INTERNATIONAL STANDARD

ISO 17822

First edition
2020-11

Corrected version
2020-12

In vitro diagnostic test systems — Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens — Laboratory quality practice guide

Systèmes d'essai pour diagnostic in vitro — Modes opératoires d'examen in vitro qualitatifs fondés sur l'acide nucléique pour la détection et l'identification d'agents pathogènes microbiens — Guide pratique sur la qualité dans les laboratoires

Reference number
ISO 17822:2020(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems.*

This first edition of ISO 17822 cancels and replaces ISO/TS 17822-1:2014, which has been technically revised. The main changes are as follows:

— Clause 4 has been updated and merged from ISO/TS 17822-1:2014.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html

This corrected version of ISO 17822:2020 incorporates the following correction:

— The title on the cover page and page 1 has been corrected to remove the part name.

Introduction

Nucleic acid amplification-based tests (NAATs) are now commonly used in in vitro diagnostic (IVD) tools in laboratory medicine for the detection, identification and quantification of microbial pathogens. The NAAT result is influenced by all steps of the entire diagnostic workflow (i.e. pre-examination, examination, post-examination). Therefore, this document considers all critical aspects of the entire diagnostic workflow when designing, developing and implementing and using a specific microbial pathogen NAAT examination.

NAAT examinations include PCR technology as well as other amplification-based technologies such as, but not limited to, loop-mediated isothermal amplification (LAMP), transcription-mediated amplification (TMA) and strand displacement amplification (SDA).

This document covers the implementation of commercially available IVD(s) into the medical laboratory routine use as well as the design, development and implementation of laboratory developed tests (LDT).

This document will address the additional specific considerations, requirements and recommendations for the detection of microbial pathogens with sampling, nucleic acid extraction, genetic heterogeneity and the laboratory containment category which is required.

Due to high analytical sensitivity of nucleic acid-based examination procedures, special attention to their design, development and use is required. This includes verification of analytical and validation of clinical performance characteristics.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

In vitro diagnostic test systems — Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens — Laboratory quality practice guide

1 Scope

This document describes the particular clinical laboratory practice requirements to ensure the quality of detection, identification and quantification of microbial pathogens using nucleic acid amplification tests (NAAT).

It is intended for use by laboratories that develop, and/or implement and use, or perform NAAT for medical, research or health-related purposes. This document does not apply to the development of in vitro diagnostic (IVD) medical devices by manufacturers. However, it does include verification and validation of such devices and/or the corresponding processes when implemented and used by the laboratories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189, *Medical laboratories — Requirements for quality and competence*

ISO 15190, *Medical laboratories — Requirements for safety*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accuracy
closeness of agreement between a test result or measurement result and the true value

Note 1 to entry: In practice, the accepted reference value is substituted for the true value.

Note 2 to entry: The term “accuracy”, when applied to a set of test or measurement results, involves a combination of random components and a common systematic error or bias component.

Note 3 to entry: Accuracy refers to a combination of trueness and precision.

[SOURCE: ISO 3534-2:2006]