JMCR | P-ISSN: 3063-4288 | E-ISSN: 3063-2366 | Vol. 1 No. 2 (2024) | OPEN ACCESS
https://doi.org/10.58740/jmcr.v1i2.284

Journal Of
Multidiscipline and Collaboration Research

# Results of Internal Quality Assurance for Ureum Parameters at H. Andi Sulthan Daeng Radja Hospital

**Asdinar[1], A. R. Pratiwi Hasanuddin[2*], Jusriani[3]**
[1,2,3]STIKES Panrita Husada Bulukumba

**Article History:**
Received: November 08, 2024
Revised: December 10, 2024
Accepted: December 16, 2024
Published: December 18, 2024

**Keywords:**
Accuracy, Analytical Error, Internal Quality Assurance, Precision, Urea Parameters

***Correspondence Author:**
a.r.pratiwihasanuddin@gmail.com

**Abstract:** Internal Quality Assurance (PMI) is a preventive and supervisory activity in the laboratory to ensure precise and accurate examination results. This study aims to evaluate the precision, accuracy, and types of analytical errors in PMI urea parameters in the laboratory of H. Andi Sulthan Daeng Radja Hospital, Bulukumba Regency. This descriptive study uses a mixed method with secondary data from PMI results for October–December 2023. The results showed that the average (Mean) urea value in October was 35.53 mg/dL, SD 1.77 mg/dL, CV 4.99%, and d 0.77%; November 35.48 mg/dL, SD 1.74 mg/dL, CV 4.89%, and d 0.88%; December 35.43 mg/dL, SD 1.81 mg/dL, CV 5.10%, and d 1.03%. The CV (precision) and d (accuracy) values are within the maximum control limits (CV ≤8%, Bias ±10%). Westgard rule analysis showed violations of the 1-2s rule in October, in the form of warnings without affecting the validity of the control, while no violations were found in November–December. Conclusion: The precision and accuracy of urea parameters are in the good category based on the Levey-Jennings graph analysis and the Westgard rule.

## INTRODUCTION

The laboratory is a critical health facility responsible for measuring, testing, and analyzing human body samples to aid in determining diseases, their causes, conditions, or underlying factors. To enhance service quality and ensure patient safety, laboratories must implement effective quality assurance programs to guarantee reliable test results (Bastian & Maria Ulfa, 2023). This is essential because laboratory results serve as the foundation for medical decisions, from diagnosis to treatment evaluation. Quality assurance in clinical laboratories is a vital element in maintaining service standards. Regular quality assurance practices detect potential errors that may arise during examinations. Clinical laboratories provide services across various fields, such as hematology, clinical chemistry, microbiology, parasitology, and immunology (Amalia et al., 2019). This underscores the necessity for accuracy and precision in laboratory data management to avoid errors that could negatively impact patients.

Laboratory quality is closely tied to the accuracy and reliability of analytical test results. High-quality laboratory data must meet technical standards that ensure both accuracy and precision. Laboratory examinations play an essential role in screening, diagnosis, disease progression monitoring, and treatment evaluation. Inaccurate results can

lead to incorrect treatment, endangering patients' lives and harming the reputation of laboratory services (Kusmiati et al., 2022). Quality assurance in laboratories encompasses two primary aspects: internal quality assurance (PMI) and external quality assurance (PME). PMI involves ongoing preventive and supervisory activities conducted by the laboratory to minimize errors and ensure accurate results across the pre-analytical, analytical, and post-analytical stages. PME, on the other hand, is conducted periodically by external parties to evaluate the quality of specific laboratory tests (Anggraini et al., 2022). A comprehensive quality assurance program involves enhancing the technical and management capabilities of laboratory staff, employing advanced technologies, and conducting regular evaluations of examination methods. Internal quality assurance serves as the cornerstone for ensuring reliable results in clinical laboratories, including those in hospitals (Pratama et al., 2021).

Lifestyle changes and technological advancements significantly affect public health. Reduced physical activity due to technological developments has contributed to an increase in metabolic and degenerative diseases. Chronic kidney failure, associated with urea parameters, has a prevalence of 3.8% in Indonesia (Gire et al., 2023). Urea testing is essential for diagnosing and monitoring this condition, as urea levels are influenced by factors such as protein intake, kidney function, and hydration status.

