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ANALYSIS OF TRIGLYCERIDE TEST CONTROL RESULTS USING THE SIGMA MATRIX METHOD IN THE LABORATORY OF HEART HOSPITAL DIAGRAM

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Abstract

Quality control in triglyceride tests is carried out to improve the quality of test results and prevent irregularities, so that the accuracy and accuracy of test results can be guaranteed and trusted. Accuracy and accuracy are shown by the coefficient of variation and bias. Sigma matrix is a method to measure the performance of a process by analyzing the root of the problem and showing the number of error factors that occur. This study aims to analyze the results of triglyceride examination control using the sigma matrix method at the Diagram Heart Hospital Laboratory. The research methodology in this study is quantitative descriptive with a cross sectional design using a sample of triglyceride quality control data for the period March to May 2023 with 2 levels of control, namely normal and pathogenic. Sigma matrix analysis involves coefficient of variation (CV), bias and Total Allowable Error (TEa). In this study, the lowest sigma value was in April 2023 level 1 of 4.95 in the good category and the highest sigma value was in March level 1 of 11.73 which was included in the worldclass category, so there was no need to do QGI. The triglyceride control value in this study did not show any deviation at the level of the sigma and QGI matrix, so that the precision and accuracy of the triglyceride test results can be guaranteed in quality.

Keywords : Bias, CV, Quality control, Sigma matrix, QGI.

1. Introduction

Strengthening laboratory quality is an activity that ensures the accuracy and accuracy of laboratory test results. There are two activities to strengthen laboratory quality, namely External Quality Stabilization (PME) and Internal Quality Stabilization (PMI). Internal Quality Stabilization (PMI) is carried out in each part of each laboratory installation to implement preventive and supervisory measures against irregularities.*Error* continuously, in order to get the correct examination results. External Quality Stabilization (PME) is an activity organized by the outside of the laboratory concerned and is carried out periodically to assess and evaluate laboratories in certain areas of inspection (Tuntun Siregar et al., 2018). *Good Laboratory Practice* (GLP) is a guideline that establishes requirements and criteria to ensure quality with Standard Operating Procedures (SOPs), personnel training, and how to work in a laboratory (Annisa, 2021).

Quality Control (QC) is a test evaluation process in procedures that aims to ensure the proper functioning of the quality management system, ensure laboratory inspection results, and minimize irregularities.*Error* and its sources (D, 2018). Precision (precision),

which is often said to be an impression, shows how close the laboratory results are if repeated sample examinations are carried out. Accuracy (accuracy) or inaccuracy is used to assess how close a result is to a predetermined actual value (Kusmiati et al., 2022). Besides *Westgard Multirules*, there are other analyses such as sigma matrices that analyze and determine the presence of process variations and eliminate factors that cause errors to improve the quality of laboratory test results. Sigma matrices involve refractive and impressionistic values through calculations *Total Error Allowable* (The), *Coefficient of Variation* (CV), and bias (Maharani et al., 2022).

A sigma matrix is one of the methods that can describe any process irregularities and show how often defects are likely to occur (Pratama et al., 2021). Sigma matrix measures the performance of a process with a level of *Defects-Per-Million-Opportunities* (DPM or DPMO). Sigma matrix programs include techniques such as *Define-Measure-Analyze-Improve-Control* (DMAIC) and analyze the root of the problem in order to eliminate errors or defects and variations in a process (Hidayati & Maradhona, 2018). Sigma matrices in quality control processes can provide more quantitative performance assessments for process improvement. Sigma values are usually indicated on a scale of 0-6. The higher the sigma value, the better and more accurate the results of the laboratory examination (Salsabella & Aryani, 2022).

Quality Goal Index (QGI) shows the extent to which bias and precision meet their respective goals. *Quality Goal Index* Used to analyze low-value sigma factors by showing problems in the form of impression and inaccuracy or both (Kumar & Mohan, 2020). Research conducted Aggarwal dkk. (2019) Indicating a sigma value that has exceeded 6 allows false rejection to be greatly reduced so that it can save reagents, time and effort. Research Teshome dkk. (2021) A poor sigma value indicates the presence of impressions and inaccuracies caused by untrained and incompetent laboratory staff, improper transportation/storage of control reagents, incorrect tools or tools that are not in good condition.

This study aims to analyze the results of triglyceride examination control using the sigma matrix method at the Diagram Heart Hospital Laboratory. The reason why researchers chose Diagram Heart Hospital is that triglyceride tests at Diagram Heart Hospital are often requested related to the diagnosis of heart disease, so triglyceride tests must be controlled so that the results of the tests can be trusted through *quality control*. The implementation of QC is carried out routinely every day before the tool is used to start the inspection.

