



Verification of total cholesterol testing method using an automated chemistry analyzer based on accuracy, precision, and linearity parameters at Cimanggu I Public Health Center

Nia Putri Sari¹, Yusuf Eko Nugroho¹, Ira Pangesti¹

¹ Department of Medical Laboratory Technology, Faculty of Pharmacy, Science and Technology, Universitas Al-Irsyad Cilacap, Central Java, Indonesia

Correspondence

Nia Putri Sari
Jalan Cerme No. 24, Sidanegara, Cilacap Tengah,
Indonesia
Email: Niaputrisari11@gmail.com

Received: 2026-06-22

Revised: 2026-10-14

Accepted: 2026-10-11

Available online: 2026-10-21

DOI: <https://doi.org/10.53699/joimedlabs.v7i2.365>

Citation

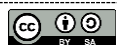
Sari NP, Nugroho YA, Pangesti I. Verification of total cholesterol testing method using an automated chemistry analyzer based on accuracy, precision, and linearity parameters at Cimanggu I Public Health Center. *Journal of Indonesian Medical Laboratory and Science*, 7(2), 76-84.
<https://doi.org/10.53699/joimedlabs.v7i2.365>

Abstract

Background: Checking total cholesterol is one of the most common lab tests to spot and keep track of high cholesterol. To get reliable results, the tests need to be accurate, precise, and consistent. **Objectives:** This study looked at how well the Rayto Chemray 240 automated chemistry analyzer measures total cholesterol, focusing on accuracy, precision, and consistency. **Materials and Methods:** We did an experimental lab study at the Clinical Laboratory of Cimanggu I Public Health Center. To check precision, we measured quality control serum ten times in one run and calculated the coefficient of variation (CV). Accuracy was checked by measuring quality control serum over twenty days and reporting recovery percentage, bias, and total error. We checked linearity using a range of cholesterol standard concentrations (0-100%) and analyzed it with linear regression. **Results:** The precision test gave an average value of 144.67 mg/dL, a standard deviation of 3.07, and a CV of 2.12%. Accuracy results showed a recovery of 103.07%, bias of 3.07%, and total error of 9.61%, which is under the allowed limit of 10%. The linearity test produced the regression equation $y = 1.95x + 19.85$ with a correlation coefficient (r) of 0.999 and R^2 of 0.998. **Conclusions:** The total cholesterol test using the Rayto Chemray 240 analyzer met the standards for precision, accuracy, and linearity, so it's good to use for regular lab tests.

Keywords

Accuracy, Automated chemistry analyzer, Cholesterol, Linearity, Precision.



Copyright: © 2026 by the authors. Submitted for possible open access publication under the terms and conditions of the Creative Commons Attribution (CC BY SA) license. (<https://creativecommons.org/licenses/by-sa/4.0/>).

1. Introduction

Cholesterol is an essential lipid component that plays important roles in the synthesis of steroid hormones, vitamin D, and bile acids. Physiologically, cholesterol is obtained from endogenous synthesis, primarily in the liver, and from dietary intake. Although cholesterol is necessary for normal body functions, elevated blood cholesterol levels can increase the risk of cardiovascular diseases, including coronary heart disease, hypertension, and stroke (Hanifah et al., 2024; Nabilla et al., 2022). Hypercholesterolemia is recognized as one of the major modifiable risk factors contributing to cardiovascular morbidity and mortality worldwide.

The prevalence of hypercholesterolemia remains high globally and continues to increase. Previous reports estimated that approximately 45% of the world's population experiences elevated cholesterol levels, while the prevalence in Southeast Asia and Indonesia reaches approximately 30% and 35%, respectively (Hanifah et al., 2024). Hypercholesterolemia is often asymptomatic and can only be identified through laboratory examinations, making cholesterol testing an important tool for early detection and disease prevention. Elevated cholesterol levels may promote the formation of atherosclerotic plaques within arterial walls, thereby increasing the risk of cardiovascular complications (Puspasari et al., 2024; Robert Lourdes et al., 2024).

