

First edition  
2020-11

Corrected version  
2020-12

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**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*

[ISO 17822:2020](https://standards.iteh.ai/catalog/standards/iso/da61febc-9df6-4eed-ae92-89046adb3a57/iso-17822-2020)

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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](http://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](http://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](http://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](http://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.

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