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Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard

This document addresses performance goals for analytical accuracy and precision for multichannel hematology analyzers; the relationship of these goals to quality control systems and medical decisions; and recommendations for minimum calibrator performance and the detection of measurement errors.



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Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard

Abstract

Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard (NCCLS document H26-A) provides recommendations for performance goals for the internal quality control of multichannel hematology analyzers on the basis of the use of physical and chemical standards, accepted reference methods, subcommittee recommendations on what is currently achievable, and the concept of medical usefulness. Critical performance characteristics of quality control systems (i.e., the probabilities of error detection and false rejection) also are considered. A well-designed internal quality control program must achieve the level of error detection specified in this standard; yet it should not be so sensitive as to falsely reject valid results.

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Foreword

The primary objective of quality control in the clinical laboratory is to ensure that the analytical values are sufficiently reliable to be used in the care of patients. Once quality goals are established for an assay, their results can be evaluated in terms of clinical usefulness. This approach can have distinct advantages in the quality control of multichannel hematology analyzers.

This standard examines the effects of the following variables on performance goals:

- Calibration of the instruments
- Imprecision of the analytical measurements
- Analyte variations within an individual
- Inherent differences in values among persons.

The first two of these sources of variation define opportunities for improvement in analyzer design. The second two define irreducible biological variables.

In this document, the Subcommittee on the Blood Count provides goals for standards of performance that are useful for diagnosis, patient monitoring and control of therapeutic regimens. These performance goals set the stage for a review of quality control options that are intended to provide a framework for ensuring that patients' assays are made as precisely and accurately as the analyzer allows. To this end, the production of a companion document is planned that will address the principles and methods of quality control that will help users and makers of automated hematology analyzers achieve these goals. This approach should stimulate improvements in analyzer design and interpretation of assay results. One goal is that manufacturers will recognize the need to coordinate the performance of different analytical methods so that assay results from different analyzers will have a reasonable degree of interchangeability. A further goal in this context is for designers to strive to minimize some of the existing disparities between analyzer and reference assays.

Universal Precautions

Because it is often impossible to know which might be infectious, all patient blood specimens are to be treated with universal precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention [MMWR 1987; 36 (Suppl 2S) 2S-18S]. NCCLS document M29-T2, *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue—Second Edition; Tentative Guideline*, deals specifically with this issue.

Key Words

Accuracy, analytical bias, calibration, calibrator, imprecision, linearity, quality control, sensitivity, specificity, value.

Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard

1 Introduction

The elements of the complete blood cell count (CBC) included in this standard are the measurement of hemoglobin concentration (Hb), hematocrit (Hct), erythrocyte count (RBC), mean cell volume (MCV), leukocyte count (WBC), and platelet count (Plt). Goals for the derived red cell indices, mean cell hemoglobin (MCH), and mean cell hemoglobin concentration (MCHC) are not included.

The widespread acceptance of automated whole blood analyzers and concomitant improvements in calibrators and control materials has had a major effect on the efficiency of laboratory operation. Also, a marked improvement in intralaboratory and interlaboratory precision and accuracy has occurred. For values in the adult reference range, within-laboratory coefficients of variation (CV) of less than 1.0% for RBC, Hb and MCV are readily achieved on the newest generation of analyzers, while WBC counts show CVs less than 2% and Plt counts CVs less than 3%.¹⁻⁵ However, maintaining accuracy by preventing or predicting drift during routine operation remains a problem with some types of analyzers.

2 Scope

This document presents performance goals for analytical accuracy and precision of multichannel hematology analyzers capable of being calibrated. These clinical performance goals relate the majority of routinely produced analytical values to reference populations and to action limits established by the laboratory.

Goals for standards for specimen handling, equipment operation, electronic checking, preventive maintenance, and reagent quality are not included in this document, but their effect on performance is discussed where relevant.

This standard will be useful to laboratory directors, supervisors, quality control officers, and others who have responsibilities for ongoing quality control in hematology

laboratories, particularly in the light of current regulatory pressures. It is a starting point for national and international discussion of the issues surrounding the design of quality control systems for multichannel hematology analyzers and as an aid to manufacturers who seek to improve the performance of their products.

3 Definitions

Within this document, terms are defined as follows:^{*}

Accuracy: A measure of agreement between the estimate of a value and a "true" value; quantifiable in terms of departure from accuracy; expressed as systematic error or bias.

- **Accuracy, of an analytic process:** Expressed as the difference between the average result obtainable by a method under specified conditions and the result accepted as true or standard; expressed in the same units as the result, or as a percentage of the standard result (relative accuracy).

NOTE: The lower the difference, the higher the accuracy (the lower the inaccuracy). Conventionally, this difference includes only process inaccuracy (process bias or systematic error) because the contribution of process imprecision (random error) is minimized by the averaging of multiple determinations.

- **Accuracy, of a result:** Expressed as the difference between a result and the "true" value.

* References include ICSH, *Rules and Operating Procedures*, 1991; ISO, *International Vocabulary of Basic and General Terms in Metrology*, 2nd Edition, 1993; NCCLS, NRSL8-P2, *Nomenclature and Definitions for Use in NRSL and Other NCCLS Documents—2nd Edition; Proposed Guideline*.