TECHNICAL SPECIFICATION

ISO/TS 22583

First edition
2019-11

Guidance for supervisors and operators of point-of-care testing (POCT) devices

Reference number
ISO/TS 22583:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.*

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.

Introduction

Due to the ease of use and rapidness of point-of-care-testing (POCT), POCT equipment is widely used as a tool for making decisions related to the health, management or care needs of patients. Such decisions can include admission to hospital, evacuation to more appropriate care environments and directed patient management. There can also be significant civil and/or legal implications that arise from POCT such as cessation or termination of employment, family court rulings or revocation of bail or parole.

The availability of simple-to-use point of care equipment has led to continuous development in POCT, examples include testing for diabetes management, blood clotting factors, infectious disease markers, haemoglobin, white blood cell counts, pregnancy tests, cardiac markers, illicit drug use and performance enhancing chemical testing.

Whilst examinations of a patient's body fluids, excreta and tissues have been performed traditionally in the controlled and regulated environment of a medical laboratory, globally, POCT is increasingly being performed outside of a traditional laboratory setting and by operators without medical laboratory support.

Circumstances where POCT testing can occur include but are not limited to hospitals, medical practices, pharmacies, paramedics, long-term care facilities, outreach clinics in remote and rural settings, in emergency and natural disasters and community settings such as law enforcement, workplace health and safety, sporting facilities, academia, the military and public areas such as shopping centres.

As POCT results can be used to make important decisions about patients, it is vital that the equipment works properly to yield the correct results and that the operators are trained and competent. This requires that a quality testing structure is provided by supervisors and made available to the operators.

Testing should be of benefit to the patient being tested, if the testing is not performed within a defined quality testing structure then incorrect results can have a negative effect on the patient in terms of health outcomes or punitive action taken.

This document has been written in easy to understand language. Its purpose is to provide supervisors and operators of POCT services guidance for assessing the appropriateness of proposed POCT, test and equipment selection, as well as skill requirements for technical performance and result interpretation that will ensure that the reliability, quality and interpretation of the results produced is of a quality appropriate to the intended use.

It is recommended that manufacturers and their distributors draw this this document to the attention of purchasers of POCT equipment and encourage them to follow this document.

NOTE 1 The Annexes provide detailed information and add context that is not included in the main body of this document. Therefore, to appreciate this document fully the reader is encouraged to ensure the relevant annexes are read in conjunction with main body of this document.

NOTE 2 It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

NOTE 3 In some sections readers of this document are referred to medical laboratory professionals. Medical laboratory professionals with the required competence to offer advice can be found in laboratories adhering to international standards including ISO 15189, *Medical laboratories — Requirements for Quality and Competence* and ISO 22870, *Point-of-care testing (POCT) — Requirements for quality and competence.*

Guidance for supervisors and operators of point-of-care testing (POCT) devices

1 Scope

This document gives guidance for supervisors and operators of point-of-care testing (POCT) services where POCT is performed without medical laboratory training, supervision or support. It includes the key components that should be considered to provide safe and reliable POCT results.

Self-testing is excluded from this document.

2 Normative references

There are no normative references in this document.

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
analyte
item that is being measured, tested or calculated

EXAMPLE Glucose, troponin, concaine, HIV antibodies.

3.2
biological reference interval
reference range
normal range
normal value
specified interval of the distribution of values taken from a biological reference population

Note 1 to entry: A reference interval is composed of the values or range for an *analyte* (3.1) that are expected for a “healthy person”. They are sometimes called "normal" values. Whilst “normal” ranges can give an indication about the wellbeing of a *patient* (3.10), things which should be considered are that a result within the “normal” range does not necessarily mean the *patient* (3.10) is healthy, or a result outside of the “normal” range does not necessarily mean the *patient* (3.10) is unhealthy. It is also important to note that “normal ranges” can differ from *equipment* (3.6) to *equipment* (3.6) and population to population.

Note 2 to entry: In some cases, such as drugs of abuse testing the normal value should be negative or not detected.

[SOURCE: ISO 15189:2012, 3.4, modified — NOTE 1 to NOTE 4 have been deleted and Note 1 to entry has been added.]