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Quality Control Inspection Results Platelets and Leukocytes Based on *the Westgard Rule* and *Six Sigma* at RS PKU Muhammadiyah Bantul

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ABSTRACT
Internal Quality Consolidation (PMI) is a preventive and monitoring activity carried out by each laboratory continuously so that *errors* or deviations do not occur so that correct inspection results are obtained, one of which is carrying out *quality control* (QC) using *the Westgard Rule* and *Six Sigma* . *The Westgard rule* is used to see whether there are analytical errors that occur with the 12 s , 13 s , 22 s , R4 s , 41 s , 10 X series of rules . *Six sigma* is used to assess the quality of a laboratory's performance by looking at the minimum *sigma value level* with a value of 3σ and a maximum of ≥6σ. This research aims to evaluate *quality control* (QC) results including accuracy, precision, *Levey-Jennings control charts* based on *the Westgard rule, as well as six sigma* values along with DPMO. The research method used was a quantitative descriptive method using secondary data from the results of examination of platelet and leukocyte control materials in January, February and March 2024. The calculation results from the accuracy (d %) and precision (CV %) values of platelet examination were 5.18% and 3.32%, while the leukocyte examination was -3.08% and 0.97%. Evaluation with *the Westgard rule* in platelet examination gets the 12s, 13s, 22s and 10x rules, while leukocyte examination gets the 12s and 13s rules. The *six sigma* and DPMO values for platelet examination were 5.97 and 5.4, 4.26 and 3.467, 4.71 and 687 while leukocyte examination were 18.64 and 0.001, 7.01 and 0.019, 9.6 and 0.001. This research can it was concluded that the examination of platelets and leukocytes had good accuracy and precision, there were control values that followed *the Westgard rule,* as well as *six sigma values* ≥ 3σ and DPMO ≤66.807.

Keywords: Quality Control, Westgard Rule, Six Sigma

INTRODUCTION
The clinical laboratory consists of hematology, clinical chemistry, parasitology, microbiology, anatomical pathology and immunology (Lianti et al., 2020) . In the field of hematology, there are two types of examinations, namely complete blood tests and routine blood tests. One of the parameters for routine blood tests is platelet and leukocyte examination (Lianti et al., 2020) .

Platelets or platelets are blood cells that do not have a nucleus and are disc-shaped and play an important role in the blood clotting process. The normal value ranges from 150,000 – 400,000/µl (Agatha et al., 2020) . Leukocytes or white blood cells are cells that play a role in the body's defense system to protect the body from infectious disease agents (Gita, et al., 2019). The normal value ranges from 3,200 – 10,000 cells/ ^{mm3} (Giyartika & Keman, 2020).

Valid platelet and leukocyte examination results are very helpful in establishing a diagnosis and providing therapy. Therefore, efforts to strengthen internal and external quality are needed. Internal Quality Consolidation (PMI) is a preventive and monitoring

activity carried out by each laboratory continuously to ensure that errors or irregularities do not occur so that correct examination results are obtained (Kosasih & Rampo, 2023).

Quality control (QC) is one of the efforts to carry out PMI in the laboratory. The purpose of QC is to guarantee laboratory examination results, identify and minimize deviations, and identify the source of deviations (Jemani & Kurniawan, 20190.

Evaluation using *the Westgard rule* and *six sigma* is one part of implementing *quality control. The Westgard rule* is a series of rules used to detect random errors *and* systemic errors (Karyaty & Rosdarni, 2018). Meanwhile, *six sigma* is used to evaluate performance results in the laboratory so that the examination results issued remain accurate (Dewia & Widiyantob, 2016) .

Previous research conducted by Aulia and Astuti (2021) on platelet examination parameters obtained the Westgard 12s and 13s rule series. Meanwhile, in research conducted by Farikha, Astuti and Hadi (2023) , the examination of platelets and leukocytes obtained the Westgard 12s rule and a *six sigma value* of ≥6σ. Furthermore, research by Prasetya, Muhajir and Dumatubun (2021) regarding leukocyte examination obtained a *six sigma value* with a very good scale (*world class*) ≥6σ.

