Received: 8 January 2023 | Accepted: 1 November 2023

DOI: 10.1111/ijlh.14212

REVIEW

ISLH International Journal of Laboratory Hematology WILEY

ICSH guidance for internal quality control policy for blood cell counters

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Funding information
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Abstract

This paper is a description of the ICSH guidance for internal quality control (IQC) policy for blood cell counters. It follows from and links to a separate ICSH review for such policies and practices. The ICSH has gathered information regarding the current state of practice through review of published guidance from regulatory bodies, a questionnaire to six major cell counter manufacturers and a survey issued to 191 diagnostic laboratories in four countries (China, the Republic of Ireland, Spain, and the United Kingdom) on their IQC practice and approach to the use of commercial IQC materials. This has revealed diversity both in guidance and in practice around the world. There is diversity in guidance from regulatory organizations in regard to IQC methods each recommends, clinical levels to use and frequency to run commercial controls, and finally recommended sources of commercial control materials. The diversity in practice among clinical laboratories spans the areas of IQC methods used, derivation of target values, and action limits used with commercial control materials, and frequency of running commercial controls materials. These findings and their implications for IQC Practice are addressed in this guidance document, which proposes a harmonized approach to address the issues faced by diagnostic laboratories.

KEYWORDS
cell counters, general haematology, guidance, ICSH, quality control

1 | INTRODUCTION

The ICSH set out to review practices for internal quality control (IQC) of blood cell counters worldwide and to issue a consensus guidance. Historical methods for the use of IQC materials included the preparation of in-house material made from human donor or animal blood preserved using various forms of fixation to provide stability and extended life,[1] and tested using available reference methods to assign target values and acceptable ranges. Today there is a reliance on commercially produced control materials due to health & safety concerns, staff time constraints, convenience and the need to have an IQC material that will assess all the parameters of the extended blood count, several of which may be specific to the particular manufacturer's instrument.[2–4]

There is a modern need for accreditation of clinical laboratories to international standards such as the International Organization for Standardization (ISO) 15 189[2] or the Clinical and Laboratory Standards Institute (CLSI)[4] and enforcement with regulatory agencies such as the College of American Pathologists (CAP)[3] deemed status enforcer of Clinical Laboratory Improvement (CLIA)'88[5] and subsequent amendments with frequent revisions of these standards. This has increased focus and scrutiny of laboratory practice for IQC. In the absence of clear and considered policy guidance in this area, the application of the standards may be open to interpretation leading to variation in practice and variance in expectations of what should be considered acceptable. The ICSH examined differences and inconsistencies that exist between the guidance of these regulatory bodies

and advice provided by the suppliers of commercial IQC materials and set out to provide new guidance.

The following guidance is based on information gathered in the ICSH Review of IQC Policy for Blood Cell Counters.[6]

2 | METHODS

The ICSH review collected information using the following methods:

1. A review of the published literature including recommendations and requirements of international quality standards.
2. Information gathering from six major cell counter manufacturers (Abbott Diagnostics, Beckman Coulter, Horiba Medical Diagnostic Instruments, Mindray Medical International, Siemens Healthcare Diagnostics, Sysmex Corporation), by questionnaire which included five questions as follows:

   A. Their recommendation to customers for IQC of their instruments, to include all QC methods they recommend (such as the XB analysis of patient mean values) and the recommendation for frequency of running the QC materials they supply
   B. Their policy for validation of their supplied IQC material, if possible
   C. To indicate whether their IQC material is supplied by a third-party manufacturer and if so to identify that manufacturer
   D. Their policy for ensuring traceability of their IQC materials to reference methods and determining uncertainty measurement of such IQC material(s)
   E. Their recommended or supplied statistical method to determine whether control results are out of range or require action, for example, use of Westgard rules or other method.

3. An international survey of quality practices across 191 laboratories in 4 countries (China, the Republic of Ireland, Spain, and the United Kingdom) to gather information on quality control practices in clinical diagnostic laboratories.
4. An examination and study of the differences between upper and lower action limits for IQC failure used in responding laboratories, expressed in the numerical distance in Standard Deviations either side of the observed mean.