Total cholesterol examination is one of the most commonly performed clinical chemistry tests in healthcare facilities. Currently, enzymatic colorimetric methods, particularly the CHOD-PAP (Cholesterol Oxidase–Phenol Aminophenazone) method, are widely used because of their high sensitivity, good analytical performance, and compatibility with automated chemistry analyzers (Fitri et al., 2024). Automated analyzers have become increasingly important in clinical laboratories because they improve analytical efficiency, reduce manual errors, and provide more consistent results than manual methods. The implementation of laboratory automation has been reported to significantly reduce analytical variability and improve the reliability of laboratory testing (Kusmiati et al., 2022).

Reliable laboratory results are essential because laboratory data serve as the basis for clinical decision-making, including diagnosis, treatment monitoring, and disease screening. Therefore, analytical methods used in laboratory testing must demonstrate acceptable performance characteristics before being routinely applied. Method verification and validation activities are conducted to ensure that laboratory examinations produce accurate, precise, and reliable results in accordance with established quality requirements (Lianti et al., 2023). These activities are particularly important when implementing analytical methods in specific laboratory settings because instrument performance may be influenced by environmental conditions, operator competency, reagent quality, and maintenance practices.

Several analytical performance parameters are commonly evaluated during method verification, including accuracy, precision, and linearity. Accuracy describes the closeness of measurement results to the true or assigned value, while precision reflects the consistency of repeated measurements under specified conditions. Linearity evaluates the ability of an analytical method to generate results that are directly proportional to analyte concentration within a defined measurement range (Marcelino et al., 2025; Wahyuni et al., 2022). Assessment of these parameters provides evidence that a testing method is capable of producing reliable analytical results suitable

for routine laboratory use.

The Clinical Laboratory of Cimanggu I Public Health Center utilizes the Rayto Chemray 240 automated chemistry analyzer for total cholesterol examination. Although the instrument and reagents have been developed according to manufacturer specifications, verification of analytical performance under local laboratory conditions remains necessary to ensure compliance with quality requirements and to support confidence in laboratory results. Therefore, this study aimed to verify the analytical performance of total cholesterol examination using the Rayto Chemray 240 analyzer based on accuracy, precision, and linearity parameters. The findings of this study are expected to provide evidence regarding the suitability of the method for routine clinical laboratory testing and contribute to quality assurance practices in primary healthcare laboratories

2. Materials and Methods

2.1. Study Design

This study employed an experimental laboratory design to assess the analytical performance of total cholesterol measurement using an automated chemistry analyzer. The verification process was conducted by evaluating accuracy, precision, and linearity parameters. Subsection

2.2. Study Location and Period

The study was conducted at the Clinical Laboratory of Cimanggu I Public Health Center, Cilacap Regency, Central Java, Indonesia. Laboratory testing and data collection were carried out six month.

2.3. Instruments and Materials

The instruments employed in this study comprised a Rayto Chemray 240 automated chemistry analyzer, a centrifuge, micropipettes, and sample cups. The materials included Proline total cholesterol reagent based on the CHOD-PAP method, a cholesterol standard solution, and commercial quality control (QC) serum with assigned target values.

2.4. Precision Verification

Precision was assessed using within-run precision analysis. A commercial quality control serum was measured ten consecutive times under identical operating conditions using the Rayto Chemray 240 analyzer. The results obtained were analyzed by calculating the mean, standard deviation (SD), and coefficient of variation (CV%). The coefficient of variation was calculated using the following formula:

$$CV(\%) = (SD / \text{Mean}) \times 100$$

A lower CV value indicates greater analytical precision (Endrianti, 2023).

2.5. Accuracy Verification

Accuracy was assessed using a commercial quality control serum with an assigned target value provided by the manufacturer. The control material was analyzed once daily for twenty consecutive days under routine laboratory conditions.

Accuracy was evaluated by calculating recovery percentage (%Recovery), bias percentage (%Bias), and total error (TE).

Recovery percentage was calculated using the following formula:

$$\text{Recovery}(\%) = (\text{Observed Value} / \text{Target Value}) \times 100$$

Bias percentage was calculated using:

$$\text{Bias}(\%) = ((\text{Observed Value} - \text{Target Value}) / \text{Target Value}) \times 100$$

Total error was calculated using:

$$TE = |\text{Bias}| + (1.65 \times CV)$$

The method was considered acceptable when the recovery value was within the acceptable range and the total error did not exceed the Total Allowable Error (TEa) for total cholesterol examination.