Based on a preliminary study carried out at the PKU Muhammadiyah Bantul Hospital Laboratory using a Mindray BC-6200 *Hematology Analyzer,* daily control activities have been routinely carried out using three different levels of control material, namely low, normal and high. This daily control activity was carried out randomly every day using two different levels of control material. The control material used every day is a normal level control material. In the platelet examination parameters, errors in reading the results often occur due to clumping *which* clogs the instrument tube, while in the leukocyte examination parameters *the hematology analyzer* cannot read cells that have an abnormal shape. Quality control evaluation has been carried out by evaluating using graphs based on the range values on *the insert kit,* however evaluation using *the Westgard rule* and *six sigma* has not been carried out. Therefore, it is necessary to carry out research regarding the evaluation of *quality control results* in platelet and leukocyte examinations based on *the Westgard rule* and *six sigma.*

RESEARCH METHODS

This research used a quantitative descriptive research design with a *cross sectional approach* which was carried out at the PKU Muhammadiyah Bantul Hospital Laboratory in March - May 2024. The material used in this research was secondary data taken from the results of daily quality control activities on platelet and leukocyte examinations using normal level control material on the *Mindray* BC-6200 Hematology Analyzer during the period 14 January 2024 to 31 March 2024.

Data processing is carried out by calculating the average value (*mean*), accuracy or bias (d%), *standard deviation* (SD) and precision (CV%). Next, a *Levey-Jennings* graph was created using *the mean* and SD values in the preliminary period, then an evaluation was carried out using *the Westgard rule* with the rule series 12s, 13s, 22s, R4s, 41s and 10x. Evaluation with *six sigma* is also carried out by determining *the Total Error Allowable* (TEa), bias (d %) and *Coefficient of Variation* (CV %) values.

RESULTS AND DISCUSSION

This study uses data from control material examination results on platelet and leukocyte parameters during the period 14 January to 31 March 2024. The following are the calculation results of the platelet examination parameters:

Table 1. Accuracy (d%) and Precision (CV%) Values of Platelet Examination

Actual Value (NA)	*Mean*	Elementary school	Bias Range (d%)	Bias Value (d%)	CV% Range	CV% Value
206	216.67	7.19	±10	5.18	<5	3.32

Based on Table 1, it is known that the Actual Value (NA) of the BC-6D control material for platelet examination parameters is 206, the *mean value for* January 2024 is 216.67 and the SD value is 7.19. So the accuracy or bias value (d%) is 5.18% and the precision value (CV%) is 3.32%. After getting *the mean* and SD values in January 2024, the *Levey-Jennings graph was then created* and then evaluated using *the Westgard Rule.* The following are the parameters for platelet examination in February 2024:

Figure 1. *Levey-Jennings* graph for platelet examination in February

Table 2. Evaluation of *the Westgard Rule* for Platelet Examination in February

12 s	13 s	22 s	R4 s	41 s	10 x
Days 4 and 11	Days 1, 8, 9, 10, 12, 13, 14	Day 6	-	-	Day 20

Based on Figure 1 and Table 2, the platelet examination in February 2024 obtained a series of rules westgard. Days 4 and 11 get the 12 s rule series. Days 1, 8, 9, 10, 12, 13 and 14 get a series of 13 s rules. Day 6 gets a series of 22 s rules. Next, on day 20 get the 10 x rule series. Rules 12s and 13s are included in random errors, while rules 22s and 10x are included in systemic *errors.* The following are the parameters for platelet examination in March 2024:

