 1;40(6):593-611.
5. Coskun A, Inal T, Unsal I, Serteser M. Six Sigma as a Quality Management Tool: Evaluation of Performance in Laboratory Medicine Quality Management and Six Sigma. InTechOpen: Rijeka, Croatia. 2010:248–61.

6. Angmo D, Kant S. Six sigma implementation in healthcare industry: Past, present and future. Int J Eng Res Technol. 2015;4(6):1078-82.
7. Plebani M. The CCLM contribution to improvements in quality and patient safety. Clinical Chemistry and Laboratory Medicine (CCLM). 2013 Jan 1;51(1):39-46.
8. Zhou B, Wu Y, He H, Li C, Tan L, Cao Y. Practical application of Six Sigma management in analytical biochemistry processes in clinical settings. Journal of clinical laboratory analysis. 2020 Jan;34(1):e23126.
9. Widodo A, Soediantono D. Benefits of the Six Sigma Method (DMAIC) and Implementation Suggestion in the Defense Industry: A Literature Review. International Journal of Social and Management Studies. 2022 Feb 12;3(3):1-2.
10. Mao X, Shao J, Zhang B, Wang Y. Evaluating analytical quality in clinical biochemistry laboratory using Six Sigma. Biochemiamedica. 2018 Jun 15;28(2):253-6.
11. PRADHAN DP, PANDIT D, SAHOO S, RATTAN R, MOHANTY S. Six Sigma Metrics: An Evolving Indicator of Quality Assurance for Clinical Biochemistry. Journal of Clinical & Diagnostic Research. 2022 Aug 1;16(8)
12. Gupta M, Ranapurwala M, Kansara K, Chhatriwala M. Application of sigma metrics in haematology laboratory.
13. Kumar BV, Mohan T. Sigma metrics as a tool for evaluating the performance of internal quality control in a clinical chemistry laboratory. Journal of laboratory physicians. 2018 Apr;10(02):194-9.
14. Westgard JO, Westgard SA. Quality control review: implementing a scientifically based quality control system. Annals of clinical biochemistry. 2016 Jan;53(1):32-50.