

C46-A
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Blood Gas and pH Analysis and Related Measurements; Approved Guideline

This document provides clear definitions of the quantities in current use, and provides a single source of information on appropriate specimen collection, preanalytical variables, calibration, and quality control for blood pH and gas analysis and related measurements.

A guideline for global application developed through the NCCLS consensus process.



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NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

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Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

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The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

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- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

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Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

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VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Blood Gas and pH Analysis and Related Measurements; Approved Guideline

Abstract

This guideline is a consolidation of six NCCLS documents and projects. The Area Committee on Clinical Chemistry and Toxicology concluded that NCCLS's constituencies (professions, government, and industry) would be better served with the production of a single document that retains the essential information from the six original documents while making it even more relevant and useful. It addresses blood gas, pH, and related measurements (e.g., fractional oxyhemoglobin, oxygen content, hemoglobin-oxygen saturation, and selected electrolytes as measured in whole blood). It defines terminology and discusses performance characteristics as well as preanalytical variables and analytical considerations. It also addresses quality control issues.

This guideline consolidates and updates:

- C12-A— *Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard;*
- C21-A— *Performance Characteristics for Devices Measuring pO_2 and pCO_2 in Blood Samples; Approved Standard;*
- C25-A— *Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement and Reporting; Approved Guideline;*
- C27-A— *Blood Gas Pre-Analytical Considerations: Specimen Collection and Controls; Approved Guideline;*
- C32-P— *Considerations in the Simultaneous Measurement of Blood Gases, Electrolytes and Related Analytes in Whole Blood; Proposed Guideline;* and
- C33— *Practical Blood Gas and pH Quality Control* (unpublished).

Sections of another NCCLS document, H11— *Procedures for the Collection of Arterial Blood Specimens*, have also been included; however, H11 will remain a separate document, because its content is of interest to a broader audience.

NCCLS. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*. NCCLS document C46-A (ISBN 1-56238-444-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

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Foreword

This guideline is the result of the decision of the Area Committee on Clinical Chemistry and Toxicology to combine and update four approved-level documents, one proposed-level document, and one unpublished document. The intent is for this document to serve more effectively the three major constituents (professions, government, and industry) of NCCLS. The challenge for the working group was to retain the essential elements of each document while making the content current and increasing its relevance for the users.

This guideline consolidates and updates:

- C12-A—*Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard;*
- C21-A—*Performance Characteristics for Devices Measuring pO_2 and pCO_2 in Blood Samples; Approved Standard;*
- C25-A—*Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement and Reporting; Approved Guideline;*
- C27-A—*Blood Gas Pre-Analytical Considerations: Specimen Collection and Controls; Approved Guideline;*
- C32-P—*Considerations in the Simultaneous Measurement of Blood Gases, Electrolytes and Related Analytes in Whole Blood; Proposed Guideline;* and
- C33—*Practical Blood Gas and pH Quality Control* (Unpublished).

Sections of H11—*Procedures for the Collection of Arterial Blood Specimens*, also have been included; however, H11 will remain a separate document, because its content includes greater detail and is of interest to a broader audience.

In the process of consolidating and updating, several factors were considered. Because regulations exist regarding record keeping, quality control, calibration, and other operational practices, it is no longer necessary to include or explain some aspects of these in this guideline. In addition, some of the originally discussed quantities are no longer considered appropriate, and these have been omitted. When C21 was developed, whole blood tonometry was considered the reference for assessing quality. This guideline discusses tonometry as one means to assess quality, but omits the detailed instructions that are more appropriate for manufacturers' manuals. The reader is referred to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) document on whole blood tonometry.¹ C25 was developed before many of the principles and applications of multicomponent spectrophotometry were readily available in a single source. The educational and descriptive text and figures once necessary are now included in manufacturers' information. The unique preanalytical, analytical, and postanalytical considerations and how this information relates to the patient's sample are included. C32 includes considerations when measuring electrolytes simultaneously with blood gases. The necessary elements for these measurements are in this guideline.

Foreword (Continued)

With this consolidation and update, the working group believes the guideline is more laboratory-focused. Yet, the essential information found in the original six documents and important to manufacturers and government agencies remains.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to “standard precautions.” Standard precautions are new guidelines that combine the major features of “universal precautions and body substance isolation” practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80.), [MMWR 1987;36(suppl 2S):2S-18S] and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*.

Key Words

Blood gas, carbon dioxide, fractional oxyhemoglobin, hemoglobin-oxygen saturation, oxygen content, pH

Blood Gas and pH Analysis and Related Measurements; Approved Guideline

1 Introduction

There are several aspects of blood pH and gas analysis that are unique among clinical laboratory determinations, and, at the same time, no other test results have more immediate impact on patient care. This area of laboratory medicine also has the reputation of being somewhat confusing and difficult to understand, partly because of the many different measured and derived quantities that have been used over the years. This document provides clear definitions of the several quantities in current use and includes information on appropriate specimen collection, preanalytical variables, and quality control. There is also a section containing a list of performance characteristics pertinent to blood gas analyzers which can be used by manufacturers to provide operational specifications in a uniform way, to facilitate comparison by potential customers of different instruments.

This guideline is primarily intended for laboratory technologists, respiratory and critical care practitioners, and others responsible for obtaining and analyzing blood for pH, oxygen, carbon dioxide, and related measurements. It will also be useful to manufacturers and those responsible for teaching this subject to medical students, residents, and allied health personnel.

2 Scope

This guideline addresses blood gas, pH, and related measurements (e.g., fractional oxyhemoglobin, oxygen content, hemoglobin-oxygen saturation, and selected electrolytes as measured in whole blood).

This document defines terminology and discusses performance characteristics as well as preanalytical variables, analytical considerations, and quality control issues.

3 Concepts and Definitions

This section contains terms and definitions in standard NCCLS format (NRSCL8—*Terminology and Definitions for Use in NCCLS Documents*) integrated with related information and concepts. The formal definitions are accompanied by supplementary information necessary to understand and apply the concepts of blood gases and related quantities. The definitions and supplemental information contained in this section have been developed with the intent of providing maximum clarity for the typical reader of this document. This results in some definitions differing from the full definition as found in NRSCL8. While the definitions reflect the essence of those contained in the NCCLS standard on terminology, they are not, in all cases, word-for-word.

The reader is referred to the definitions and explanatory notes found in NRSCL8—*Terminology and Definitions for Use in NCCLS Documents*, both for related terms and definitions not contained in this document and for a more precise understanding of a term's concept.

3.1 pH

pH, *n* - the symbol for the negative (decadic) logarithm of the relative molal hydrogen ion activity (α_{H^+}), which is a measure of the effective concentration of hydrogen ions in solution; **NOTE:** Historically, pH arose as a symbol for the "power of hydrogen."

$$\text{pH} = -\log \alpha_{H^+} \quad (1)$$