Figure 2. *Levey-Jennings* Chart for Platelet Examination in March

Table 3. Evaluation of *the Westgard Rule* for Platelet Examination in March

12 s	13 s	22 s	R4 s	41 s	10 x
Day 26	Days 10, 11, 12, 13, 14	Days 1 and 8	-	-	-

Based on Figure 2 with Table 3 on platelet examination in March 2024 there are control results that obtain *Westgard rules.* Day 26 gets the 12 S rule series. Days 10, 11, 12, 13 and 14 get the 13 S rule series. Days 1 and 8 get the 22 S rule series. Rules 12s and 13s are included in random errors, while rule 22s is included in systemic *errors.*

Table 4. *Six Sigma* and DPMO Values for Platelet Examination

Month	TEa% (CLIA)	Bias (d%)	CV%	*Six Sigma*	DPMO
January	25	5.18	3.32	5.97	5.4
February	25	6.26	4.4	4.26	3,467
March	25	5.32	4.18	4.71	687

Based on Table 4, it is known that the TEa% platelet value is 25. In January 2024, the *six sigma value was* 5.97 and DPMO 5.4. In February 2024, a *six sigma value* of 4.26 and a DPMO of 3.467 were obtained. Meanwhile, in March 2024, *a six sigma value* of 4.71 and a DPMO of 687 were obtained. Furthermore, here are the calculation results from the leukocyte examination:

Table 5. Accuracy (d%) and Precision (CV%) Values of Leukocyte Examination

Actual Value (NA)	*Mean*	elementary school	Bias Range (d%)	Bias Value (d%)	CV% Range	CV% Value
7.46	7.23	0.07	±10	-3.08	<5	0.97

Based on Table 5, it is known that the Actual Value (NA) of the BC-6D control material for leukocyte examination parameters is 7.46, the *mean value* for January 2024 is 7.23 and the SD value is 0.07. So the accuracy or bias value (d%) is -3.08% and the precision value (CV%) is 0.97%. The following is the creation of a *Levey-Jennings* graph based on *the Westgard rule* on leukocyte examination parameters in February 2024:

Figure 3. *Levey-Jennings* graph for leukocyte examination in February

Table 6. Evaluation of *the Westgard Rule* for Leukocyte Examination in February

12 s	13 s	22 s	R4 s	41 s	10 x
Days 7, 22, 29	Days 1, 11, 24	-	-	-	-

Based on Figure 3 with Table 6 on the leukocyte examination in February 2024 There are several control results that obtain *Westgard rules.* Days 7, 22 and 29 get a series of 12 $_{s\ rules.}$ Days 1, 11 and 24 get a series of 13 $_{s\ rules.}$ Rules 12s and 13s are included in random *errors.* Furthermore, the parameters for leukocyte examination in March 2024 are as follows:

Figure 4. *Levey-Jennings* graph for leukocyte examination in March

Table 7. Evaluation of *the Westgard Rule* for Leukocyte Examination in March

12 s	13 s	22 s	R4 s	41 s	10 x
Day 2, 25, 30	Days 5 and 13	-	-	-	-

Based on Figure 4 with Table 7 on the leukocyte examination in March 2024 There are several control results that obtain *Westgard rules.* Days 2, 25 and 30 get a series of 12 $_{s\ rules.}$ Days 5 and 13 get a series of 13 $_{s\ rules.}$ Rules 12s and 13s are included in random *errors.*

Table 8. *Six Sigma* and DPMO Values for Leukocyte Examination

Month	TEa% (CLIA)	Bias (d%)	CV%	*Six Sigma*	DPMO
January	15	-3.08	0.97	18.64	0.001
February	15	0.55	2.06	7.01	0.019
March	15	0.41	1.52	9.6	0.001

Based on Table 8, it is known that the TEa% value for leukocyte examination is 15. In January 2024, *the six sigma value was* 18.64 and the DPMO was 0.001. In February 2024, a *six sigma value* of 7.01 and a DPMO of 0.019 were obtained. Meanwhile, in March 2024, *a six sigma value* of 9.6 and a DPMO of 0.001 were obtained.

Discussion

This research was conducted to evaluate *the quality control results* of platelet and leukocyte examination at the PKU Muhammadiyah Bantul Hospital by assessing the accuracy, precision, *Levey-Jennings graph* using *the Westgard Rule*, along with the *Six Sigma* and DPMO values.

