TECHNICAL SPECIFICATION

ISO/TS 17822-1

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In vitro diagnostic test systems — Qualitative nucleic acid-based *in vitro* examination procedures for detection and identification of microbial pathogens —

Part 1: General requirements, terms and definitions

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 —

Partie 1: Exigences générales, termes et définitions

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

ISO/TS 17822 consists of the following parts, under the general title *In vitro diagnostic test systems — Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens*:

— *Part 1: General requirements, terms and definitions*

— *Part 2: Quality practice guide for medical laboratories*

Introduction

Nucleic acid-based *in vitro* diagnostic examination procedures are now commonly used in laboratory medicine for the detection and identification of microbial pathogens. These examination procedures have become particularly valuable for the detection of infectious agents that are difficult to grow in culture. For a review of recent advances and current practices associated with *in vitro* diagnostic examination procedures based on nucleic acid-amplification and detection technology ("molecular diagnostics"), see References [38], [35], [36], [37], [39], [41], and [42].

ISO/TS 17822-1 defines concepts and establishes general principles for the design, development, and performance of qualitative nucleic acid-based *in vitro* diagnostic examinations for the detection and identification of microbial pathogens in human specimens.

Traditional PCR examination procedures typically consist of three steps: (1) sample preparation and nucleic acid extraction, (2) nucleic acid amplification, and (3) nucleic acid detection and identification. The analytical technology is continuing to evolve. Recent kinetic approaches ("real-time PCR") incorporate detection in the amplification step, and multiplex PCR includes the entire system in a cassette.

Due to the inherent complexity and unparalleled analytical sensitivity of nucleic acid-based examination procedures, special attention to their design, development, and use is required, including determination of analytical and clinical performance characteristics, documentation of instructions for use, design of medical laboratory facilities, implementation of appropriate quality assurance practices, verification of the performance characteristics by the medical laboratory in conditions of actual use, and risk management.

As with all *in vitro* diagnostic examination procedures, suitability of a nucleic acid-based examination procedure for its intended clinical uses must be demonstrated as part of the development process. Analytical performance characteristics must be determined and validated for the detection and identification of the target pathogen. Clinical performance characteristics must be determined and validated based on clinical evidence, including evaluation of the benefits and risks to patients. Instructions for use must be clearly documented and effective quality assurance procedures must be specified.

Prior to examination of patient specimens, satisfactory implementation of the examination procedure must be verified by the medical laboratory under conditions of actual use. In other words, the successful transfer of the validated examination procedure from the development laboratory or IVD manufacturer to the end-user medical laboratory must be demonstrated by objective evidence. Any modification of the examination procedure after this transfer may require validation that the analytical and/or clinical performance remains suitable for its intended uses, including reassessment of any risks that could be affected by the modification.

In vitro diagnostic test systems — Qualitative nucleic acid-based *in vitro* examination procedures for detection and identification of microbial pathogens —

Part 1: General requirements, terms and definitions

1 Scope

This Technical Specification is intended for

— IVD medical device manufacturers, medical laboratories, and research and development laboratories that develop nucleic acid-based qualitative *in vitro* diagnostic examination procedures for the detection and identification of microbial pathogens in human specimens, and

— medical laboratories that perform nucleic acid-based *in vitro* diagnostic examinations for the detection and identification of microbial pathogens in human specimens.

This part of ISO/TS 17822 does not apply to

— nucleic acid-based examinations that are not intended for *in vitro* diagnostic use, or

— quantitative nucleic acid-based *in vitro* diagnostic examination procedures.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15189:2012, *Medical laboratories — Requirements for quality and competence*

ISO 15190:2003, *Medical laboratories — Requirements for safety*

ISO 18113-1:2009, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

ISO 18113-2:2009, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use*

ISO 18113-3:2009, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use*

ISO 23640:2011, *In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents*

BIPM JCGM 200:2012, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM), 3rd edition*