2. Research Methods

This type of research is quantitative descriptive using *a cross sectional* approach. The population in this study is all data from the QC results of triglyceride examination for the period March-May 2023 as many as 184 data using 2 levels of control, namely normal control and pathogen control obtained from daily quality control results using *the Cobas Roche C311 Chemistry Analyzer* tool at the Diagram Heart Hospital Laboratory, This study

uses secondary data. Data collection activities were carried out using a total sampling technique. The data of the triglyceride QC results obtained from *the Cobas Roche C311 Chemistry Analyzer* tool using *HCLAB software, then the QC data was processed using* Microsoft Office Excel with editing and tabulation stages. The data is processed to obtain an average or average ($\bar{x}$), SD, CV, Bias %, then a *Levey-Jennings* graph is created using *Westgard* rules using *Microsoft Excel*. The sigma matrix is determined by bias and the TEa value obtained from *the Clinical Laboratory Improvement Amandement* (CLIA) and *Quality Goal Index* (QGI) criteria will be performed if the sigma value is <3.

Coefficient of Variation (CV) or coefficient of variation is used to assess the degree of precision of the results. The greater the value of the coefficient of variation, the more inthorough the examination results are considered to be (Indonesia, 2020). The CV formula is:

$$CV(\%) = \frac{SD}{\bar{x}} \times 100\%$$

Percentage bias is used to determine inaccuracy or inaccuracy (Indonesia, 2020). Rumus bias :

$$d\% = \frac{\bar{x} - nilai\ benar}{nilai\ benar} \times 100$$

Total Error Allowable (TEa) is the total limit *error* allowed, one of which according to *Clinical Laboratory Improvement Amandement* (CLIA). In the triglyceride test, the TEa value was ±25% ((CLIA), 2022). The sigma formula is:

$$Sigma(\sigma) = \frac{TEa - bias)}{CV}$$

Table 1. Sigma Matrix Interpretation

Sigma	Interpretation of results	Error rate per million tests	Percentage accuracy
1	*Unacceptable*	3,4	31
2	*Poor*	233	69,1
3	*Marginal*	6210	93,3
4	*Good*	66,807	99,4
5	*Excellent*	308,537	99,98
6	*Worldclass*	698,000	99,9997

Quality Goal Index (QGI) shows the extent to which bias and precision meet their respective goals. *Quality Goal Index* Used to analyze low-value sigma factors by showing problems in the form of impression and inaccuracy or both (Kumar & Mohan, 2020). *Quality Goal Index* can be calculated with the formula :

$$QGI = \frac{bias}{(1{,}5 \times CV)}$$

Table 2. QGI Interpretation

QGI	Problem
< 0.8	Enterprises
0,8-1,2	Impression and accuracy

QGI	Problem
>1,2	Inakurasi

3. Results and Discussion

In this study, the results of triglyceride control were obtained as many as 184 data, with the period of March-May 2023. Mean, SD, and CV values are calculated using *Microsoft Excel*. The *Levey-Jennings* graph is created with predetermined SD boundaries and uses *Westgard* rules to see if there are or are not deviations. Bias and sigma values were calculated manually using *Total Error Allowable* (TEa) values obtained from *the Clinical Laboratory Improvement Amendment* (CLIA) criteria. The calculation *of the Quality Goal Index* (QGI) is carried out if there is a sigma value of <3 to analyze the low-value sigma factor by showing problems in the form of impressions and inaccuracies.

Table 3. Results of Average, SD, CV, and Bias Analysis on Triglyceride QC Results for the March-May 2023 period

Moon	Level control	Account			Range (Reagen)	Insert kit			Allowed CV (Ricos)%	Bias	Permissible bias (Ricos)%
		Rerata	SD	CV		Rerata	SD	CV			
March	Normal	117,84	2,27	1,92	97-133	115,00	6,00	5,22	19,9	2,47	9,57
	Pathogen	217,74	4,93	2,26	183-249	216,00	11,00	5,06		0,81	
April	Normal	120,43	4,94	4,10	97-133	115,00	6,00	5,22		4,72	
	Pathogen	220,90	5,26	2,38	183-249	216,00	11,00	5,06		2,27	
May	Normal	121,52	3,05	2,51	97-133	115,00	6,00	5,22		5,67	
	Pathogen	219,32	5,66	2,58	183-249	216,00	11,00	5,06		1,54	