The results of calculating the accuracy of platelet and leukocyte examination can be said to be accurate because they obtain a bias value (d%) that does not exceed the range limit of ±10% (Putra et al., 2017). Accuracy is used to see the suitability or accuracy between the inspection results and the actual value (NA/ *True Value*). The refractive value (d%) of platelet examination is positive so it shows a higher result than the actual value. Meanwhile, the bias value (d%) of leukocyte examination is negative, thus showing results that are lower than the actual value.

The results of calculating the precision of platelet and leukocyte examination can be said to have good precision because they get a CV value of <5% (Ningsih et al., 2022). Precision is used to provide the same results in each repetition of the examination. The value (CV%) of leukocyte examination is lower than platelet examination. This shows that if the precision value (CV%) is lower it will produce high accuracy, whereas if the value (CV%) is higher it will produce low accuracy (RI, 2013) .

Quality control activities are also carried out by creating *Levey-Jennings charts* and then evaluating them using *the Westgard Rule*. In this study, platelet examination obtained the *Westgard rule series* including 12s, 13s, 22s and 10x. Meanwhile, the leukocyte examination parameters get the 12s and 13s rule series.

Rule 12s is a warning rule that indicates a problem with the instrument or inaccuracy of the method used and includes random error (Kusmiati et al., 2022). This rule occurs if there is one control value outside the ±2SD limit but still within the ≤±3SD limit. Rule 13s is a rejection rule that indicates a random error (Praptomo, 2018). This rule occurs if there is one control value that is outside the limit of ≥±3SD.

Completion of rules 12s and 13s can be done by using more than one level of control material and we see whether at other levels there are control values that are within the limits of ±2SD or ±3SD. If the control values at other levels are outside the limits of ±2SD or ±3SD, corrections are needed before examining patient samples. However, if other level control values are within ±2SD or ±3SD, examination of patient samples can still be carried out (Permatasari, 2017).

Completion of rules 12s and 13s using one level of control material can be done by looking at the previous control value whether it is within the limits of ±2SD or ±3SD. If the previous control value is within the limits of ±2SD or ±3SD then examination of patient samples can still be carried out without prior correction. However, if it was previously outside the limits of ±2SD or ±3SD, corrections must be made first before examining the patient sample. Improvements can be made by paying attention that the control material removed from the refrigerator must be at room temperature first, and the control material must be properly homogenized before checking the control material.

The 22s rule is a rejection rule characterized by the presence of two control values outside the ±2SD limit but still within the <±3SD limit. This rule detects systemic errors (*systematic errors*). The 10x rule is a rejection rule characterized by the output of 10 control values in a row that are on the same side of the mean value limit (x) up to ≤±2SD. This rule indicates the occurrence of a systemic error (deli Rahayu, 2020).

Completion of the 22s and 10x rules can be done by repeating the inspection with the same control material until the control results fall within the predetermined range. If the control results still come out, it is necessary to re-examine with new control material with a new LOT number. If the control results are still not received, it is

necessary to calibrate the tool and re-control using control material with a new LOT number until the control results are received. If the control results are still not received, *maintenance of* the equipment is required by a technician and calibration and re-control are carried out.

The 12s, 13s, 22s, 10x rule obtained on the *Levey-Jennings control chart* for platelet and leukocyte examination at the PKU Muhammadiyah Bantul Hospital is caused by random errors *and* systemic *errors* . Random errors can occur when daily control activities are carried out, the control material taken out of the refrigerator is not yet at room temperature and the control material has not been properly homogenized. Meanwhile, systemic errors can occur due to clumping *which* blocks the tool tube so that the tool cannot read and shows low results on platelet examination. The *hematology analyzer* also cannot read cells that have abnormal shapes in the leukocyte examination parameters so that this will affect the examination results.

