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# Systematic Review: Internal Quality Assurance of The Hematology Laboratory

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## Abstract

*Quality in the laboratory is closely related to the results of the analysis test. The data from the analysis test is said to be high if the data can make customers/patients feel satisfied by considering technical values so as to achieve accuracy and precision. Quality assurance of health laboratories is all activities that are shown to ensure the accuracy and precision of laboratory examination results. Several factors that influence internal quality assurance include commitment to achieve quality results, facilities, funds, competent staff, control measures for pre-analytical, analytical and post-analytical factors, statistical control monitoring and the existence of problem-solving mechanisms. This article aims to analyze the results of internal quality assurance that have been carried out in hematology laboratories, whether they have been running well and correctly. Data collection of PMI results for a month was observed using the Westgard multirules system rules, Levey-Jennings charts that have been routinely programmed on each laboratory tool. The results obtained from the PMI hematology laboratory that has been carried out are good and accurate, so that the laboratory can produce examinations that can be trusted -and accounted for.*

Keywords: Internal Quality Assurance (PMI), Hematology Laboratory, Laboratory Results.



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## 1. Introduction

Laboratory services are an integral part of health services needed to support efforts to improve health, prevent and treat diseases, and restore health. As an important component in health services, laboratory test results are used to determine diagnosis, provide treatment and monitor treatment results, and determine prognosis. Therefore, laboratory examination results must always be guaranteed in terms of quality (Ministry of Health of the Republic of Indonesia, 2013).

Laboratory quality assurance is one of the elements assessed in hospital accreditation. In the AP.5.9 standard, it is stated that hospitals establish regulations to implement laboratory service quality control

procedures, evaluated and recorded as documents (KARS, 2017). Quality control refers to the steps or processes undertaken to ensure that test results are accurate and reliable. As a primary healthcare facility, laboratory management must ensure that test results are reliable (Wicaksono et al., 2019).

Laboratories need to conduct quality assurance activities to ensure the accuracy and precision of laboratory examination results. Laboratory quality assurance activities include the following components: Internal Quality Assurance (PMI), External Quality Assurance (PME), verification, validation, audit, and education and training of laboratory personnel (Ministry of Health of the Republic of Indonesia, 2013).

The stages of quality control involve identifying quality needs, formulating standards and procedures, monitoring and measuring performance, and taking action for continuous improvement (F. Kahar et al., 2025). In the laboratory quality control stage, it is important to pay attention to factors that can affect the quality of laboratory tests, such as the examination method and the calibration of laboratory instruments (F. Kahar, 2022). Routine calibration of laboratory equipment is crucial to produce reliable, accurate, and precise test results (F. Kahar et al., 2025). For example, regarding the examination method used, namely the urine protein examination, an assessment carried out using the Westgard chart resulted in all methods, including the dip strip method, the 6% acetic acid heating method, and the sulfosalic acid method, having a reasonable level of accuracy for use in conducting the examination (Sari et al., 2023). By routinely conducting quality assurance in the laboratory, it will improve work safety and reduce the risk of accidents in the laboratory (Hadipranoto et al., 2022).

*Hematology* parameters are screening tests to help clinicians establish a diagnosis. To obtain valid and reliable laboratory results, you must ensure that the laboratory examination is carried out according to the standards that should be. In order for the laboratory examination process to run according to the aspects of precision and accuracy, internal quality assurance in the hematology field must be carried out. (Tuntun, 2018).

Internal quality assurance in hematology is a preventive and supervisory activity carried out by clinical laboratories continuously in order to obtain hematology examination results that meet technical aspects, namely precision and accuracy. (Tuntun, 2018).

The scope of internal quality assurance includes pre-analytical, analytical and post-analytical stages (Ministry of Health of the Republic of Indonesia, 2013). Activities in Internal Quality Assurance in Clinical Laboratories include:

**1 Pre-analytical control**

**a. Specimen preparation**
Before the specimen is taken, the patient must first be well prepared in accordance with the requirements for taking the specimen, for which it is necessary to create written instructions for patient preparation for each laboratory examination.

**b. Specimen collection and handling**
Specimens must be taken correctly by paying attention to time, location, volume, method, equipment, specimen container, preservative/anticoagulant, in accordance with specimen collection requirements.

**c. Storage and transport of specimens**
The method of specimen transportation, separation and storage must comply with applicable provisions so as not to affect the examination results.

**d. Patient identification and recording**
Before conducting an examination, it is necessary to pay attention to the identification and recording of patient data correctly.

**e. Equipment calibration**
One of the factors that can affect the results of laboratory tests is laboratory equipment, therefore the equipment needs to be maintained and calibrated periodically according to the manufacturer's instructions. Calibration of equipment for equipment issued by a particular factory can be done by the factory that produces the equipment. For equipment that is not issued by a particular factory, it can be done by an authorized agency/institution.
Calibration is done with a calibrator, done the first time the tool is operated, periodically, if the control does not meet the requirements or after the tool is repaired. Can be done by yourself or with the help of a supplier (vendor).