In table 3, the results of the analysis of triglyceride control materials using 2 levels of control, namely, normal and pathogenic. The average value can be compared to the range of control values on the reagent. The average score in the March-May 2023 period can be said to be in the category *in control* Because the average value of the control result is included in the range of control values contained in the reagent. The highest SD score was found in May at the pathogen level of 5.66 and the lowest in March at the normal level of 2.27. The highest CV value was found in April at the normal level of 4.10 and the lowest in March at the normal level of 1.92. The CV values that have been obtained from this study show that triglyceride control has a good level of precision because it does not exceed the permissible limit, which is 19.9% (Ricos dkk., 2014). The highest refractive value was found in May at the normal level of 5.67 and the lowest in March at the pathogen level of 0.81. Based on the refractive values that have been obtained from this study, it can be said that the triglyceride control has a good level of accuracy because it does not exceed the permissible limit of 9.57% (Ricos dkk., 2014). CV scores and bias in the March-May 2023 period do not exceed the standard score *Rico's biological variation*.

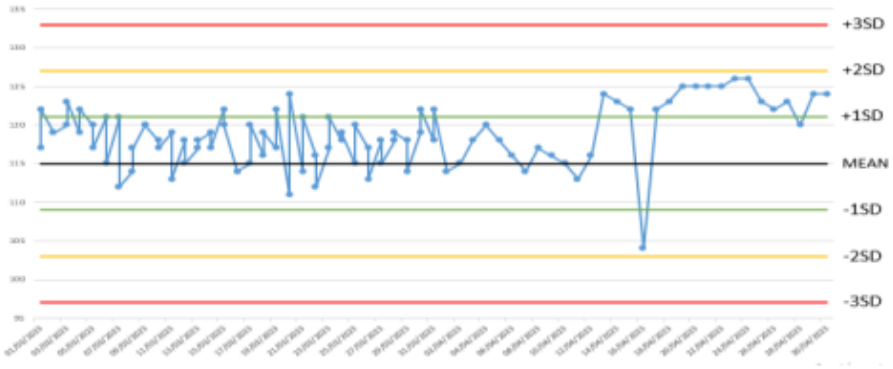

Figure 1. *Levey-Jenning's* Normal Level Chart for March-May 2023

Based on the results of QC analysis with *the Levey-Jennings graph,* triglyceride examination at normal levels for the March-May 2023 period was not a control that exceeded the 3SD limit, so no triglyceride control was rejected. On the *Levey-Jennings* chart for the April period, there are deviations in *Westgard*'s rules. The 10x rule deviation occurred from April 17, 2023 to April 26, 2023. A 10x rule deviation occurs when there are 10 continuous controls on the same side as the reata. Deviations from the 10x rule indicate a systematic error.

In research Konoralma dkk. (2018) indicates a deviation from the 10x rule which indicates a systematic error. Systematic errors are caused by poor standards, calibrations or instruments. Systematic errors are caused by poor standards, calibrations or instruments. Systematic errors lead to examination results that lead to high or low values. In research Son et al. (2020) Regarding the results of internal quality strengthening with graphs *Levey-Jennings* and evaluated using rules *Westgard* indicates a 10x deviation. Rule *Westgard* 10x indicates the presence of a systematic error and is related to accuracy (accuracy). Systematic errors are usually caused by poor standards, calibrations, or instruments.

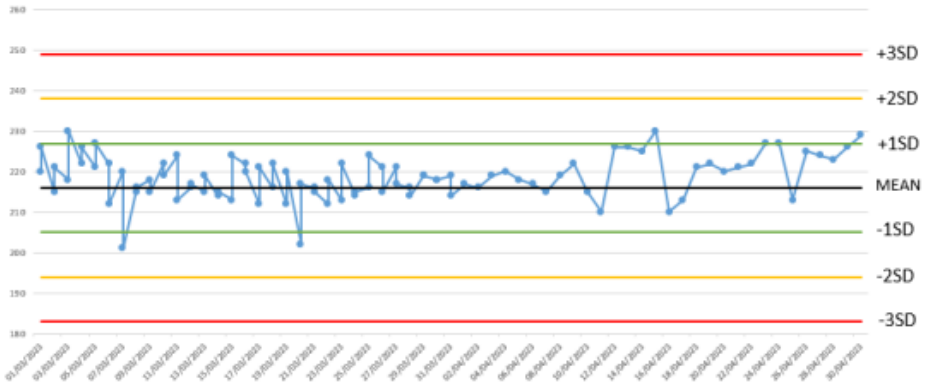

Figure 2. *Levey-Jenning's* Normal Level Chart for March-May 2023

Based on the results of QC analysis with graphs *Levey-Jennings* triglyceride examination at the pathogen level for the March-May 2023 period there was no control that exceeded the 3SD limit, so no triglyceride control was rejected. Triglyceride control in March-May 2023 pathogen levels can be said to be in the category *in control* and does not show any random or systematic errors in the rules *Westgard*. In research Purnama et al.

