

Evaluation and Follow-up of Internal Quality Control of Total Bilirubin Testing at RSIA "X"

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ABSTRACT

Background & Objective: A decrease in the sigma value of laboratory test parameters requires a comprehensive evaluation to identify the causes of instability and establish improvement strategies through internal quality control. **Method:** The research method is a descriptive study involving analysis of the *Quality Goal Index* (QGI), information collection through interviews, identification of causal factors using the *Root Cause Analysis* (RCA) approach, and the development of corrective and preventive action lists. **Result:** The cause of the decrease in *sigma* values in total bilirubin testing was found to be the reconstitution process of control materials that were not dissolved in low light conditions, resulting in decreased stability and sigma values in total bilirubin testing. This was due to the relocation of the laboratory to a new room with many light sources. The corrective action to be taken is to improve and add SPO for the dilution of *quality control* materials, which must be done in low light conditions. The preventive action taken is to ensure that SPO is implemented properly, as a way to minimize light absorption by covering the control material storage with aluminum foil. **Conclusion:** The results indicate that the decrease in *sigma* in total bilirubin testing is due to light exposure. A comprehensive system improvement is necessary to prevent further decreases in sigma values in total bilirubin testing.

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Introduction

Quality Control (QC) is a series of internal quality assurance measures aimed at assessing the quality of analytical data. Every test performed in the laboratory must use control materials so that the accuracy and precision of each test can be monitored and its validity ensured. In the implementation of internal QC in clinical laboratories,

the results are evaluated using Levey-Jennings charts and checked for violations of Westgard rules (Abdurrahman et al. 2010).

Six Sigma is a quality indicator that can be used to evaluate a process, including in clinical laboratories. Laboratories can improve their quality systems and, most importantly, enhance patient safety and contribute to patient care by using *Six Sigma* (Westgard, 2017).

Total bilirubin parameters are very important at RSIA "X" because most patients are newborn infants who require close monitoring of bilirubin levels. Total bilirubin testing at RSIA "X" uses the diazo sulfinate method.

Based on internal quality control data from RSIA "X," the sigma values for parameters at RSIA "X" are generally stable; however, data from the past six months show instability in total bilirubin parameters. The *sigma* value for total bilirubin has decreased to a low of 2.7. Based on examination data from the RSIA "X" Laboratory, the monthly demand for total bilirubin examinations reaches 160 tests per month.

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Based on internal quality control data at RSIA "X," the sigma values for parameters at RSIA "X" are generally stable; however, data from the past six months indicate instability in the total bilirubin parameter. The *sigma* value for the total bilirubin parameter has decreased to its lowest value of 2.7. Based on testing data from the RSIA "X" Laboratory, the monthly demand for total bilirubin testing reaches 160 tests per month. Based on internal quality control data for the total bilirubin parameter from October 2023 to July 2024, many sigma values were ≤ 3 .

Based on previous research, if a parameter in a method has a *sigma* value less than three, it can be concluded that the method cannot be used as a routine method. The method requires changes and concrete corrective actions and must be evaluated regarding process instability. *Sigma* values can be used to establish quality control strategies.

According to (Maharani, et al., 2022), the higher the sigma value, the easier it is for a laboratory to establish quality control design and procedures. Therefore, the study "*Evaluation and follow-up of internal quality control in total bilirubin testing at RSIA 'X'*" was conducted.

Objective

1. Analyze the causes of *sigma* reduction in total bilirubin tests.
2. Know the corrective actions that must be taken when there is a reduction in *sigma* in total bilirubin tests
3. Know the preventive measures that must be avoided so that there is no reduction in *sigma* in total bilirubin tests.

Method

This study is a descriptive study that analyzes the internal quality assurance system, which has experienced a decline in the performance of total bilirubin testing. Descriptive research is a research method that reveals facts, conditions, variables, phenomena, and circumstances that occur during the research process and presents them as they are.

Data was obtained from secondary data sources, specifically data derived from the evaluation of internal quality control for total bilirubin testing conducted by the quality control team at RSIA "X" Laboratory between October 2023 and July 2024. A *quality goal index* calculation was then performed to determine the type of error causing the decrease in *sigma* for total bilirubin testing. Next, information on potential causes that could lower the *sigma* value in total bilirubin testing was collected through observations or interviews with 21 ATLMs at RSIA "X." All causal factors were identified using *root cause analysis* to determine the root cause, followed by proposing corrective and preventive actions as well as follow-up measures to prevent further *sigma* decline.

Results

Six out of ten data points from total bilirubin *quality control* checks between October 2023 and July 2024 had a *sigma* value of 3, with the results only occurring at level 1.

