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Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition

This document provides guidance for evaluation and documentation of the detection capability of clinical laboratory measurement procedures (ie, limits of blank, detection, and quantitation), for verification of manufacturers' detection capability claims, and for the proper use and interpretation of different detection capability estimates.

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) 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. We are recognized worldwide for the application of our 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 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 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 appropriate consensus committee.

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CLSI's voluntary consensus process establishes formal criteria for the following:

- Authorization of a project
- Development and open review of documents
- Revision of documents in response to users' comments
- Acceptance of a document as a consensus standard or guideline

Invitation for Participation in the Consensus Process

Core to the development of all CLSI documents is the consensus process. Within the context and operation of CLSI, voluntary consensus is substantial agreement by materially affected, competent, and interested parties that may be obtained by following the consensus procedures defined in

CLSI's Administrative Procedures. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and are willing to accept the resulting agreement. CLSI documents are expected to undergo evaluation and modification in order to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

Comments on Draft Documents

CLSI's voluntary consensus process depends on experts who serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate. All comments along with the committee's responses are retained on file at CLSI and are available upon request.

Comments on Published Documents

The comments of users of published CLSI documents are essential to the consensus process. Anyone may submit a comment. All comments are addressed according to the consensus process by a committee of experts. A summary of comments and committee responses is retained on file at CLSI and is available upon request. Readers are strongly encouraged to comment at any time on any document.

APPEALS PROCESS

CLSI consensus procedures include an appeals process that is described in detail in the CLSI Administrative Procedures.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects.

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

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Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document EP17-A2—*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition* provides guidance for evaluating the detection capability of clinical laboratory measurement procedures (ie, limits of blank, detection, and quantitation), for verification of manufacturers' detection capability claims, and for the proper use and interpretation of different detection capability estimates. EP17 is intended for use by manufacturers of *in vitro* diagnostic tests, regulatory bodies, and clinical laboratories.

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The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org. If your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at: Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: customerservice@clsi.org; Website: www.clsi.org