**f. Selection of examination method**
- Using standard inspection methods, and recommended by international agencies/institutions.
- Using stable reagents.

- The reagent has good sensitivity and specificity values.
- It is better to use a method that is easy to do.
- Check for continuity of the reagents.

**g. Selection of standard solutions, calibrators and control materials**

Traceability of test results often depends on the quality of control and calibration materials issued by the manufacturing plant. Good quality control and calibrator materials and consistent methods are used to validate the methods and reagents used.

**h. Work method documentation**

The steps of the examination method (SOP) are important to document to maintain the consistency of the quality of the examination results when used by different ATLM (Medical Laboratory Technologists). SOPs must be reviewed and updated periodically.

**i. Competence of the examining officer**

Officers who play a role in the examination process in the laboratory must have an adequate level of education and skills to carry out the examination process properly. Education is very necessary in addition to training and workshops held by professional organizations periodically.

**2 Analytical control**

Analytical process monitoring is done by conducting accuracy and precision tests using control materials. In using control materials, their implementation must be treated the same as specimen examination materials, without special treatment of tools, examination methods, reagents or examiners. (Tuntun, 2018).

In carrying out this accuracy and precision test, *assayed control materials are used,* at least 2 control materials are used with different levels (normal and abnormal). To assess the results of the examination carried out whether they are controlled or not, the Control Chard Levey-jennings and the Westgard rule are used. This system aims to monitor variations that arise during the examination, both system and random variations.

The analytical stage in internal quality assurance is one of them by implementing Quality Control (QC) using control serum whose levels are already known. The control serum used in implementing the accuracy test in internal quality assurance in laboratories is usually a commercial control serum. This control serum is taken from animals (Muslim, Kustiningsih, and Yuniarti, 2001).

The requirements of the control material include having the same or similar analyte composition as the specimen. Another requirement is that the components contained in the control material must be stable, meaning that during the storage period the control material must not experience any changes (Ministry of Health of the Republic of Indonesia, 2013).

Research from WHO (1986) stated that the use of control materials from animal serum such as cows and horses is more recommended than human serum, on the grounds that animal serum is free from infectious diseases such as HIV, HBV and HCV and the use of this animal serum is very good as a quality test material. Control serum in the form of cow serum is expected to be an alternative to replace commercial control serum.

**3 Post analytical control**

The results of the QC accuracy test are that if the examination results are within the calculation limits (mean +- 2SD), then the results of the control material examination are declared well controlled so that all specimen examinations on the examination day are considered acceptable.

If the examination results are in the warning area (mean +-2SD to mean +-3SD), then there is a possibility of deviation from the control material examination results so that the examination procedure needs to be examined but there is no need to re-examine.

The results of the examination are declared to be deviant if:

1. There are results of control material examinations that are outside the control limits (mean +-3 SD)
2. The results of the control material examination for 2 consecutive times were outside the warning limits (mean +- 2SD) on the same party.
3. The results of the control material examination for 4 consecutive times were more than the mean +-1SD and were on the same side.
4. The results of the control material examination for 7 consecutive days tend to increase or decrease (called TREND).
5. The results of the control material inspection for 7 consecutive days are located on the same

party (called SHIFT).

According to the Ministry of Health in 2008, the objectives of internal quality improvement were:

a. Establish and refine examination methods by considering analytical and clinical aspects;

b. Increase the readiness of personnel, so that incorrect results do not occur and error corrections can be carried out immediately;

c. Ensure that all processes from patient preparation, specimen collection, specimen delivery, specimen storage and processing to recording and reporting of results have been carried out correctly;

d. Detecting errors and knowing their source;

e. Assisting in improving patient care through increased internal quality assurance.

### A. PMI Method in Hematology Laboratory

PMI method in the laboratory uses Levey Jennings charts and Westgard rules. The following are the Westgard Rules*:*

| No | Information | Symbol | Error Type |
|---|---|---|---|
| 1 | 1 control value outside 3SD | 1-3s | Random |
| 2 | 2 consecutive control values outside 2SD on the same side 2-2S | 2-2s | Systemic |
| 3 | 2 of 3 consecutive values outside 2SD (2 of 3-2S) | 2 of 3-2s | Random |
| 4 | The range between 2 consecutive control values outside 2SD on opposite sides (R-4S) | 4-1s | Systemic |
| 5 | 4 consecutive control values outside 1SD on the same side (4-1S) | 4-1s | Systemic |
| 6 | 10 consecutive control values are on the same side of the mean (10-x) | 10-X | Systemic |

Below are general guidelines regarding actions to be taken if the quality assurance graph is not controlled:

1. Observe possible sources of error, e.g. calculation, pipette, clogged probe.
2. Repeat the control serum examination.
3. If the repeat results are still bad, use a new control serum.
4. If there is no improvement, observe the instruments used, whether maintenance has been carried out or not.
5. Use a control serum of known value. If the test results show improvement, it means there is damage to the control serum.
6. If there is doubt, use a control serum that has a different value.
7. Use new standards.
8. Change reagent.
9. Check equipment.