3 | RESULTS OF SEPARATE ICSH REVIEW—SUMMARY OF FINDINGS

The details of the review findings summarized below are provided in the separate ICSH Review of IQC Policy for Blood Cell Counters.[6]

- There is some divergence in the recommendations of regulatory organizations for IQC practice, in regard to IQC methods each recommends, clinical levels to use and frequency to run commercial controls, and finally recommended sources of commercial controls.[2–4] These are summarized in Table 1 below.
- There is also divergence in the recommendations and information provided by cell counter manufacturers for use of commercial IQC materials, sometimes dependent on the geographic area where the diagnostic laboratory is located. These are summarized in Table 2 below.

TABLE 1 Summary of the IQC practice guidance for cell counting instruments by the regulatory bodies and standards agencies.

IQC Policy area	ISO[2]	CAP[3]	CLSI H26-A2[4]
IQC methods recommended	Use quality control materials that react to the examining system in a manner as close as possible to patient samples. No other stipulation on IQC methods	1. Stabilized whole blood controls 2. Patient moving average monitoring 3. Retained patient specimens	1. Stabilized whole blood controls 2. Intra-laboratory comparison such as use of patient samples 3. Weighted moving averages 4. Blood film morphology
Clinical levels of stabilized controls to use	The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values	At least 2 different controls must be assayed and evaluated every 24 h. Recommendation to use normal and high-level controls, rather than low level control.	Recommendation as per CAP
Frequency to run stabilized control materials	Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result	There should be some relationship between the frequency of control runs and the number of patient samples processed	Local laboratory to decide policy. There should be some relationship between the frequency of control runs and the number of patient samples processed
Source of commercial controls	Independent third-party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer	No stipulation regarding source of commercial controls	No stipulation regarding source of commercial control

TABLE 2 Summary of manufacturer recommendation to customers for IQC of their instruments, including QC methods they recommend.

IQC methodology	Replies from six instrument manufacturers
Use of commercially-supplied control material	All consider these should be run at least daily
Frequency and levels to run commercially supplied controls	Most recommend that "multi-level controls" be run, some recommend this should include three levels daily (low, medium and high); one recommends "minimum basic two levels every 24 h."
Use of patient moving average analysis	All recommend; some considered optional
Use of delta-checks of previous results	All recommend; some considered optional
Use of retained patient specimens	All recommend; some considered optional

- There is also divergence in practice among diagnostic laboratories in the four countries surveyed, in regard to:
  - Types of IQC methods in use, since some methods were not used
  - Derivation of control targets and limits used with commercial IQC material, depending on whether the IQC material provider's targets and action limits are used, or they are statistically calculated, or a combination of both
  - Frequency of running commercial control materials,
  - Use of patient means and/or retained patient specimens as part of overall IQC strategy (these methods were not used in some laboratories).

Note: In answer to Question B "their policy for validation of their supplied IQC material, if possible," the answers to this question varied between manufacturers. One stated that this requirement differs between manufacturers versus customers. Another stated that validation is carried out by their third-party IQC supplier. Most suppliers stated that cross-over (overlap) studies should be performed when implementing a new kit or lot of control material, by running old and new lots concurrently to allow comparison with the existing lot. Some stated that the local laboratory should establish their own mean values, or verify the manufacturer's mean. Interestingly, one supplier stated that in this regard "requirements differ based on geography." Several cell counter suppliers offered no specific guidance or requirement to their laboratory users in this regard.

4 | DISCUSSION

IQC practices for blood cell counting have evolved since the era when IQC materials were routinely prepared and tested within the local laboratory.[1,7] Today there is a reliance on commercially-produced IQC materials supplied by the cell counter manufacturer or by third-party suppliers.[8–10] The ICSH study found evidence that even in remote regions of the world, laboratories use commercial control materials supplied by the cell counter manufacturer and have temperature control to store these materials.[6] An effective IQC policy should also incorporate many other lower cost or zero-cost methodologies.[11,12] The ICSH International Survey of Quality Practices across 191 laboratories showed that there continues to be variation in practice worldwide and even within countries, variation in manufacturer recommendations, sometimes depending on the geographic area, and even some divergence in guidance on best practice among leading regulatory bodies and agencies.[2–4,6] This guidance proposes a harmonized, fit for purpose approach, addressing the issues faced by diagnostic laboratories, provide guidance to manufacturers on information they should issue to cell counter customers, and to recommend a policy for IQC procedures that diagnostic laboratories should adopt.

