Quality Control of Automated Cell Counters

George S. Cembrowski, MD, PhD[a,*], Gwen Clarke, MD, FRCPC[b]

KEYWORDS

• Quality control • External quality assessment • Hematology • Delta checks
• Biologic variation • Average of patients • Critical values

KEY POINTS

- Hematology quality control should be simplified.
- The use of averages of red blood cell indices for quality control is outmoded and should be replaced with truncated patient averages of all directly measured parameters.
- Patient specimens that have critical concentrations do not need to be repeated in an attempt to improve their accuracy.

QUALITY CONTROL AND EXTERNAL QUALITY ASSESSMENT

Quality control refers to a laboratory's internal assessment of analytical quality. This assessment is accomplished by the regular measurement of quality control (reference) samples. In laboratory hematology, the manufacturer of the laboratory's hematology instrument generally supplies two or three levels of quality control material every 30 to 90 days. The manufacturer's targets for limits of acceptability are generally too broad to be used as quality control limits. With each new lot of control, the hematology laboratory must revalidate or revise its own limits of quality control acceptability to the new control mean $\pm$ a multiple of the usual standard deviation. The laboratory's repeated measurements of the quality control (reference) samples by the same analyzer permits the assessment of instrument precision. External quality control (external quality assurance [EQA]), or proficiency testing, allows for the assessment of instrument accuracy and is demonstrated by the laboratory's analyzer/reagent combination producing results that are close to the proficiency provider's target values. Specimens sent to laboratories for EQA are generally acquired by subscription and arrive at the laboratory at bimonthly or longer intervals. Results are generated and

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[a] Laboratory Medicine and Pathology, 4B1.24 Mackenzie Health Sciences Centre, University of Alberta Hospital, 8440-112 Street, Edmonton, AB T6G 2B7, Canada; [b] Canadian Blood Services, Medical Office 8249 -114th Street, Edmonton, AB T6G 2R8, Canada
* Corresponding author.
E-mail address: george.cembrowski@albertahealthservices.ca

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Abbreviations

CBC	Complete blood count
EQA	External quality assurance
Hct	Hematocrit
Hgb	Hemoglobin
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
RBC	Red blood cell

returned to the proficiency testing provider where they are collated and compared with the results from other participants using the same analyzer and reagent combination. Results of this comparison should be available once all participants have submitted results, potentially days or weeks following testing. This article focuses on quality control. For more specific reading on hematology and EQA, the reader is directed to the work of Cembrowski.[1]

In the hospital environment, quality control samples are routinely analyzed two or three times per day. Reference laboratories tend to run quality control with batches of patient samples, often being inserted at the beginning and end of the patient run. The quality control results are assessed with one or more quality control rules and are available for subsequent charting and evaluation. A wide assortment of quality control rules (**Table 1**) can be used to interpret the quality control results and classify the analytical run as in control, out of control, or as a warning. Each control rule has a specific error detection capability with some control rules being sensitive to systematic errors (shifts) and others sensitive to increased random error (increased imprecision). Because hematology quality control specimens can control the analysis of 16 or more constituents of the complete blood count (CBC), overly narrow limits (eg, $\pm$ 2 SD, $\pm$ 2.5 SD, and even $\pm$ 3 SD) can result in overly frequent "out of control" misclassifications of in control analytical runs.

Caution

We occasionally encounter hematology laboratories that use previously analyzed patient specimens that are then reanalyzed over the next 4 to 24 hours as a secondary control. We do not advise this practice because these specimens are generally less stable than reference sample quality controls and their target range is poorly defined because it is a product of just one or two assays.

BIOLOGIC VARIATION AND ITS INFLUENCE ON THE SELECTION OF QUALITY CONTROL RULES

Patient-related preanalytical influences can affect almost every quantitative test performed in the clinical laboratory. For example, hematocrit (Hct) is increased with exertion (eg, running up several flights of stairs) or just by drawing the blood specimen while the patient is standing compared with sitting or lying down.[2] To minimize these influences and to obtain the most reproducible and comparable test result, diagnostic blood samples should be collected under standard conditions. Even when these recommendations are strictly followed, patients demonstrate nonanalytical variations in the measured analytes. These "usual" within-subject variations are relatively constant from subject to subject. Measurement of this within-subject biologic variation involves the regular sampling of healthy subjects and rapid stabilization of their plasma.