

DAFTAR PUSTAKA

- Abraham, J. *et al.* (2018) *Clinical Chemistry Principles, Techniques, and Correlations*, Wolters Kluwer.
- Adaran, T. *et al.* (2025) 'Quality Management Systems implementation in public medical laboratories; A sustainable approach to health system strengthening in Lagos State, Nigeria', *Plos One*, 20(6 June), pp. 1–14. Available at: <https://doi.org/10.1371/journal.pone.0319409>.
- Anggra, W.N. and Yusuf, R.N. (2021) 'Comparasion Between Pooled Sera Material and Commercial Serum on the Accuracy of Triglyceride Check', 39(SeSICNiMPH), pp. 330–334.
- Arrobas Velilla, T. *et al.* (2023) 'Consensus document for lipid profile determination and reporting in Spanish clinical laboratories. What parameters should be included in a basic lipid profile', *Nefrologia*, 43(4), pp. 474–483. Available at: <https://doi.org/10.1016/j.nefro.2023.02.002>.
- Aryani, T., Putri, N.E. and Rahmawati, Y. (2024) 'Quality Control of Cholesterol and Triglyceride Testing Using Commercial Control Materials After Room Temperature Storage', 7(10), pp. 3712–3718. Available at: <https://doi.org/10.56338/jks.v7i10.5578>.
- Astriani, R.D., Nuraeni, H.S. and Hamtini, B. (2025) 'Reserch Article Homemade Control Material Stability for Hemoglobin Examination', 3(1), pp. 17–20.
- Azmi, M. *et al.* (2025) 'Evaluation of the Quality of Commercial Control Materials and Homemade Lyophilized on Clinical Chemistry Parameters with the Sigma Metric Method', 18(3), pp. 145–156.
- Baneu, P. *et al.* (2024) 'The Triglyceride/HDL Ratio as a Surrogate Biomarker for Insulin Resistance', *Biomedicines*, 12(7). Available at: <https://doi.org/10.3390/biomedicines12071493>.
- Bastian, B., Ulva, M. and Rahmadani, I.R. (2024) 'Pemanfaatan Pooled Sera sebagai Bahan Kontrol Pemantapan Mutu Internal Pemeriksaan SGPT', *Jurnal Kesehatan Vokasional*, 9(2), pp. 115–125. Available at: <https://doi.org/10.22146/jkesvo.95611>.
- Biorad (2025) *A Practical Guide to Six Sigma*. Available at: https://www.biorad.com/en-id/resources/quality-controls/qc-resources/practical-guide-to-six-sigma-in-the-clinical-lab?utm_source.
- Cavallari, S. (2024) 'Quality control in clinical laboratories : Ensuring accuracy and patient safety .', 6(6), pp. 1–2. Available at: <https://doi.org/10.35841/aacplm-6.6.242>.
- Chaudhry, A.S., Inata, Y. and Nakagami-Yamaguchi, E. (2023) 'Quality analysis of the clinical laboratory literature and its effectiveness on clinical quality improvement: a systematic review', *Journal of Clinical Biochemistry and Nutrition*, 73(2), pp. 108–115. Available at:

<https://doi.org/10.3164/jcbln.23-22>.