5 | ICSH GUIDANCE FOR IQC POLICY FOR BLOOD CELL COUNTERS

The following guidance is based on the information gathered in the ICSH Review of IQC Policy for Blood Cell Counters.[6]

This ICSH study has shown existing diversity both in guidance and in practice exists in the area of IQC of cell counters. It is important that a diagnostic laboratory formulates a policy for IQC of cell counters that is both effective in ensuring that errors in patient results are minimized and is cost-effective.[13]

5.1 | Calibration of cell counters

Blood cell counters should be calibrated before use and as prescribed thereafter by the manufacturer (e.g., after maintenance) and by previous guidance[13–15] It is self-evident that commercial materials used as calibrators, should be fully traceable to the use of reference methods and materials where possible and this information should be made available by the manufacturer.[16–24] All calibration data such as calibration factors applied, reasons for calibration, and dates and time should be available to and kept by the diagnostic laboratory itself. Any calibration carried out by supplier engineers should only be done with the agreement of the diagnostic laboratory and the calibration data made available to the laboratory.

5.2 | Frequency to run commercial controls and biological levels to use

Laboratories should use commercial control materials, where available, run at a frequency appropriate for the volume of patient samples being analyzed between control runs.[5,13] Our survey showed that two or three levels are commonly used, almost always including a normal level, run most commonly once to three times daily. The minimum

frequency recommended is once every 24 h, however the frequency must take account of the stability of the cell counter system, determined from its IQC performance,[25] to ensure safety of patient results. At least 2 control levels should be run daily, which should include a normal level control and both low and high-level controls run alternately, to help control costs.

5.3 | Derivation of target values and action limits to use with commercially supplied controls

In regard to action limits employed to detect QC failure, the diagnostic laboratory should calculate the numerical differences from the observed mean or target value in standard deviations, of the action limits they are using. They should then tighten those limits if the parameter of the FBC/CBC is considered clinically important but the limits in use are unlikely to detect analyzer error. They should choose whether to apply their own calculated action limits as prescribed by CLSI H26-A2,[9] or to tighten the limits provided by the manufacturer. They must document their policy and keep a record of their actions.

All suppliers of commercial stabilized controls, whether the cell counter manufacturer or supplier of "independent third-party controls" should state clearly with product inserts, how they consider the product can or should be used, to promote consistency of practice around the world. For example, if a cell counter manufacturer does not recommend that the target and limit values supplied with the assay sheet be used routinely (as they informed the ICSH in reply to our questionnaire) or whether they should be verified before use by the diagnostic laboratory, this should be clearly stated in the product insert. We also propose that the manufacturer should clearly indicate their provided action limits as multiples of SD for their common analyzers in order to further inform their users.

5.4 | Source of IQC materials to use

In consideration of the fact that the ICSH review[6] found that the six cell counter manufacturers surveyed stated that their commercial IQC materials are produced by only two manufacturers (either Streck Laboratories, PO Box 45625, Omaha, Nebraska 68145, USA or R&D Systems, MN, USA, part of Bio-Techne), IQC products from third-party suppliers other than cell counter manufacturers may not be inherently superior. Therefore, the laboratory may use third-party controls, if this helps control costs, but should not be obliged to use them if this adds no additional quality. We recommend that all suppliers of control materials, both cell counter manufacturers and third-party suppliers, provide information to the end-user regarding the source, place of manufacture, method and extent of testing applied to determine the assay targets and limits. This would allow the end-user laboratory to make an informed decision as to which control materials to use, as well as which targets and action limits to use with the material as part of local IQC policy.

5.5 | Other IQC methods to use

The diagnostic laboratory should employ other forms of IQC available in addition to commercial controls to add to the safety of patient results and facilitate early detection of instrument problems. These include the use of retained fresh patient specimens (<12 h old) at least daily to assess imprecision and for inter-instrument comparison[12]; patient moving averages (such as Bull's algorithm $\bar{x}$) to detect drift between control runs[11]; delta-check with previous patient results to detect pre-analytical errors and wrong-blood-in-tube errors[26]; and finally verification of cell counter results by blood film examination. The cell counter IQC policy should be detailed in the laboratory's IQC policy and applied in practice to include local processes used and appropriate thresholds, with adequate documentation and periodic

TABLE 3 Summary of guidance recommendation to cell counter manufacturers and suppliers of cell counter control materials.

