GP34-P
Vol. 29 No. 22

Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Proposed Guideline

PLEASE

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This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (ie, candidate for advancement) for 60 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

28 December 2009

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700, or to the following e-mail address: standard@clsi.org.

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COMMENT

This document provides guidance for conducting verification and validation testing for venous and capillary blood collection tubes.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

Clinical and Laboratory Standards Institute (CLSI, formerly 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 health care 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 health care issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and health care services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

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.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for

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

Most 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 consensus level.

Proposed A consensus document undergoes the first stage of review by the health care 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.

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

Our 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 CLSI's established consensus procedures. Provisions in CLSI 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

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are addressed by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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Abstract

Clinical and Laboratory Standards Institute document GP34-P—*Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Proposed Guideline* is a guideline for manufacturers of venous and capillary blood collection tubes and users of blood collection tubes for serum, plasma, and whole blood testing. GP34 provides guidelines for validation and verification of examination performance.

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Foreword

Currently, no guideline is available for either *in vitro* diagnostic (IVD) manufacturers or clinical laboratories to validate or verify use of the various venous and capillary blood collection tubes within each of the following laboratory medicine disciplines: chemistry, immunochemistry, hematology, and coagulation. However, for microbiology assays or culture methods, several documents address validation and quality control of collection tubes (see CLSI documents M40, M47, and M15).[1-3]

This guideline contains information on tubes for venous and capillary blood collection. It is written for manufacturers of venous and capillary blood collection devices; for assay/instrument manufacturers; for all clinical laboratory personnel; and for those who are responsible for acquisition, handling, and use of the equipment described in this document.

Specimen collection devices, especially venous and capillary blood collection tubes, are classified as IVD devices. Because these devices are used to collect patient blood samples that are analyzed on highly sensitive clinical instrumentation, it is extremely critical for accurate and precise test results that these collection devices be verified for use on this instrumentation.

IVD manufacturers are challenged by regulatory agencies to ensure safety and efficacy of their devices as part of the validation process before release of the devices for use in the clinical laboratory. Tube manufacturers can use this guidance document to establish and standardize their validation process for both current and new blood collection tubes. In addition to this document, CLSI standard H01, *Tubes and Additives for Venous Blood Specimen Collection*[4]—a complimentary document to this guideline—details the requirements for materials, manufacturing, and labeling of blood collection devices.

Additionally, accrediting organizations challenge clinical laboratories to ensure the acceptability or compatibility of their venous and capillary blood collection devices, with their current instrumentation and patient population.[5] This type of verification will help the clinical laboratories ensure accurate and precise test results for their collection device and test system.

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all CLSI documents is the consensus process. Within the consensus process, CLSI members and other interested parties (1) have the opportunity to review and comment on CLSI publications in development; and (2) are assured that their comments will be given serious consideration. All CLSI documents evolve, as does the technology affecting laboratory and health care procedures, methods, and protocols; and therefore, through the operation of the consensus process, CLSI documents are expected to undergo cycles of evaluation and modification.

The Area Committee on Quality Systems and Laboratory Practices has attempted to engage the broadest worldwide representation in the committee deliberations to develop this document. Consequently, it is expected that issues may still remain unresolved when the proposed level document is published. Review and comment within the CLSI process is the mechanism for resolving such issues.

The CLSI voluntary consensus process depends on the expertise of worldwide reviewers whose comments add value to the final document. At the end of a 60-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all substantive comments. When appropriate, modifications will be made to improve the document, and all comments along with the subcommittee's responses will be included in an appendix when the document is published at the next consensus level.

Key Words

Capillary blood collection, instrumentation, validation, venous blood collection tubes, verification

Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Proposed Guideline

1 Scope

This document provides step-by-step recommendations for validation and verification of venous and capillary blood collection devices. Capillary blood collection devices addressed in this document include only microcollection devices (see Section 3.2). It also includes guidance for ascertaining the acceptability/compatibility for clinical performance in chemistry, immunochemistry, hematology, and coagulation. This guideline does not address validation and verification for clinical performance in immunohematology, molecular diagnostics, arterial blood gas analysis, proteomics, or genomics.

This document is written for manufacturers of venous and capillary blood collection devices; assay/instrument manufacturers; all clinical laboratory personnel; and those who are responsible for acquisition, handling, and use of the equipment described in this document.

2 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.[6] 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.[7]

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards focuses on harmonization of terms to facilitate the global application of standards.

In order to align the use of terminology in this document with that of ISO, the terms *preexamination*, *examination,* and *postexamination* were adopted in place of pretest, test, and posttest, and the term *sample* replaces the term *specimen* where appropriate. The users of GP34-P should understand that the fundamental meanings of the terms are identical in many cases, and are defined in the guideline's Definitions section (see Section 3.2). The terms in this document are consistent with those defined in the ISO 15189, ISO 17025, and ISO 9000 series of standards.

