BS EN ISO 19001:2013

Incorporating corrigendum August 2013

BSI Standards Publication

In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

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National foreword

This British Standard is the UK implementation of EN ISO 19001:2013. It supersedes BS EN 12376:1999 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2013.

Amendments/corrigenda issued since publication

Date	Text affected
31 August 2013	Implementation of CENELEC correction notice 24 April 2013: Supersession information corrected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19001

March 2013

ICS 11.100.10; 11.040.55

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (ISO 19001:2013)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant avec les réactifs de coloration de diagnostic in vitro utilisés en biologie (ISO 19001:2013)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller von in-vitro-diagnostischen Reagenzien für biologische Färbungen (ISO 19001:2013)

This European Standard was approved by CEN on 14 March 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 19001:2013: E

Foreword

This document (EN ISO 19001:2013) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by March 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12376:1999.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19001:2013 has been approved by CEN as EN ISO 19001:2013 without any modification.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 19001 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 19001:2002), which has been technically revised.

Introduction

This International Standard relates to ISO 18113-1 and ISO 18113-2, which can be used in conjunction with it.

The use of reagents required for staining in biology as well as the specific examples of information supplied by the manufacturer for two staining procedures as provided in Annex A are based on a European consensus; they constitute the scientific justification for the requirements listed in Clause 4. This information is intended to assist manufacturers, suppliers and vendors of dyes, stains, chromogenic reagents and other reagents used for staining in biology in complying with the required specific product data.

INTERNATIONAL STANDARD **ISO 19001:2013(E)**

In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

1 Scope

This International Standard specifies requirements for information supplied by the manufacturer with reagents used in staining in biology. It applies to producers, suppliers and vendors of dyes, stains, chromogenic reagents and other reagents used for staining in histology and cytology including bacteriology, haematology, histochemistry, as performed in medical laboratories, both routine and research bacteriology. The requirements for information supplied by the manufacturer specified in this International Standard are a prerequisite for achieving comparable and reproducible results in all fields of staining in biology.

2 Normative references

The following referenced documents are indispensable for the application 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 80000-1, *Quantities and units — Part 1: General*

ISO 80000-9, *Quantities and units — Part 9: Physical chemistry and molecular physics*

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

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

3 Terms and definitions

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

3.1
antibody
specific immunoglobulin formed by B-lymphocytes in response to exposure to an immunogenic substance and able to bind to this

Note 1 to entry: The molecule of an immunogenic substance contains one or more parts with a characteristic chemical configuration, an epitope.

3.2
blocking reagent
reagent that is used to reduce the inherent background of a sample before staining

3.3
chromogenic reagent
reagent that reacts with certain chemical groups present or induced in cells and tissues with the formation of a coloured compound in situ

EXAMPLE Diazonium salt, Schiff's reagent.