Area of IQC for cell counting policy	Recommendations to the manufacturers and suppliers of quality control materials
Calibration of cell counters	The manufacturer should supply calibration materials tested using reference methods and traceable to available standards. All calibration data such as calibration factors applied, reasons for calibration and date and time must be available to and maintained as a record by the diagnostic laboratory.
Advice to clinical laboratories on IQC methods to use	Manufacturer's literature and package inserts should list all IQC methodologies recommended in this guideline, not just restricted to the use of commercial control materials. These include patient mean ($\bar{x}$) analysis and use of retained fresh patient samples for inter-instrument comparisons.
Instructions to clinical laboratories for use of commercial IQC materials	1. Indicate the source of manufacture of control materials and the testing regime used to assign target values and action limits 2. Give clear advice to the clinical laboratory as to how the material should be used, including storage conditions and preparation before use. 3. Provide proposed upper and lower action limits for IQC failure as multiples of SD used to derive them 4. Indicate clearly the stability and anticipated recovery values of the control material. 5. Indicate whether the manufacturer considers that the clinical laboratory should or may assign their own values to the control material, and if so, within which tolerance limits this should be done.

TABLE 4 Summary of guidance on the IQC policy to clinical diagnostic laboratories.

Area of IQC for cell counting policy	Recommendations on the IQC policy
IQC methods to use	1. Manufacturer's commercial control or equivalent that provides assessment of every parameter reported. 2. A "third-party" control, as an option if shown to add value to the detection of analyzer errors or known to be produced by a different manufacturer to the instrument supplier's commercial controls. 3. Patient mean or moving average ($\bar{x}$) analysis, provided sufficient patient samples are run daily (at least 100). 4. Retained fresh patient specimens (<12 h old) to assess reproducibility and inter-instrument comparisons, at least daily. 5. "Delta-check" with previous patient results to detect mis-labeled samples or other pre-analytical errors such as sample deterioration or dilution. 6. Verification of patient results by blood film examination, where performed.
Biological levels of commercial control to run	1. Two control levels as a minimum – Normal and high levels to assess calibration status. The high control level could be alternated with use of a low control level to control costs. 2. Low level can also be run to mimic patient samples with results at clinical decision levels such as triggers for transfusion.
Frequency to run commercial controls	Controls should be run at a frequency that will detect any likely errors. This should be risk-assessed, taking into account numbers of patient samples tested daily and analyzer stability based on observed error rate. The minimum recommended frequency is to run each control level once every 24 h.
Statistical methods to analyze IQC data	Levey-Jennings[27] charts or similar should be used to plot IQC data, with use of trend analysis or rule-based system such as Westgard rules,[28] at least for the clinically important parameters WBC, RBC, Hb, MCV and Platelets.
Derivation of target values and action limits to use with commercially-supplied controls.	Laboratories should at a minimum carry out verification of the control material, if using the supplier's target values and action limits before using routinely. The laboratory should calculate the acceptable range in +/−SD from the mean or target value of the action limits they are using and then either calculate their own limits as prescribed by CLSI H26-A2,[9] or tighten the manufacture supplied limits based on the observed IQC performance of the instrument and the importance of the parameter. They should closely observe the performance daily and perform trend analysis of the commercial control results over time. The laboratory may assign narrower limits to the control as proposed by CLSI, if the control trend is observed to be stable in a calibrated analyzer.

Note: The laboratory should document its policy for IQC and keep written records of any adjustments made to values or limits. The policy should also include material used, storage and stability, determination of action limits, frequency of testing, document control, review process and trouble-shooting recommendations for IQC failures. It should also specify the personnel responsible for decisions regarding action to be taken in the event of analyzer IQC failure, who may be senior laboratory scientists or supervisors according to relevant local legislation.

review by the responsible staff, who may be senior laboratory scientists or supervisors. In addition to providing the classical Bull's moving averages,[11] haematology analyzers may in the future be able to provide regular moving averages for other parameters and programmable for adjusting outlier limits and the number of patient results averaged.