2.6. Linearity Verification

Linearity was assessed using serial concentrations prepared from a cholesterol standard solution. Five concentration levels, representing 0%, 25%, 50%, 75%, and 100% of the standard, were prepared and measured in triplicate using the Rayto Chemray 240 analyzer.

The measured values were plotted against the theoretical concentrations and analyzed using linear regression to determine the regression equation, correlation coefficient (r), and coefficient of determination (R²). A correlation coefficient close to 1 indicates good linearity of the analytical method.

2.7. Statistical Analysis

Data were analyzed descriptively. Precision data were presented as mean, standard deviation, and coefficient of variation. Accuracy data were presented as recovery percentage, bias percentage,

and total error. Linearity data were analyzed using simple linear regression to determine the regression equation, correlation coefficient (r), and coefficient of determination (R^2).

3. Results and Discussion

3.1. Precision Verification

Precision verification was conducted by measuring commercial quality control serum ten consecutive times under identical analytical conditions. The results of the precision assessment are shown in Table 1.

Table 1. Precision Verification Results of Total Cholesterol Examination

Parameter	n	Mean	Minimum	Maximum	SD	CV (%)
Control Serum	10	144.67	140.0	148.6	3.07	2.12

The precision evaluation yielded a mean value of 144.67 mg/dL, with a standard deviation of 3.07 mg/dL and a coefficient of variation (CV) of 2.12%. The CV observed in this study closely aligns with the manufacturer's reported precision of 2.1%, indicating minimal variability in repeated measurements and demonstrating good analytical stability. A lower CV indicates better repeatability and consistency of measurement outcomes (Endrianti et al., 2023).

Precision is a crucial analytical performance characteristic as it reflects a method's ability to consistently generate the same results when the same sample is measured multiple times under identical conditions. High analytical precision minimizes random errors and enhances confidence in laboratory findings. The CV obtained in this study indicates that the Rayto Chemray 240 analyzer, when used with the Proline reagent, delivers stable and reproducible results for routine total cholesterol testing.

The findings are consistent with previous studies that reported acceptable precision performance in automated clinical chemistry analyzers used for cholesterol measurement. (Kusmiati et al., 2022) noted that quality control evaluation is a crucial component of laboratory quality assurance, as it ensures the consistency and reliability of analytical results. Similarly, (Marcelino et al., 2025) highlighted that low CV values indicate good analytical performance and support the routine application of laboratory testing methods.

3.2. Linearity Verification

Linearity verification was performed using serial concentrations of cholesterol standards **ranging** from 0% to 100%. Each concentration level was measured three times and analyzed using simple linear regression. The results are shown in Table 2.

Table 2. Linearity Verification Results of Total Cholesterol Examination

Parameter	Result
Concentration range	0-100%
Regression equation	$y = 1.95x + 19.85$
Correlation coefficient (r)	0.999
Coefficient of determination (R^2)	0.998

The linearity study demonstrated a strong linear relationship between theoretical concentrations and measured cholesterol values, as indicated by the regression equation $y = 1.95x + 19.85$. The correlation coefficient obtained was 0.999 with a coefficient of determination (R^2) of 0.998.

A correlation coefficient approaching 1 indicates that the analytical method is capable of producing results proportional to analyte concentration across the tested measurement range (Wahyuni et al., 2022). The high R^2 value observed in this study suggests that almost all variations in measured cholesterol concentrations can be explained by changes in theoretical concentrations.

Good linearity is essential for quantitative laboratory examinations because it ensures that increases or decreases in analyte concentration are accurately reflected in the reported results. In clinical chemistry laboratories, inadequate linearity may lead to inaccurate interpretation of patient results, particularly when analyte concentrations approach clinical decision limits. Therefore, the excellent linearity observed in this study indicates that the analytical system is capable of providing reliable quantitative measurements within the evaluated concentration range.

3.3. Accuracy Verification

Accuracy verification was evaluated using commercial quality control serum with an assigned target value provided by the manufacturer. Measurements were performed over twenty consecutive days under routine laboratory conditions. The results are presented in Table 3.