Urea testing is frequently recommended to detect kidney dysfunction. Urea, the end product of protein metabolism, is excreted through the kidneys. Elevated blood urea levels can indicate impaired kidney function or dehydration. Consequently, precise and accurate laboratory results are crucial for guiding appropriate treatment decisions. The H. Andi Sulthan Daeng Radja Hospital Laboratory in Bulukumba Regency has implemented an internal quality assurance program across multiple disciplines, including clinical chemistry, hematology, immunoserology, microbiology, urinalysis, and body fluid analysis. These daily quality assurance activities ensure accurate and reliable test results for medical professionals and patients, reflecting the laboratory's commitment to service quality.

Internal quality assurance involves three stages: pre-analytical, analytical, and post-analytical. The pre-analytical stage focuses on correct sample collection, while the analytical stage emphasizes the use of calibrated instruments and standardized methods during testing. The post-analytical stage ensures accurate result processing and reporting. High-quality laboratory results not only support effective treatments but also bolster patient trust in healthcare services. The laboratory of H. Andi Sulthan Daeng Radja Hospital continuously enhances its quality standards through periodic evaluations of its internal quality assurance program. Quality assurance in clinical chemistry, particularly for urea parameters, is a critical focus due to the relevance of urea testing in detecting chronic kidney disorders. By implementing internal quality assurance measures, the laboratory can identify and mitigate potential errors at each examination stage. This commitment forms the foundation for delivering high-quality laboratory services and ensuring patient safety.

The purpose of this study was to evaluate the implementation of internal quality assurance for urea parameters in the laboratory of H. Andi Sulthan Daeng Radja Hospital,

Bulukumba Regency. The findings of this study are expected to contribute to improving laboratory quality by enhancing the accuracy and precision of urea parameter test results.

## METHOD

This study is descriptive research employing a mixed-method approach that combines quantitative and qualitative techniques. The research design was cross-sectional and conducted at the Laboratory of H. Andi Sulthan Daeng Radja Hospital, Bulukumba Regency. The data used in this study include the results of Internal Quality Assurance (PMI) for urea parameters, obtained through various data collection methods. The data collection process involved interviews with the clinical chemistry laboratory supervisor to gather information on Internal Quality Assurance (PMI) procedures. Additionally, direct observations were conducted in the laboratory to verify the implementation of internal quality assurance, along with the collection of secondary data from laboratory archives. The collected data included Internal Quality Assurance (PMI) results for urea parameters obtained from the Pentra C400 device for the period of October to December 2023. The sampling technique used in this study was total sampling, where the entire population served as the sample, resulting in the sample size being equal to the population. Instruments used in the study included a research permit and secondary data on Internal Quality Assurance (PMI) results or quality control outcomes for urea parameters on the Pentra C400 device.

The data were processed using Microsoft Excel to generate a Levey-Jennings chart. The data processing began with the calculation of the mean, standard deviation (SD), coefficient of variation (CV), bias value, and standard deviation index (Z1). Once calculated, the data were used to create a Levey-Jennings chart in Microsoft Excel using the insert line feature. This chart displays the mean, along with control limits set at ±1SD, ±2SD, and ±3SD, which are key indicators for quality control.

Levey-Jennings charts are extensively used in laboratories, particularly in the healthcare industry, to ensure the stability and accuracy of test methods. These charts plot quality control results on the y-axis against time on the x-axis, with standard deviations defining the control limits. The charts are evaluated using Westgard rules, which include criteria such as 1-2s, 2-2s, and R-4s. These rules help detect significant deviations and ensure that test results remain within acceptable control limits.

## RESULT AND DISCUSSION

This study was conducted in the clinical chemistry laboratory at H. Andi Sulthan Daeng Radja Hospital, Bulukumba Regency, which was conducted on March 22-26, 2024 with the aim of knowing the Overview of Internal Quality Assurance Results (PMI) in the Field of Clinical Chemistry Urea Parameters in the Laboratory of H. Andi Sulthan Daeng Radja Hospital, Bulukumba Regency. The results of the study were obtained in the form of urea parameter control results for the period October to December 2023. The results of the study can be seen in table 1 along with figures 1, 2, and 3 below.