5.6 | Approach to online "peer" comparison of IQC results

We recommend that diagnostic laboratories also formulate a policy for their use of online comparison of their IQC results with peer laboratories, where this is available from cell counter manufacturers. For example, where they participate in such a scheme, they should decide how they will use the data generated and how they would respond to out-of-consensus results.

The ICSH intends that the guidance provided in Tables 3 and 4 above will be useful to both cell counter manufacturers and to diagnostic laboratories and will promote harmonization of practice worldwide. It reinforces guidance by the regulatory bodies listed in Table 1 above, but is intended to be more comprehensive and specific in the areas of IQC methods to use, biological levels of controls to use, frequency to run commercial controls and statistical methods to analyze IQC data. It provides guidance on derivation of target values and action limits to use with commercially-supplied controls, which agrees with CLSI H26-A2[9] but currently varies in practice around the world. It makes a recommendation on source of IQC materials to use, which is that for blood cell counting the laboratory may use third-party controls, if this helps control costs, but should not be obliged to use them if this adds no additional quality. The ICSH guidance in addition makes recommendations for cell counter manufacturers and suppliers of cell counter control materials not made by the other regulatory bodies.

AUTHOR CONTRIBUTIONS

Richard McCafferty, George Cembrowski, and Barbara de la Salle wrote the paper. Mingting Peng gathered data from China for the

International Survey of Clinical Diagnostic Laboratories. Eloisa Urrechaga gathered data from Spain. Barbara de la Salle gathered data from the United Kingdom. Richard McCafferty gathered data from the Republic of Ireland. All authors read, requested edits and agreed to the wording of the final paper.

ACKNOWLEDGMENTS

The authors are grateful to Ismail Surtina-Azarov of the University of Alberta, Edmonton, Alberta, Canada, who collated returned Excel documents, tabulated results and carried out analysis of the survey data returned from the four contributing countries. The authors are also grateful to Hemalatha Shanmugam of the Division of Laboratory Medicine, University of Malaya Medical Centre, Kuala Lumpur, who distributed and collected an ICSH questionnaire regarding the use and availability of commercial IQC materials for cell counting to laboratories in Malaysia.

FUNDING INFORMATION

This study was financially supported by the ICSH. The ICSH is a not-for-profit organization sponsored by unrestricted educational grants from its corporate and affiliate members, a list of whom is available on request.

CONFLICT OF INTEREST STATEMENT

George Cembrowski declares the following: "G.S. Cembrowski and M.A. Cervinski are co-owners of patent number 10338085, "Devices and Methods to Determine Whether to Calibrate a Laboratory Analyzer." G.S. Cembrowski, "AlteringPatient Care Based on Long Term SDD," publication number: US-2019-0035490 (with Junyi Mei), "Method And Apparatus For Calibration and Testing of Scientific Measurement Equipment," United States Patent numbers: 8538727 and 10 332 621 (with David Tran)." Barbara de la Salle declares that she has received an honorarium from Abbott Diagnostics for speaking at a meeting within the past 2 years. Richard McCafferty and Mingting Peng and Eloisa Urrechaga have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

Data available in article supplementary material.

ICSH STATEMENT

While the advice and information in this guidance is believed to be true and accurate at the time of going to press, the authors, ICSH, and the publishers do not accept any legal responsibility for the content of this guidance.