- Christin, A. *et al.* (2025) 'Evaluation of Commercial Control Materials vs . Homemade Lyophilisates For Kidney Function Tests Using Sigma Metric', 5(4), pp. 172–177.
- Control, U.Q. (2025) *External Quality Assesment*. Available at: <https://unityweb.qcnet.com/Documentation/Help/UnityWeb/399.htm>.
- Cui, D. *et al.* (2025) 'Cholesterol metabolism: molecular mechanisms, biological functions, diseases, and therapeutic targets.', *Molecular biomedicine*, 6(1), p. 72. Available at: <https://doi.org/10.1186/s43556-025-00321-3>.
- Das, S., Garg, M. and Sharma, N. (2024) 'Sigma Metrics Assessment as Quality Improvement Methodology in a Clinical Chemistry Laboratory', *Indian Journal of Medical Biochemistry*, 27(2), pp. 23–27. Available at: <https://doi.org/10.5005/jp-journals-10054-0218>.
- Dietzen, D.J. *et al.* (2020) *Part I, Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics*.
- Erdogan, Y. *et al.* (2024) 'Performance Evaluation of a Coagulation Laboratory Using Sigma Metrics and Quality Goal Index', *Clin Lab*, 1. Available at: <https://doi.org/https://doi.org/10.7754/clin.lab.2024.240619>.
- Erica Fatica, Sarah Jenkins, Renee Scott, Darci R. Block, Jeffrey Meeusen, Nikola Baumann, Amy Saenger, L.D. (2021) 'Biological Variability of Small Dense LDL, HDL3, and Triglyceride-Rich Lipoprotein Cholesterol', p. 2021. Available at: <https://doi.org/10.1093/ajcp/aqab189>.
- Fadhilah, F., Riyadi, S.A. and Yuliani, E. (2022) 'Effect of Varied Concentrations of Ethylhene Glycol as Pooled Serum Preservative on the Stability of Alkaline Phosphatase (ALP) Ezyme', *Nusantara Science and Technology Proceedings*, 2022, pp. 25–30. Available at: <https://doi.org/10.11594/nstp.2022.2204>.
- Geto, Z. *et al.* (2022) 'Evaluation of Sigma Metrics and Westgard Rule Selection and Implementation of Internal Quality Control in Clinical Chemistry Reference Laboratory, Ethiopian Public Health Institute', *Indian Journal of Clinical Biochemistry*, 37(3), pp. 285–293. Available at: <https://doi.org/10.1007/s12291-021-00994-x>.
- Goel, P. *et al.* (2021) 'Analysis of performance of clinical biochemistry laboratory using Sigma metrics and Quality Goal Index', *Practical Laboratory Medicine*, 23(December 2020), p. e00195. Available at: <https://doi.org/10.1016/j.plabm.2020.e00195>.
- Gruber, L., Hausch, A. and Mueller, T. (2024) 'Internal Quality Controls in the Medical Laboratory: A Narrative Review of the Basic Principles of an Appropriate Quality Control Plan', *Diagnostics*, 14(19). Available at: <https://doi.org/10.3390/diagnostics14192223>.

- Handayati, A. (2022) 'Design of Home Made Lyophilized Serum as a Control Material for Internal and External Quality Control in Clinical Laboratories', *Health Notions*, 6(12), pp. 502–507. Available at: <http://heanoti.com/index.php/hnhttp://heanoti.com/index.php/hn/article/view/hn61203>.
- Van Heerden, M., George, J.A. and Khoza, S. (2022) 'The application of sigma metrics in the laboratory to assess quality control processes in South Africa', *African Journal of Laboratory Medicine*, 11(1), pp. 1–7. Available at: <https://doi.org/10.4102/AJLM.V11I1.1344>.
- Hu, M. *et al.* (2025) 'The Application of Six Sigma to Assess the Analytical Performance of Plasma Proteins and Design a Risk-Based Statistical Quality Control Strategy: A Multicenter Study', *Journal of Clinical Laboratory Analysis*, 39(16), pp. 1–11. Available at: <https://doi.org/10.1002/jcla.70080>.
- Ibrahim, A. *et al.* (2022) 'Quality Assurance in Clinical Laboratories: Best Practices and Continuous Improvement Strategies', *Journal of Population Therapeutics and Clinical Pharmacology*, 29(04), pp. 1365–1374. Available at: <https://www.jptcp.com/index.php/jptcp/article/view/5831%0Ahttps://www.jptcp.com>.
- ISO15189 (2022) 'International Standards Medical laboratories — Requirements for quality and competence', 4, p. 72. Available at: <https://www.iso.org/>.
- Kanani, F.Z., Haider Kazmi, A. and Kaleem, B. (2021) 'Sigma metrics of Alinity ci system - A study on thirty-nine clinical chemistry and immunoassay parameters', *Advances in Laboratory Medicine*, 2(2), pp. 267–275. Available at: <https://doi.org/10.1515/almed-2021-0001>.
- Kannan, N., Ramalingam, K. and Ramani, P. (2024) 'Revolutionising Quality Management in the Oral Pathology Laboratory: A Deep Dive Into the Six Sigma Methodology', *Cureus*, 16(1), pp. 1–9. Available at: <https://doi.org/10.7759/cureus.52651>.
- Karaattuthazhathu, A.R. *et al.* (2023) 'Sigma Metrics as a Valuable Tool for Effective Analytical Performance and Quality Control Planning in Clinical Laboratory: A Retrospective Study', *National Journal of Laboratory Medicine*, 12(2), pp. 14–18. Available at: <https://doi.org/10.7860/njlm/2023/60440.2714>.
- Kayamori, Y. *et al.* (2021) 'Comparison of the Japan Society of Clinical Chemistry reference method and CDC method for HDL and LDL cholesterol measurements using fresh sera', *Practical Laboratory Medicine*, 25(April 2020), p. e00228. Available at: <https://doi.org/10.1016/j.plabm.2021.e00228>.
- Kim, S., Cho, Y. and Yun, S.G. (2021) 'Sigma Metrics를 이용한 자동화학분석기의 성능 평가 Evaluating the Performance of an