**Table 1.** True Value, Range, Mean, Standard Deviation, CV, and Bias of control results from October to December 2023

| Month | TV (mg/dL) | Range (mg/dL) | Mean (mg/dL) | SD (mg/dL) | CV (%) | CV Standard (%) | Bias (d%) | Standard Bias (%) |
|---|---|---|---|---|---|---|---|---|
| Okt | 35,8 | 31,8-39,8 | 35,53 | 1,77 | 4,99 | 8 | 0,77 | ±10 |
| Nov | 35,8 | 31,8-39,8 | 35,48 | 1,74 | 4,89 | 8 | 0,88 | ±10 |
| Des | 35,8 | 31,8-39,8 | 35,43 | 1,81 | 5,10 | 8 | 1,03 | ±10 |

Based on table 1, the results of urea parameter quality control obtained precision values seen as Coefficient of Variations (CV) values, the lowest CV value was obtained in November, namely 4.89% and the highest CV value in December, namely 5.10%. The accuracy value is seen as a bias value (d%), the lowest bias value was obtained in October, namely 0.77% and the highest bias value was 1.03%. The CV and bias values from October to December did not exceed the maximum limits that had been determined, namely CV 8% and bias ±10%.

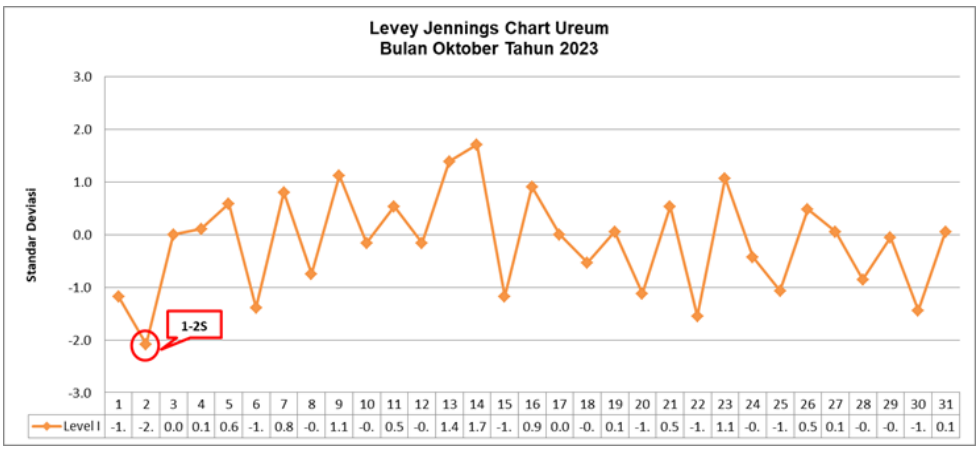


**Figure 1.** Levey Jennings Chart Urea October 2023

Based on Figure 1, which is a Levey-Jennings graph of urea parameters for October 2023, there was one deviation from the Westgard Rule 1-2s on the second day. This deviation occurred because the control value exceeded the -2SD limit, but was still within the -3SD limit. Violation of the 1-2s rule is an early warning and not an error that requires immediate intervention, because the control value is still acceptable. This deviation can be caused by factors such as instability of room temperature, quality of reagents used, or inconsistencies in the examination procedure. However, this graph generally shows good examination results because the control value is within the control limit on other days. In other words, the testing method during October is quite stable and the results are reliable.