Table 3. Accuracy Verification Results of Total Cholesterol Examination

Parameter	n	Mean (mg/dL)	Target Value (mg/dL)	Recovery (%)	Bias (%)	Total Error (%)
Accuracy	20	146.36	142.00	103.07	3.07	9.61

The average value measured from twenty observations was 146.36 mg/dL, compared to the assigned target value of 142.00 mg/dL. The recovery percentage was 103.07%, indicating that the measured values were closely aligned with the target concentration. The calculated bias was 3.07%, reflecting only a minor systematic deviation from the target value. Accuracy denotes the closeness of a measurement result to the true or assigned value and serves as a critical indicator of analytical reliability (L et al., 2020). In laboratory practice, a method exhibiting high accuracy minimizes systematic errors and enhances the validity of clinical interpretations.

The calculated total error was 9.61%, remaining below the Total Allowable Error (TEa) limit of 10% for total cholesterol testing. This result indicates that the analytical method satisfies the established quality standards and is capable of producing results within acceptable performance limits. The minimal bias and acceptable total error observed in this study suggest that the analytical system provides reliable cholesterol measurements appropriate for routine laboratory use.

These findings are corroborated by previous studies, which demonstrate that acceptable recovery, bias, and total error values reflect satisfactory analytical accuracy and contribute to overall laboratory quality assurance (Lianti et al., 2023; Nurtya et al., 2023).

3.4. Overall Analytical Performance

Based on the results of precision, linearity, and accuracy verification, the total cholesterol assay using the Rayto Chemray 240 automated chemistry analyzer exhibited satisfactory analytical performance. The method demonstrated excellent repeatability (CV = 2.12%), strong linearity ($r = 0.999$), and acceptable accuracy (Recovery = 103.07%; Bias = 3.07%; Total Error = 9.61%).

These results indicate that the analytical system is capable of providing reliable, consistent, and proportional measurement results and can therefore be utilized for routine total cholesterol testing at the Clinical Laboratory of Cimanggu I Public Health Center. The study also underscores the importance of regular verification activities as part of laboratory quality assurance programs to

maintain confidence in analytical performance and ensure the reliability of patient test results.

4. Conclusions

This study verified the analytical performance of total cholesterol testing using the Rayto Chemray 240 automated chemistry analyzer by evaluating precision, accuracy, and linearity parameters.

The method showed acceptable analytical performance with a coefficient of variation (CV) of 2.12%, a correlation coefficient (r) of 0.999, a recovery value of 103.07%, a bias of 3.07%, and a total error of 9.61%. These results indicate that the analytical system is capable of providing precise, accurate, and linear measurements within the tested range.

Therefore, the total cholesterol testing method implemented at the Clinical Laboratory of Cimanggu I Public Health Center meets analytical performance standards and can be reliably used for routine laboratory examinations. Periodic verification and quality control monitoring are recommended to ensure continued analytical performance and laboratory quality assurance.

Acknowledgments: The authors would like to sincerely express their gratitude to the Clinical Laboratory of Cimanggu I Public Health Center for providing facilities and support during this study. They also extend their thanks to the Department of Medical Laboratory Technology, Faculty of Pharmacy, Science and Technology, Universitas Al-Irsyad Cilacap, for their academic guidance and assistance throughout the research process.

Funding: This research received no external funding.

Conflicts of Interest: The authors declare that they have no conflict of interest in relation to the publication of this article.

Declaration of Use of AI in Academic Writing: The author used ChatGPT in the writing process to improve readability and remove grammatical errors. However, he took full responsibility for the content

Author Contributions: NPS : Conceptualize and implement research and data analysis. YEN and IP : Evaluate and review research until it becomes a draft manuscript.

