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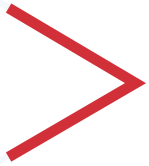
Blood Gas and pH Analysis and Related Measurements; Approved Guideline—Second Edition



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 Clinical and Laboratory Standards Institute consensus process.

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For additional information on committee participation or to submit comments, contact CLSI.

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Blood Gas and pH Analysis and Related Measurements; Approved Guideline—Second Edition

Volume 29 Number 8

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Abstract

This guideline is a consolidation of six CLSI documents and projects. The Area Committee on Clinical Chemistry and Toxicology concluded that CLSI'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 (eg, fetal hemoglobin and hemoglobin fractions, oxygen content, hemoglobin-oxygen saturation, electrolytes, and selected metabolites) as measured in 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 previously published CLSI/NCCLS documents 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;* C23-A—*Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting*; *Approved Guideline;* C27-A—*Blood Gas Preanalytical Considerations: Specimen Collection and Controls*; *Approved Guideline;* and C32-P—*Considerations in the Simultaneous Measurement of Blood Gases, Electrolytes and Related Analytes in Whole Blood; Proposed Guideline;* and unpublished CLSI document C33—*Practical Blood Gas and pH Quality Control.*

Sections of another CLSI document H11 also are included; however, H11 will remain a separate document, because its content is of interest to a broader audience.

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Contents

Contents (Continued)

Foreword

The previous edition of this document, C46-A, was 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 was for this document to serve more effectively the three major constituents (professions, government, and industry) of CLSI.

C46-A consolidated the following documents:

- 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 Preanalytical 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 CLSI/NCCLS document H11[1] were also included; however, H11[1] remained a separate document, because its content includes greater detail and is of interest to a broader audience.

The current revision of the document, C46-A2, includes the following updates:

- Section 5, *Preanalytical Considerations*, was expanded to include a discussion specific to transport of specimens (see Section 5.3). Section 5.4, In Vivo *Effects on Measurements*, replaces the former section, *Patient Condition,* and was expanded.
- Section 6, *Analytical Interferences*, was expanded significantly, including references to recent literature.
- Section 7, *Blood Gas Analyzer Calibration*, was expanded significantly, including current requirements for calibration traceability.
- Section 8, *Blood Gas Quality Control,* includes newer approaches for "alternative" quality control.
- Appendix B, *Recommendations for Measurement and Reporting of Hemoglobin Fractions and Related Quantities*, was added.
- Appendix C, *Measurement Technologies Used in Instruments for Analysis of Blood Gases, pH, and Related Analytes*, was added.

Key Words

Electrolytes, fractional hemoglobins, hemoglobin-oxygen saturation, metabolites, oxygen content, partial pressure of carbon dioxide, partial pressure of oxygen, pH

Blood Gas and pH Analysis and Related Measurements; Approved Guideline—Second Edition

1 Scope

This guideline addresses blood gas, pH, and related measurements (eg, hemoglobin and hemoglobin fractions, oxygen content, hemoglobin-oxygen saturation, electrolytes, hematocrit, glucose, and lactate) as measured in blood. The guideline is limited to devices for measurement of these quantities *in vitro*. Devices for *in vivo* monitoring and patient-attached, *ex vivo* monitors for blood gas, pH, and related measurements, although common in many respects to devices for *in vitro* measurements, are not specifically addressed.

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

This guideline is primarily intended for laboratory technologists, respiratory therapists, 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 Introduction

Several aspects of blood pH and gas analysis 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, 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 QC. 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.

3 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.[2] For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to CLSI document M29.[3]

4 Terminology

4.1 Concepts and Definitions

This section contains terms and definitions in standard CLSI format integrated with related information and concepts. The formal definitions are accompanied by supplementary information necessary to