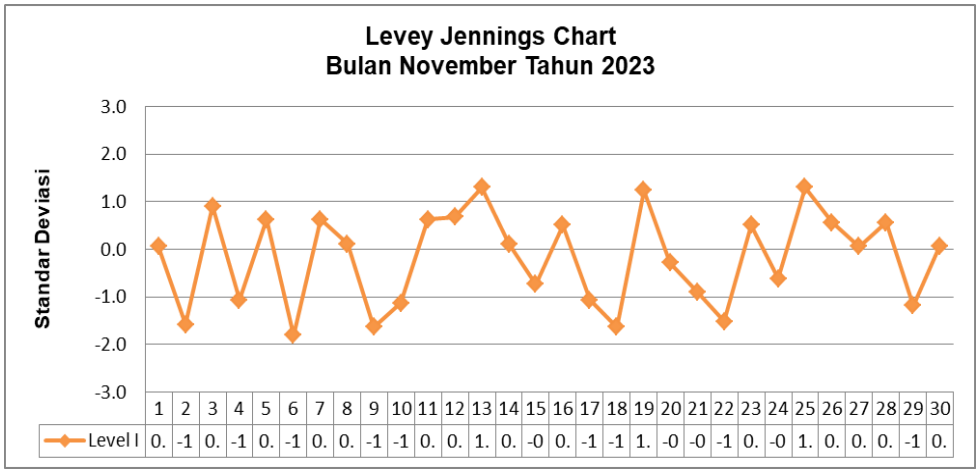


**Figure 2.** Levey Jennings Chart November 2023

In Figure 2, the Levey-Jennings chart for November 2023 shows good results without any deviations or violations of the Westgard rules. All control values are within the specified control limits, which are ±2SD. This shows that the examination in November has a high level of precision and accuracy. The absence of deviations reflects that all factors in the analytical process, such as instrument calibration, reagent conditions, room temperature, and examination procedures, run consistently and in accordance with operational standards. Thus, the examination results for November can be categorized as having very good accuracy and precision.

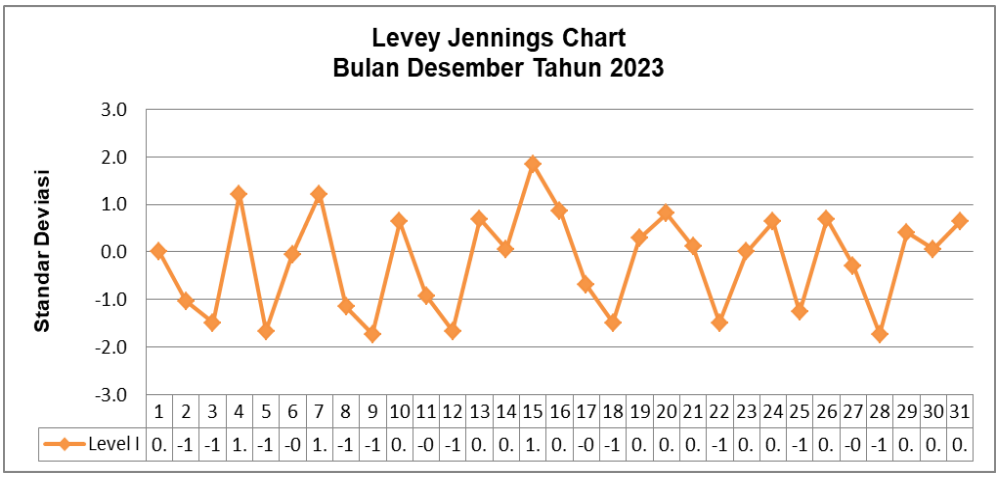


**Figure 3** Levey Jennings Chart December 2023

In Figure 3, the Levey-Jennings graph for December 2023 also shows good results, with all control values within the control limits of ±2SD. There are no deviations from the Westgard rule in this graph, so it can be concluded that the examination process during December went well. The high precision and accuracy in December indicate that the test

method is able to produce consistent results and in accordance with the true value. This also indicates that the quality control process carried out by the laboratory succeeded in maintaining the stability of the urea examination method during that month.

Based on the research results in Table 1 for the period October to December 2023, the target value (True Value/TV) that has been determined for urea parameter quality control is 35.8 mg/dL with a range of 31.8-39.8 mg/dL. From the data obtained, in October the average value (Mean) was 35.53 mg/dL, standard deviation (SD) 1.77 mg/dL, coefficient of variation (CV) 4.99%, and bias (d%) of 0.77%. In November, the average value was 35.48 mg/dL, standard deviation 1.74 mg/dL, CV 4.89%, and bias (d%) of 0.88%. Meanwhile, in December, the average value was 35.43 mg/dL, standard deviation 1.81 mg/dL, CV 5.10%, and bias (d%) 1.03%.

Precision results, as seen from the Coefficient of Variation (CV) value, show that the CV value in October was 4.99%, November 4.89%, and December 5.10%. No CV value was found that exceeded the maximum limit determined by the 2013 Indonesian Minister of Health Regulation, which is 8%. This shows that the examination has a good level of precision, where the test results are consistent and stable when repeated. A low CV value reflects a minimal level of random error, which can be caused by factors such as the stability of the tool, reagents, and test conditions.