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REFERENCES

1. Bain BJ, Lewis SM. Basic haematological techniques. I. *Dacie and Lewis Practical Haematology 10th Ed*. Churchill Livingstone Elsevier; 2006.
2. International Organization for Standardization (ISO). ISO 15189:2012 Medical laboratories – Requirements for quality and competency. 2012 http://www.iso.org/iso/catalogue_detail?csnumber=56115
3. College of American Pathologists (CAP), Commission on Laboratory Accreditation. *Hematology and Coagulation Checklist*. College of American Pathologists; 2009.
4. C24-A3: Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Third edition. Clinical and laboratory standards institute. ISBN 1–56238–613-1. 2006.
5. Clinical Laboratory Improvement Amendments of. 102 Stat. 2903, US Public Law 100–578. 1988 www.cdc.gov/clia/law-regulations
6. McCafferty R, Cembrowski G, DelaSalle B, Peng M, Urrechaga E. ICSH review of internal quality control policy for blood cell counters. *Int J Lab Hematol*. 2023; Submitted.
7. Lewis SM. International standard for haemoglobinometry. *J Clin Path*. 1967;20:791-792.
8. Wayne PA, Clinical Laboratory Standards Institute (CLSI). Laboratory quality control based on risk management; approved guideline. *CLSI document EP23-A*. Clinical and Laboratory Standards Institute; 2011.
9. Wayne PA, CLSI. *Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard*. Second ed. CLSI document H26-A2 Clinical and Laboratory Standards Institute; 2010a.
10. Wayne PA, CLSI. *Expression of Measurement Uncertainty in Laboratory Medicine; Approved Guideline*. CLSI document EP29-A:. Clinical and Laboratory Standards Institute; 2010b.
11. Bull BS, Elashoff RM, Heilbron DC, Couperus J. A study of various estimators for the derivation of quality control procedures from patient erythrocyte indices. *Am J Clin Pathol*. 1974;61:473-481.
12. Cembrowski G, Luvetzsky E, Patrick C, Wilson M. An optimized quality control procedure for haematology analyzers with the use of retained patient specimens. *Am J Clin Pathol*. 1988;89(2):203-210.
13. Cembrowski G, Clarke C. Quality control of automated cell counters. *Clin Lab Med*. 2015;35:59-71.
14. Vis JY, Huisman A. Verification and quality control of routine hematology analyzers. *Int J Lab Hem*. 2016;38(Sup 1):100-109.
15. International Council for Standardization in Haematology (ICSH). ICSH guidelines for the evaluation of blood cell analysers including those used for differential leucocyte and reticulocyte counting. *Int J Lab Hem*. 2014;36:613-627.
16. England JM. The expert panel in cytometry of the ICSH: the assignment of values to fresh blood used for calibrating automated blood cell counters. *Clin Lab Haematol*. 1988;10:203-212.
17. Wayne PA. Reference and selected procedures for the quantitative determination of hemoglobin in blood. Approved Standard-Third Edition; CLSI document H15-A3, CLSI, 940 West Valley Rd., Suite 1400, 19087, USA 2000.
18. Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard - Third Edition. CLSI Document H07-A3, CLSI, 940 West Valley Rd., Suite 1400, Wayne, PA. 2000.
19. The Expert Panel in Cytometry of the ICSH. Platelet counting by the RBC/platelet ratio method. *Am J Clin Pathol*. 2001;115:460-464.
20. Reference method for the enumeration of erythrocytes and leucocytes. International Council for Standardization in Haematology expert panel on cytometry. *Clin Lab Haematol*. 1994;16:131-138.
21. Recommendations for reference method for Haemoglobinometry in human blood (ICSH standard 1995) and specifications for international Haemoglobincyanide standard (4th edition). *J Clin Pathol*. 1996;49(4):271-274.
22. Recommendations for Reference Method for the Packed Cell. ICSH expert panel on cytometry. *Clin Lab Hematol*. 2001;2001(7):148-170.
23. Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry and Supravital Dyes). Approved Guideline-Second Edition Manual method CLSI H44-A2.

24. The Joint Committee for Traceability in Laboratory Medicine (JCTLM). Bureau International des Poids et Mesures, Pavillon de Breteuil, 92312 Sevres, Cedex France. www.jctlm.org
25. Cembrowski G, Topping K, Versluys K, et al. The use of serial outpatient complete blood count (CBC) results to derive biologic variation: a new tool to gauge the acceptability of hematology testing. *Int J Lab Hem*. 2016;38:111-118.
26. Nosanchuk J, Gottmann A. Cums and Delta checks. *Am J Clin Pathol*. 1974;62:707-712.
27. Levey S, Jennings E. The use of control charts in the clinical laboratory. *Am J Clin Pathol*. 1950;20:1059-1065.
28. Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewart chart for quality control in clinical chemistry. *Clin Chem*. 1981;27(3):493-501.

How to cite this article: McCafferty R, Cembrowski G, de la Salle B, Peng M, Urrechaga E. ICSH guidance for internal quality control policy for blood cell counters. *Int J Lab Hematol*. 2023;1-7. doi:10.1111/ijlh.14212