Quality control results can be done with *Six Sigma* along with DPMO. Interpretation of *six sigma results* in January - March 2024 in platelet examination has a decrease in value, namely from *excellent level* to *good level.* Based on the *six sigma* calculations in the examination of platelet control materials, it is known that the sigma values obtained are all more than 3. A *six sigma value* ≥3σ indicates that the sigma value is in the good category, so that quality control activities can be carried out by means of routine monitoring so that you can still get good inspection results. optimal (Yudita et al., 2023).

Six sigma value of leukocyte examination provides an interpretation of *world class results* because the calculation results show a *six sigma value* of ≥6σ with the smallest sigma in February 2024 and the highest in January 2024. If an examination produces a sigma value of ≥6σ, then you can use a control procedure by carrying out control examination once every day (Kumar & Mohan, 2018). The results of the *six sigma value* on leukocyte examination parameters can provide benefits in performance in a laboratory because with excellent sigma results, the laboratory can minimize the use of one level of control material so that it can save time and costs.

Interpretation of the results of the *Defect per Million Opportunities* (DPMO) value in platelet and leukocyte examination obtained a value of <66,807. The results of the DPMO value are very closely related to the *six sigma values* that have been obtained. If the *six sigma value* is included in the good or high category, then the number of errors obtained will be smaller. Meanwhile, if the *six sigma value* is bad or low, then the number of errors obtained will be greater.

six sigma value is a quality management system tool used to evaluate laboratory performance results in order to maintain accurate laboratory examination results (Dewia & Widiyantob, 2016). Through *six sigma* calculations, the number of defects or errors that occur per one million *Defect per Million Opportunities* (DPMO) examinations in the laboratory can be determined.

Previous research conducted by Farikha, Astuti and Hadi (2023) on examination of platelets and leukocytes only obtained the Westgard 12s rule with a *six sigma value* >6σ. Meanwhile, research according to Aulia and Astuti (2021) states that the platelet parameters get the *Westgard rule series* 12s and 13s. The results of this study obtained a series of *Westgard rules* including 12s, 13s, 22s and 10x with a *six sigma value* obtained ≥ 3 σ.

After evaluating the results of the quality control data for the examination of platelets and leukocytes, it was discovered that the accuracy and precision values for the examination of platelets and leukocytes had a good level of accuracy and precision because they were within the range of bias values (d%) ±10 and CV <5%. Then,

evaluating the *Levey-Jennings graph* using *the Westgard rule* in platelet examination, more variations of the rules were obtained, including the 12s, 13s, 22s, and 10x rules, which caused random errors *and* systemic *errors*. This evaluation is associated with a smaller *six sigma value* obtained on platelet examination (<6σ) along with more errors occurring. Meanwhile, when examining leukocytes, you only get the 12s and 13s rules which indicate a random *error.* The *six sigma* value in leukocyte examination produces greater results (≥6σ) or is called *world class.*

The results of the *six sigma value* in the laboratory for leukocyte examination parameters which reached the *world class category* with a *six sigma value* ≥6σ, does not rule out the possibility that there is a Westgard rule used in the *Levey-Jennings chart* . *Six sigma* value calculations should be able to be carried out using two different types of control materials. By using different types of control materials, laboratories can identify possible variations in errors that occur. Thus, even though the leukocyte examination parameters obtained a *six sigma value* which is included in *the world class category*, this is because in this study only one type of control material level was used, namely the normal level.

CONCLUSION

The results of the quality control evaluation in the examination of platelets and leukocytes at the PKU Muhammadiyah Bantul Hospital Laboratory had good accuracy and precision, there were control values that appeared on the Levey-Jennings graph and obtained Westgard rules, and a good six sigma value ≥ 3σ with a DPMO value ≤ was obtained. 66,807. Based on this research, researchers suggest that ATLM still pay attention to the quality of the control materials used, carry out inspections according to the SOP, and future researchers are expected to be able to evaluate quality control results using two or three different levels of control materials using evaluations based on the Westgard rule and six sigma.

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