Accuracy test seen from the bias value (d%) showed good results, with bias values in October 0.77%, November 0.88%, and December 1.03%. All bias values are within acceptable limits, which is ±10%, as regulated in the 2013 Indonesian Minister of Health Regulation and the provisions of the H. Andi Sulthan Daeng Radja Regional Hospital. Good accuracy reflects the precision of the test, where the results are close to the true value. Low bias values indicate minimal systematic errors, which are usually caused by good calibration of the instrument or standard.

Based on the Levey-Jennings Chart for October 2023, there was one Westgard Rule 1-2s deviation on the second day, where the control value crossed the -2SD limit but was still within the -3SD limit. This 1-2s rule violation indicates a warning on the examination, but the control results are still acceptable. This can be caused by factors such as instability of the room temperature, reagent conditions, or inconsistencies in the examination procedure. Overall, the chart shows that the control value was within the control limits on the other days, so the test method in October can still be considered stable and accurate.

In the Levey-Jennings Chart for November 2023, there were no deviations from the Westgard rule, where all control values were within the specified control limits (±2SD). This indicates that the urea examination during November had a very good level of precision and accuracy. The absence of deviations indicates consistency in the implementation of laboratory procedures, including the stability of the equipment and the condition of the reagents used.

The Levey-Jennings chart for December 2023 also showed good results, with no deviations from the Westgard rule. All control values were within the control limits of ±2SD, reflecting excellent accuracy and precision in the examination. The stability of the test method during December showed that the laboratory was able to maintain good test

quality. The results of this study indicate that the urea parameter testing at the H. Andi Sulthan Daeng Radja Hospital laboratory for the period from October to December 2023 had good precision and accuracy. The CV% value was always below the maximum limit of 8%, while the bias value (d%) was in the range of ±10%, in accordance with the established standards. Deviations from the Westgard rule were only found in October (rule 1-2s), which was a warning, so the control was still acceptable.

This study is in line with the study conducted by Yuliana (2022), which also showed that the bias value in urea examination was within the range of ±10%. The same results were found in the study of Al-Azizah et al. (2023), which used the Levey-Jennings chart to evaluate the quality control of urea and creatinine in other laboratories. However, this study has advantages in its analytical approach, namely by applying the Westgard rule to detect analytical deviations in more detail. In addition, this study integrates a three-month observation period, which provides a more comprehensive picture of the quality control pattern in the H. Andi Sulthan Daeng Radja Hospital laboratory.

Compared with previous studies, this study also successfully demonstrated that not only precision is important in quality control, but also accuracy, as demonstrated by the calculation of bias consistently below the ±10% limit. This emphasizes the importance of implementing an internal quality assurance system in the laboratory, especially in identifying and minimizing random and systematic errors. Previous studies often only focused on precision without evaluating accuracy in detail, so this study provides added value in the analysis of laboratory quality control.

In the future, further research is expected to integrate additional parameters, such as creatinine or glucose, to provide a broader evaluation of the quality of laboratory testing. In addition, the use of more sophisticated software for Levey-Jennings chart analysis and the application of the sigma metric approach can help improve sensitivity in detecting deviations. This study provides important implications that laboratories need to continue to strengthen their quality assurance systems by adopting international standards and conducting routine training for laboratory personnel to maintain the consistency and quality of examination results.

To maintain and improve the quality of examination, it is recommended that: Laboratory equipment is always calibrated routinely, Reagent quality is checked before use, Room temperature stability is maintained during testing, SOP is consistently applied by laboratory personnel. Good laboratory quality assurance requires a control strategy that is appropriate to field conditions to produce accurate and reliable examination results.

## CONCLUSION

This study was conducted to evaluate the description of the Internal Quality Assurance (PMI) results on urea parameters in the laboratory of H. Andi Sulthan Daeng Radja Hospital, Bulukumba Regency during the period from October to December 2023. The results showed that the laboratory had good precision with a CV value below the maximum limit of 8% and optimal accuracy with a bias value in the range of ±10%, which can have a significant influence in ensuring the stability and validity of laboratory examination results. The impact of this study is increased confidence in the quality of

laboratory services and the validity of urea parameter test results, which are important for clinical decision making. The advantages of this study compared to previous studies, such as Yuliana's (2022) and Al-Azizah et al. (2023), is the use of Levey-Jennings graphic data for more detailed analysis with the Westgard Rules approach, which provides early warning of deviations from the analytical process. This study also shows that laboratory quality control at H. Andi Sulthan Daeng Radja Hospital is in accordance with international standards. It is hoped that further research can develop testing on other parameters using more comprehensive methods, such as sigma metrics, to improve the efficiency and effectiveness of laboratory quality assurance. The implication of this study is the importance of implementing stricter quality control strategies in the laboratory to ensure the accuracy and precision of examination results, as well as support better clinical decision making.