Automated Chemistry Analyzer Using Sigma Metrics', 11(1), pp. 11–16.

- Korchia, J. and Freeman, K.P. (2022) 'Total observed error, total allowable error, and QC rules for canine serum and urine cortisol achievable with the Immulite 2000 Xpi cortisol immunoassay', *Journal of Veterinary Diagnostic Investigation*, 34(2), pp. 246–257. Available at: <https://doi.org/10.1177/10406387221076129>.
- Kulkarni, S., Pierre, S.A. and Kaliaperumal, R. (2020) 'Efficacy of Pooled Serum Internal Quality Control in Comparison with Commercial Internal Quality Control in Clinical Biochemistry Laboratory', *Journal of Laboratory Physicians*, 12(03), pp. 191–195. Available at: <https://doi.org/10.1055/s-0040-1721151>.
- Kumar, B.V. and Mohan, T. (2021) 'Sigma metrics as a tool for evaluating the performance of internal quality control in a clinical chemistry laboratory', *Journal of Laboratory Physicians*, 10(02), pp. 194–199. Available at: https://doi.org/10.4103/jlp.jlp_102_17.
- Lestari, W.S. *et al.* (2022) 'Sera Pooled Stability As a Sgpt Control Material With Storage Time and Temperature Variation', *Journal of Medical Laboratory and Science*, 2(1), pp. 33–39. Available at: <https://doi.org/10.36086/medlabscience.v2i1.1255>.
- Lhajjam, H. *et al.* (2023) 'The importance of the Internal Quality Controls in medical laboratories to ensure high quality results', *Jornal Brasileiro de Patologia e Medicina Laboratorial*, 59(2), pp. 7–17. Available at: <https://doi.org/10.1900/JBPML.2023.59.02.002>.
- Maulidiyanti, E.T.S. *et al.* (2021) 'The Effect of Storage Time for Pooled Sera on Freezers on the Quality of Clinical Chemical Examination', *Medicra (Journal of Medical Laboratory Science/Technology)*, 4(2), pp. 78–82. Available at: <https://doi.org/10.21070/medicra.v4i2.1613>.
- Nadu, T. (2024) 'Quality control and its importance in good laboratory practice- Review Suchithra A 1 * and Dr . Dhana Rangesh Kumar V 2 1-Assistant Professor , Department of Biotechnology , Karpagam Academy of Higer Education , Coimbatore , Tamil Nadu , India', *Journal of University of Shanghai for Science and Technology*, 26(1), pp. 31–40.
- Naphade, M., Ankur, P.S. and Rajendra, S.R. (2023) 'Quality Control in Clinical Biochemistry Laboratory- A Glance', 17(2), pp. 2–5. Available at: <https://doi.org/10.7860/JCDR/2023/58635.17447>.
- Nisa, I.A., A, A.P.K. and Handayati, A. (2023) 'Comparison of Variant Index Score (VIS) of Homemade and Commercial Lyophilized Serum', 3(6), pp. 341–347.
- Norling, A., Bo, C.F. and Svala, E. (2021) 'Evaluating Commutability of Control Materials in Three Nordic External Quality Assessment Schemes for Lipoproteins'. Available at: <https://doi.org/10.1093/jalm/jfab058>.