### B. Results and Discussion

The results of the laboratory PMI can be seen through the QC results which are carried out every day and automatically assessed by the hematology analyzer

using the Levey Jennings graphic guidelines. The following are the results of the laboratory tool QC with the hematology analyzer.

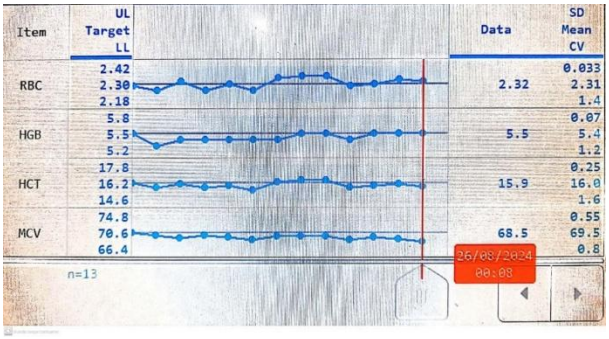


Fig. 1 Hematology Analyzer QC results during August 2024 at X Hospital

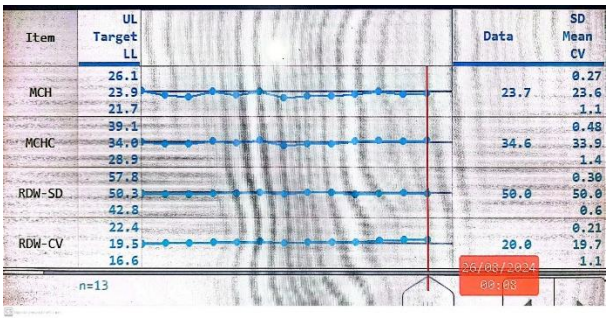


Fig. 2 QC Hematology Analyzer during August 2024 at X Hospital

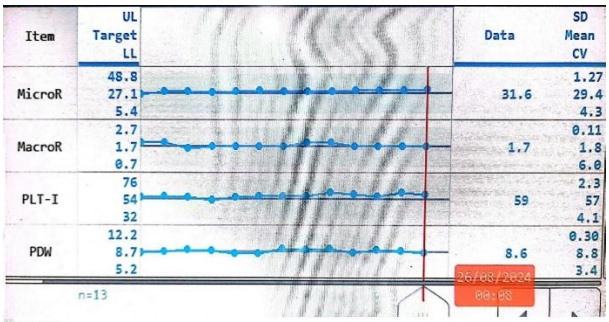


Fig. 3 QC Hematology Analyzer during August 2024 at X Hospital

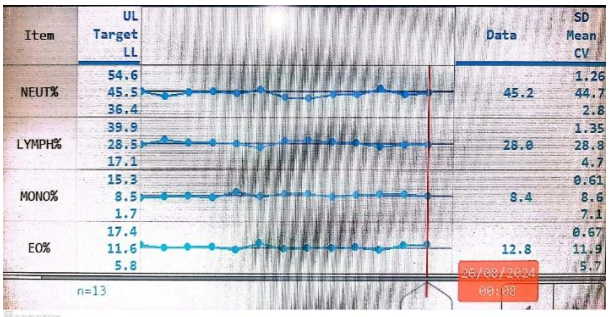


Fig. 4 QC Hematology Analyzer during August 2024 at X Hospital

Errors that usually occur in hematology laboratories are inherent and seem impossible to avoid. Improvement efforts can only minimize errors but cannot eliminate them, for example errors in setting the wavelength on the photometer or errors in setting the water bath temperature or errors in diluting standard solutions.

Technical Errors include:

- Random error: the test result varies from the expected value.
- Systematic error: the examination results tend in one direction
- The result is always greater or always less than the expected value.

Non-Technical Errors:

- Sampling errors. Examples: errors in patient preparation, hemolysis, serum exposure to sunlight.
- Writing errors, calculating results. Non-technical errors can be avoided by implementing a regular organization, working with high awareness and discipline.

From the results of the laboratory PMI that has been carried out QC every day, good results were obtained and the laboratory results are worthy of being accounted for their accuracy. Calibration carried out once a month also obtained good results and the reagents are worthy of being used for daily examinations.

## C Conclusion and Suggestions

Laboratory examination with accurate and proper results requires PMI or in this case Quality Control (QC). The results of the laboratory PMI that have been tested using the Levey Jennings chart show results in accordance with the control range of ±1SD and there are no deviations and show accurate and precise results. So that laboratory results can be given to patients with good accountability.

The advice that can be given to laboratories is to continue to maintain the quality that they currently have so that they can provide satisfaction to customers or patients who need a clear diagnosis.

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