## REFERENCES

Al-Azizah, D. A., Widyantara, A. B., Aulia, I., & Mua, U. (2023). Analisis kontrol kualitas ureum dan kreatinin menggunakan grafik Levey-Jennings dan sigma metrik. Jurnal Analis Kesehatan, 12(2), 78–84.

Amalia, P., Kurniawan, E., Rahayu, I. G., & Noviar, G. (2019). Analisis faktor-faktor kepatuhan penerapan. Jurnal Riset Kesehatan Poltekkes Depkes Bandung, 11(2), 211–217.

Anggraini, F., Khotimah, E., & Ningrum, S. S. (2022). Analisis pemantapan mutu internal pemeriksaan glukosa darah di laboratorium RS Bhayangkara. Binawan Student Journal (BSJ), 4(April), 24–30.

Awalia, R., Ridwan, A., & Islawati, I. (2024). Gambaran kadar gula darah penderita tuberkulosis (TBC) di RSUD H. Andi Sulthan Daeng Radja Kabupaten Bulukumba. Jurnal Medisains Kesehatan, 5(2), 77–86.

Bastian, M. U. (2023). Edukasi pemantapan mutu internal tahap pra-analitik pada pemeriksaan glukosa di Puskesmas Talang Pangeran Ogan Ilir. Jurnal Altifani (Penelitian dan Pengabdian Kepada Masyarakat), 3(5), 676–682. https://doi.org/10.25008/altifani.v3i5.476

Arwie, D. (2018). Penentuan kriteria penilaian kesan jumlah leukosit pada pemeriksaan apusan darah tepi. Jurnal Kesehatan Panrita Husada, 3(2), 118–127.

Kusmiati, M., Nurpalah, R., & Restaviani, R. (2022). Presisi dan akurasi hasil quality control pada parameter pemeriksaan glukosa darah di laboratorium klinik Rumah Sakit X Kota Tasikmalaya. JoIMedLabS, 3(1), 27–37.

Pratama, R. A., Yulianti, D. K., & Setiawan, D. (2021). Aplikasi metrik sigma dalam pemantapan mutu internal pada pemeriksaan ureum di salah satu laboratorium rumah sakit Kabupaten Pangandaran. Journal of Indonesian Medical Laboratory and Science (JoIMedLabS), 2(2), 175–184. https://doi.org/10.53699/joimedlabs.v2i2.64

Samsul, W. M. S., Arwie, D., & Ridwan, A. (2022). Gambaran kristal asam urat pada sediaan sedimen urine penderita gout di Puskesmas Bontobangun. Jurnal TLM Blood Smear, 3(2), 64–69.

Warite, G., & Sulaiman, E. N. (2023). Hubungan pengetahuan dan dukungan keluarga dengan kepatuhan pasien gagal ginjal kronik dalam menjalani terapi hemodialisa di RSUD Bahteramas Provinsi Sulawesi Tenggara Tahun 2023. Jurnal Penelitian Sains dan Kesehatan Avicenna, 2(3).

Yanti, H., Aryandi, R., & Hadijah, S. (2023). Gambaran parameter hematologi rutin pada pasien yang terkonfirmasi COVID-19. Jurnal TLM Blood Smear, 4(2), 58–62.

Yudita, F., Purbayanti, D., Ramdhani, F. H., & Jaya, E. (2023). Evaluasi kontrol kualitas pemeriksaan glukosa darah di laboratorium X Palangka Raya. Borneo Journal of Medical Laboratory Technology, 5(2), 358–365. https://doi.org/10.33084/bjmlt.v5i2.5184

Yuliana, R. R. (2022). Analisis hasil quality control pemeriksaan ureum dan kreatinin di laboratorium RS PKU Muhammadiyah Gamping. Naskah Publikasi.