5. References

- Endrianti, R., Ridwanna, S., Rinaldi, S., & Solihat, M. (2023). VERIFIKASI METODE HEMATOLOGY ANALYZER SYSMEX XN-330 DI LABORATORIUM KLINIK LABORA. *Jurnal Kesehatan Siliwangi*, 4, 61-69. <https://doi.org/10.34011/jks.v4i1.1491>
- Fitri, B. A., Setiawan, W. A., Loga, S., Aini, S. R., Farmasi, S., Kedokteran, F., Universitas, K., Farmasi, S., Farmasi, F., Mutiara, S., Apoteker, P., & Kedokteran, F. (2024). *Review Article : Pemeriksaan Kolesterol Total*. 4, 13069-13080.
- Hanifah, L. I., Puspodewi, D., & Pangesti, I. (2024). *PERBANDINGAN HASIL PEMERIKSAAN KOLESTEROL TOTAL MENGGUNAKAN SAMPEL SERUM DAN PLASMA EDTA SEGERA DAN DISIMPAN SELAMA 4 JAM*. 12(2), 295-303.
- Kusmiati, M., Nurpalah, R., & Restavian, R. (2022). PRESISI DAN AKURASI HASIL QUALITY CONTROL PADA PARAMETER PEMERIKSAAN GLUKOSA DARAH DI LABORATORIUM KLINIK RUMAH SAKIT X KOTA TASIKMALAYA. *Journal of Indonesian Medical Laboratory and Science*, 3(1), 27-37.
- L, S., Kumalasari, M., Kusumawati, E., & Andyarini, E. (2020). HUBUNGAN KADAR

- KOLESTEROL DENGAN HIPERTENSI PADA PEGAWAI DI FAKULTAS PSIKOLOGI DAN KESEHATAN UIN SUNAN AMPEL. *Indonesian Journal for Health Sciences*, 4, 10. <https://doi.org/10.24269/ijhs.v4i1.2321>
- Lianti, D., Riyani, A., Nurhayati, D., & Kurnaeni, N. (2023). PERBANDINGAN KADAR UREUM PADA SERUM LIPEMIK METODE BERTHELOT DENGAN ULTRAVIOLET KINETIK. *Jurnal Kesehatan Siliwangi*, 4, 284-289. <https://doi.org/10.34011/jks.v4i1.1472>
- Marcelino, A. V., Labuai, T., & Pekanbaru, K. (2025). ANALISIS PRESISI DAN AKURASI ALAT KIMIA KLINIK MEREK BIO SYSTEMS MODEL A15 DALAM PENGUKURAN GLUKOSA PRECISION AND ACCURACY ANALYSIS OF THE BIO SYSTEMS MODEL A15 CLINICAL CHEMISTRY. 6(1), 1-8.
- Nabilla, J., Ulya, N., Ardianty, R., Agiska, S., Nadifah, F., & Qomariyah, N. (2022). CHOD-PAP Method Total Cholesterol Examination Validation on Samples Stored for 1 Week In 4-8°C Temperature. *Jaringan Laboratorium Medis*, 5, 7-11. <https://doi.org/10.31983/jlm.v5i1.8690>
- Nurtya, A., Tjempakasari, A., Maimunah, U., Sulistiawati, S., & Harsa, I. M. (2023). Hypertension and Lipid Profiles in Middle-Aged Male Patients: A Study at a Tertiary Hospital in Surabaya, Indonesia. *Folia Medica Indonesiana*, 59, 321-328. <https://doi.org/10.20473/fmi.v59i4.49674>
- Puspasari, H., Herdaningsih, S., & Inderiyani. (2024). EDUKASI PENCEGAHAN HIPERKOLESTEROLEMIA PADA MASYARAKAT DI PULAU KABUNG KABUPATEN BENGKAYANG. *Jurnal Pengabdian Indonesia*, 04(01), 261-267.
- Robert Lourdes, T. G., Chong, Z. L., Saminathan, T. A., Abd Hamid, H. A., Mat Rifin, H., Wan, K. S., Ab Majid, N. L., Yoga Ratnam, K. K., Riyadzi, M. R., Ismail, H., Alias, N., & Mohd Yusoff, M. F. (2024). Diagnostic accuracy of Cardiochek® PA point-of-care testing (POCT) analyser with a 3-in-1 lipid panel for epidemiological surveys. *Lipids in Health and Disease*, 23(1), 297. <https://doi.org/10.1186/s12944-024-02270-2>
- Wahyuni, A., Afthoni, M., & Rollando, R. (2022). Pengembangan dan Validasi Metode Analisis Spektrofotometri UV Vis Derivatif untuk Deteksi Kombinasi Hidrokortison Asetat dan Nipagin pada Sediaan Krim. *Sainsbertek Jurnal Ilmiah Sains & Teknologi*, 3, 239-247. <https://doi.org/10.33479/sb.v3i1.181>