- Nowak, D. and Jakubczyk, E. (2020) 'The freeze-drying of foods⇔the characteristic of the process course and the effect of its parameters on the physical properties of food materials', *Foods*, 9(10). Available at: <https://doi.org/10.3390/foods9101488>.
- Panda, C.R. *et al.* (2023) 'The Evaluation of the Quality Performance of Biochemical Analytes in Clinical Biochemistry Laboratory Using Six Sigma Matrices', *Cureus*, 15(Cv). Available at: <https://doi.org/10.7759/cureus.51386>.
- Parkavi, G., Senghor, K.A.A. and Vinodhini, V.M. (2024) 'Appraisal of six sigma in pre-analytical phase of clinical biochemistry laboratory', *Journal of Laboratory Physicians*, 16(4), pp. 530–535. Available at: https://doi.org/10.25259/jlp_163_2024.
- Patel, D.S., Sharma, D.S. and Sharma, D.H. (2022) 'Assessment of Analytical Quality through Sigma Metrics & its Application for Selection of Westgard Rule', *International Journal of Innovative Science and Research Technology*, 7(12), pp. 1573–1577.
- Peng, S.Q. *et al.* (2021) 'Practical application of Westgard Sigma rules with run size in analytical biochemistry processes in clinical settings', *Journal of Clinical Laboratory Analysis*, 35(3), pp. 1–5. Available at: <https://doi.org/10.1002/jcla.23665>.
- Perkumpulan Endokrinologi Indonesia (2021) 'Pengelolaan Dislipidemia Di Indonesia 2021', *PB Perkeni*, pp. 1–2.
- Permenkes RI Tahun 2022* (no date).
- Prevention, C. for D.C. and (2022) 'Cholesterol Reference Method Laboratory Network (Crmln) List of Analytical Systems & Reagents Certified for Ldlc', (July), pp. 1–10.
- Rahayu, W., Handayati, A. and Rahayuningsih, C.K. (2023) 'Stability of Homemade Lyophilized Serum for use as a Quality Control Material for Cholesterol and Triglyceride Parameters', *The 5 international conference on health polytechnics of surabaya (icohps) 2*, pp. 30–36.
- Reemachandrakantlondhe and Govekar, N. (2021) 'A Review On: Quality Assurance and Quality Control in Clinical Laboratories', *International Journal of Pharmaceutical Research and Applications*, 6(2), p. 796. Available at: <https://doi.org/10.35629/7781-0602796803>.
- Ricos, C. *et al.* (2022) 'Internal quality control – past , present and future trends', 3(3), pp. 243–252. Available at: <https://doi.org/10.1515/almed-2022-0029>.
- Ruffing, U. *et al.* (2024) 'Analytical performance evaluation of a new integrated clinical chemistry and immunoassay analyzer', *Practical Laboratory Medicine*, 41(August), p. e00427. Available at: <https://doi.org/10.1016/j.plabm.2024.e00427>.