(2021) about *quality control* with rules *Westgard* shows excellent results and no control that goes out of bounds *Westgard* 1SD, 2SD, and 3SD.

Table 4. Sigma Triglyceride Values for the March-May Period 2023

Moon	Level control	TEa % (CLIA)	Sigma	Category	QGI	Problem
March	Normal	25	11,73	*Worldclass*	-	-
	Pathogen		10,70	*Worldclass*	-	-
April	Normal		4,95	*Good*	-	-
	Pathogen		9,55	*Worldclass*	-	-
May	Normal		7,70	*Worldclass*	-	-
	Pathogen		9,09	*Worldclass*	-	-

Table 4 shows that almost all of the sigma values of triglyceride control at both levels of control are included in the category *worldclass*, so it has a high accuracy rate of 99.9997% with an error rate of 698,000 per million tests. In a study conducted by Mao dkk. (2018) Obtained a sigma value of triglyceride control that exceeds 6 indicates that triglyceride control also falls into the category *worldclass* and the test results can be issued. In table 4, which is April, the normal level is obtained with a sigma value of 4.95. Even if you get the lowest score, the sigma value falls into the category *good* and has an accuracy percentage of 99.4% with an error rate of 66,807 per one million tests. A sigma value of 4.95 must be carried out quality control using 2 levels per day by activating the control rules *Westgard* on the tool, namely 13S, 22S, R4S. Research Cevlik & Haklar (2023) Regarding the evaluation of sigma to improve laboratory performance, a sigma value of 4.98 at the normal level and 4.96 at the pathogen level was obtained. From these results, it is known that there is a *imprecision* at both levels with the value of *Quality Goal Index* (QGI) obtained was 0.34 at the normal level and 0.33 at the pathogen level. At a sigma value of 4.95 using the Westgard rules 13S, 22S, R4S, an evaluation of the *systematic error* and *random error*. By rules *Westgard* can be known *problem solving* to solve problems and their causes.

Problem solving for random errors with rules 13S and R4S is to examine factors that greatly affect the precision of the examination. Random *errors* can be caused by unstable instruments, variations in reagents and calibrators. Temperature variations such as reactions, incubation reagents and instruments. Variations in the technique of examination procedures such as pipetting, mixing, incubation time. Random errors can also be affected by operator or analyst variations.

Troubleshooting for *systematic errors* with 22S, 41S, 10X rules, i.e. checking using serum control that allows the reagent to be damaged or its composition to change and repeating the control check with serum control. Double-check the standard solution used, it may be a faulty standard solution such as a blank solution and a sample or calibration factor. Recalibrate with a standard solution or use a new calibrator. Look back at *sampling systems* and *measuring systems* such as the accuracy of pipettes and instruments. The

control work can be repeated with the new reagent. Double-check the inspection procedure, if the problem has not been resolved. Systematic errors can be caused by low reagent specificity or inspection methods, improper sample blanks and reangen blanks, poor quality of calibration reagents. Systematic errors can also be caused by inaccurate pipettes, wavelengths used, and incorrect dissolution of reagents.

The results of triglyceride control using the sigma matrix method in this study had a sigma value range of 4.95-11.73 (criteria *good—worldclass*) and there is no need to do QGI calculations. The implementation is carried out QGI calculations. Implementation *Quality Control* (QC) at the Heart Hospital Diagram is routinely carried out daily using two levels of control, namely normal control and pathogen control for triglyceride examination. Sigma matrix can evaluate control procedures, reduce costs and improve work efficiency (Zhou dkk., 2020).

4. Conclusion

In this study, it can be concluded that triglyceride control in the period of March-May 2023 has good precision or precision at both normal and pathogen control levels. Precision is said to be good if the results of the examination are close to each other when done repeatedly on the same sample. Triglyceride control in the March-May 2023 period had good accuracy or accuracy at both control levels, namely normal and pathogenic. Accuracy is said to be good if the test results are close to the test results of the control Materials.

The sigma matrix level in the period of March–May 2023 with normal and pathogenic level control has a sigma value range of 4.95–11.73, so it is included in the *good-worldclass* category. The sigma value in April 2023 at the normal level needs to be evaluated using Westgard rules to improve the quality of laboratory results. Triglyceride control in the March-May 2023 period does not need to be calculated as *a Quality Goal Index*, because there is no sigma value that is < 3.

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