TABLE 1. *Quality Control Results Data*

No	Month	CV		TE	TEA	Sigma Value		Bias %	
		Lv 1	Lv 2			Lv 1	Lv 2	Lv 1	Lv 2
1.	October 2023	3,46	2,25	7,7	20,00	5,2	7,7	2,06	2,59
2.	November 2023	5,52	3,05	9,00	20,00	2,7	4,7	5,15	3,05
3.	December 2023	4,19	3,42	8,87	20,00	3,3	4,9	6,34	3,42
4.	January 2024	5,28	3,34	6,06	20,00	3,1	5,8	3,63	0,54
5.	February 2024	4,69	3,32	9,11	20,00	3,5	4,9	3,66	3,63
6.	March 2024	4,49	4,45	8,30	20,00	3,8	4,3	3,49	0,96
7.	April 2024	3,59	2,29	9,67	20,00	4,5	8,4	3,75	0,77
8.	May 2024	4,10	3,70	8,95	20,00	4,3	5,3	2,18	0,36
9.	June 2024	4,78	3,31	8,67	20,00	3,6	5,1	2,57	3,21
10.	July 2024	4,47	4,26	9,25	20,00	4,1	4,3	1,88	1,74

The results of the *quality goals index* calculation for total bilirubin testing showed a value of <0.8. This value occurred due to errors in most of the *impressions* and *inaccuracies*.

From the results of the observation checklist, eight statements were found to be inconsistent/suspected of being factors causing a decrease in the total bilirubin *sigma* value, namely:

1. The laboratory did not use third-party *quality control* materials
2. Laboratory personnel do not have internal *quality control* training certificates
3. Laboratory personnel do not routinely record *quality control* data
4. Laboratory personnel do not routinely create and plot *quality control* data on Levey-Jennings charts
5. The quality control officer establishes new *quality control* ranges and averages for control materials
6. *Quality control* materials are not dissolved at night under low light conditions
7. ATLM personnel do not dispense the control materials to be used (in aliquots) and leave them at room temperature for 30 minutes until they melt.
8. ATLM personnel do not homogenize/aspirate the control materials to be used before running them on the equipment.

Discussion

Based on the research results, six data *quality control* points with a sigma value of 3 were identified, specifically in November 2023, December 2023, January 2024, February 2024, March 2024, and June 2024. During these months, the *sigma* level 1 value was 3, with the lowest value of 2.7 in November 2023, which was categorized as “poor.” There was instability in the *sigma* values from October 2023 to July 2024.

Based on the calculation of the *quality goal index*, which is calculated by dividing the bias % by the CV%, the evaluation of sigma using the *quality goal index* identified issues of *sigma* decline due to *imprecision* and *inaccuracy*. The causes of imprecision and inaccuracy stem from random errors and systematic errors.

Based on the results of a checklist interview conducted with 21 ATLM staff at RSIA “X,” which included 52 questions, 8 issues were identified that may cause a decrease in sigma in total bilirubin testing. These 8 issues must be anticipated as they can cause a decrease in *sigma* not only in total bilirubin but also in other parameters.

From the 8 issues identified, a root cause analysis was conducted to determine the *root cause*. One specific issue was found to cause a decrease in sigma in total bilirubin testing: the control material was dissolved in low light conditions due to the relocation of the laboratory to a room with numerous lights and light sources, which caused a decrease in bilirubin concentration, resulting in imprecise results. The dilution of control materials should be performed under low light conditions; however, the abundance of artificial and natural light in the new laboratory room could be a contributing factor to the decrease in sigma in total bilirubin testing.

In this study, a significant decrease in sigma only occurred at level 1 or the normal range. This is because the average value at level 1 is smaller than the average value at level 2 or the pathological level. This causes the CV value at level 1 to be relatively high because the average value serves as the divisor in the CV formula. A high CV value causes the sigma value to decrease compared to the sigma value at level 2.

Based on these issues, corrective actions that can be taken include improving and adding provisions in the Standard Operating Procedures (SOP) for diluting *quality control* materials in low-light conditions. This ensures that precision factors are properly corrected. Preventive measures include ensuring that the SOP is properly implemented, and that the dissolution and storage of quality control materials minimize light absorption by using aluminum foil.

Conclusion

The factors causing errors that led to a decrease in sigma in total bilirubin testing were that the *quality control* material was not dissolved in low light conditions due to the relocation of the laboratory to a room with many sources of sunlight and artificial light, which could affect the stability of total bilirubin. Corrective actions to improve the performance of total bilirubin testing include revising and adding to the Standard Operating Procedures (SOP) that *quality control* materials must be diluted under low-light conditions. Preventive measures include ensuring the SOP is properly implemented, and minimizing light absorption during the dissolution and storage of quality control materials by using aluminum foil.

It is recommended that the management of RSIA “X” Laboratory implement comprehensive system improvements across pre-analytical, analytical, and post-analytical stages, particularly regarding the seven factors that can cause a decrease in

sigma, and enhance ATLM knowledge through training on the handling and regulation of quality control materials for *quality control* activities, which are part of *quality assurance* in producing high-quality results with good internal quality control.

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