- Sengupta, S. *et al.* (2023) 'Sigma metrics as quality indicators in guiding and tracking laboratory process improvement', *International Journal of Research in Medical Sciences*, 12(1), pp. 75–81. Available at: <https://doi.org/10.18203/2320-6012.ijrms20233837>.
- Seo, J. Do *et al.* (2021) 'Roche Cobas 8000 c702 자동분석장비에서의 체액 검체 화학검사 기질효과 평가', 11(4), pp. 254–266.
- Siregar, M.T. *et al.* (2018) *Bahan Ajar Teknologi Laboratorium Medik 'Kendali Mutu'*. Pertama, Pusat Pendidikan Sumber Daya Manusia Kesehatan. Pertama.
- Solnica, B. *et al.* (2024) '2024 Guidelines of the Polish Society of Laboratory Diagnostics and the Polish Lipid Association on laboratory diagnostics of lipid metabolism disorders', *Archives of Medical Science*, 20(2), pp. 357–374. Available at: <https://doi.org/10.5114/aoms/186191>.
- Syamsudin, A.A., Solihat, M.F. and Kurnani, N. (2023) 'Stabilitas Pooled Sera Dengan Penambahan Propilen Glikol, Etilen Glikol Dan Natrium Azida Sebagai Bahan Kontrol Alternatif', *Jurnal Riset Kesehatan Poltekkes Depkes Bandung*, 15(1), pp. 128–135. Available at: <https://doi.org/10.34011/juriskesbdg.v15i1.2187>.
- Teshome, M., Worede, A. and Asmelash, D. (2021) 'Total clinical chemistry laboratory errors and evaluation of the analytical quality control using sigma metric for routine clinical chemistry tests', *Journal of Multidisciplinary Healthcare*, 14, pp. 125–136. Available at: <https://doi.org/10.2147/JMDH.S286679>.
- Theodorsson, E., Meijer, P. and Badrick, T. (2024) 'External quality assurance in the era of standardization', *Clinica Chimica Acta*, 557(February), p. 117876. Available at: <https://doi.org/10.1016/j.cca.2024.117876>.
- Tumrani, R. *et al.* (2025) 'Sigma Metrics as a Measure to Evaluate Internal Quality Control Performance in a Clinical Chemistry Laboratory', 35(9), pp. 1115–1121. Available at: <https://doi.org/https://doi.org/10.29271/jcpsp.2025.09.1115>.
- Wang, W. *et al.* (2024) 'Evaluation of Coefficients of Variation for Clinical Chemistry Tests Based on Internal Quality Control Data Across 5 , 425 Laboratories in China From 2013 to 2022', pp. 245–252.
- Wati, M. *et al.* (2025) 'Analisis Quality Control Pemeriksaan Kolesterol Total dan Trigliserida Metode Six Sigma di RS Bhayangkara Polda DIY Tahun 2024', 6(September), pp. 9624–9630.
- Westgard (2025) *Westgard Rules and Multirule Quality Control*. Available at: <https://westgard.com/westgard-rules.html> (Accessed: 3 November 2025).
- Westgard, J. (2025a) *CLIA Acceptance Limits for Proficiency Testing*. Available at: <https://westgard.com/clia-a-quality/quality-requirements/2024-clia->

requirements.html (Accessed: 3 November 2020).

- Westgard, J. (2025b) *Westgard Sigma Rules*. Available at: <https://westgard.com/lessons/westgard-rules/westgard-rules/westgard-sigma-rules.html>.
- Westgard, S. (2024) 'Webinar Today ' s Drive Toward Better Quality Control SIGMA RULES WITH RUN when', pp. 16–21.
- Wheeler, S.E. *et al.* (2023) 'Quality standards and internal quality control practices in medical laboratories: an IFCC global survey of member societies', *Clinical Chemistry and Laboratory Medicine*, 61(12), pp. 2094–2101. Available at: <https://doi.org/10.1515/cclm-2023-0492>.
- WHO (2022) 'WHO manual for the preparation of reference materials for use as secondary standards in antibody testing', *Of Seas and Ships and Scientists*, pp. 310–312. Available at: <https://doi.org/10.2307/j.ctv319wqbb.26>.
- WHO Overview of External Quality Assessment (2015) 'External Quality Assessment Module', *World health Organization*, pp. 1–12. Available at: http://www.who.int/ihr/training/laboratory_quality/10_b_eqa_contents.pdf.
- Wulandari, N.N., Handayati, A. and Endarini, L.H. (2023) 'Stabilitas Serum Kontrol Liofilisat Buatan Sendiri Setelah Rekonstitusi Terhadap Kadar Kolesterol dan Trigliserida yang Disimpan dalam Freezer Suhu (-2°C) sampai (-4°C) dan (-20°C)', 14(4), pp. 67–72.
- Xiao, Y. and Chambliss, A.B. (2023) 'REVIEW A Review of Regulations , Terminology , and Practical Approaches to Reportable Range Verification', *The Journal of Applied Laboratory Medicine*, 08(04), pp. 773–788. Available at: <https://doi.org/10.1093/jalm/jfad001>.
- Yahya, M. *et al.* (2022) 'Migration Letters Quality Assurance and Quality Control in Clinical Laboratories: A Review', 8, pp. 589–598. Available at: www.migrationletters.com.
- Yoon, Y.A. *et al.* (2021) 'Standardization Status of Total Cholesterol Concentration Measurement : Analysis of Korean External Quality Assessment Data', pp. 366–371.