TECHNICAL SPECIFICATION

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Medical laboratories — Reagents for staining biological material — Guidance for users

Laboratoires médicaux — Réactifs pour coloration du matériel biologique — Directives pour les utilisateurs

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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.*

This Technical Specification addresses the need to use reagents in staining in biology that fulfill the criteria of ISO 19001, *In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*. This Technical Specification states the requirements for these reagents when used for diagnostic work in medical laboratory fields such as microbiology, molecular biology, cytology, histopathology, and haematology.

Introduction

This Technical Specification is based on ISO 19001, *In vitro diagnostic medical devices – Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*. It is written for medical laboratories that prepare their own *in vitro* diagnostic examination procedures from commercially available reagents that are not specifically intended for *in vitro* diagnostic use, as well as medical laboratories that use commercially prepared *in vitro* diagnostic reagents that are specifically intended for performing *in vitro* diagnostic examinations.

This Technical Specification describes the information that laboratories performing *in vitro* diagnostic staining in biology need to receive from the suppliers and vendors of dyes, stains, chromogenic reagents and other reagents used for staining in biology. It also provides specific guidance for use of this information, which is a prerequisite for professional users in medical laboratories to achieve reproducible and comparable results in all fields of staining in biology.

Medical laboratories — Reagents for staining biological material — Guidance for users

1 Scope

This Technical Specification provides requirements and guidance for selecting and assessing the quality of reagents to be used for *in vitro* diagnostic staining in biology.

This Technical Specification applies to the professional use of reagents for staining in biology by medical laboratories, and in particular, to those who are responsible for the requisition and evaluation of these reagents in medical laboratory disciplines such as clinical cytology, haematology, histopathology, microbiology, and molecular biology.

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

ISO 19001, *In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*

3 Terms and definitions

For the purposes of this Technical Specification, the following terms and definitions apply:

3.1
batch
lot
defined amount of material that is uniform in its properties and has been produced in one process or series of processes

[SOURCE: ISO 18113-1]

3.2
batch code
lot number
distinctive set of numbers and/or letters that specifically identifies a batch and permits its manufacturing, packaging, labelling and distribution history to be traced

[SOURCE: ISO 18113-1]

3.3
blocking reagent
reagent that is used before staining to reduce the inherent background of a sample

[SOURCE: ISO 19001:2013, 3.2, Definition has been reworded to improve clarity.]

3.4
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.

[SOURCE: ISO 19001]

3.5
component
part of a finished, packaged and labelled IVD medical device

EXAMPLE raw material, substance, piece, part, software, firmware or labelling.

Note 1 to entry: Typical kit components include antibody solutions, buffer solutions, calibrators, and/or control materials.

[SOURCE: ISO 18113-1]

3.6
control material
substance, material or article intended by its manufacturer to be used to verify the performance properties of an IVD medical device

Note 1 to entry: For staining in biology, control material may also include previously diagnosed patient samples (cellular or tissue).

[SOURCE: ISO 18113-1:2009, 3.13, The term *performance characteristics* has been changed to *performance properties*.]

3.7
dye

coloured organic compound that, when dissolved in a suitable solvent, can impart colour to a material

[SOURCE: ISO 19001]

3.8
examination
set of operations having the purpose of determining the value or characteristics of a property

Note 1 to entry: In some disciplines (e.g. microbiology), an examination can be the total activity of several examinations.

[SOURCE: ISO 18113-1:2009, 3.16, Note 1 to entry has been modified for clarity.]

3.9
expiry date
expiration date
upper limit of the time interval during which the performance properties of a material stored under specified conditions can be assured

[SOURCE: ISO 18113-1:2009, 3.17, The term *performance characteristics* has been changed to *performance properties*.]

3.10
fluorochrome
reagent that emits visible light when irradiated with excitation light of a shorter wavelength

[SOURCE: ISO 19001]

3.11
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:1999]

3.12
information supplied by the manufacturer
labelling
written, printed, or graphic matter

— affixed to an IVD medical device or any of its containers or wrappers, or

— provided for use with an IVD medical device, related to identification, technical description, and use of the IVD medical device, but excluding shipping documents

EXAMPLE Labels, instructions for use.

[SOURCE: ISO 18113-1]

3.13
instructions for use
information supplied by the manufacturer to enable the safe and proper use of an IVD medical device

Note 1 to entry: Includes warnings, precautions, and directions supplied by the manufacturer for the use, maintenance, troubleshooting and disposal of an IVD medical device.

[SOURCE: ISO 18113-1]

3.14
intended use
intended purpose
objective intent of an IVD manufacturer or the laboratory user regarding the use of a product, process or service as reflected in the specifications, instructions and information supplied by the IVD manufacturer or specified by the laboratory user

[SOURCE: ISO 18113-1:2009, 3.31, Definition has been expanded to include intent of laboratory users.]

3.15
***in vitro* diagnostic medical device**
IVD medical device
device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of primary samples derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1]

3.16
in vitro diagnostic reagent
IVD reagent
chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as an IVD medical device

[SOURCE: ISO 18113-1]

3.17
kit
set of components that are packaged together and intended to be used to perform one or more specific IVD examinations

Note 1 to entry: Kit components can include reagents (such as antibodies, enzymes, buffer and diluents), calibrators, controls and other articles and materials.

[SOURCE: ISO 18113-1]

3.18
label
printed, written, or graphic information placed on a medical device or its container

[SOURCE: ISO 18113-1]

3.19
lectin
protein of non-immunogenic origin with two or more binding sites that recognize and bind to specific saccharide residues

[SOURCE: ISO 19001]

3.20
manufacturer
natural or legal person responsible for the design, manufacture, fabrication, assembly, packaging or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on his or her behalf by a third party

[SOURCE: ISO 18113-1]

3.21
medical device
instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of *in vitro* examination of primary samples derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its intended function by such means

Note 1 to entry: The concept medical device includes *in vitro* diagnostic medical device.

[SOURCE: ISO 18113-1:2009, 3.47, Note 1 to entry has been added for emphasis.]

3.22
precaution
statement that alerts users to special care or activities necessary for safe and effective use of an IVD medical device or to avoid damage to the IVD medical device that could occur as a result of use, including misuse

Note 1 to entry: The distinction between warnings and precautions is a matter of degree, considering the likelihood and seriousness of the hazard. See the definition of *warning* (3.38).

[SOURCE: ISO 18113-1]

3.23
primary sample
specimen
discrete portion of a body fluid or tissue taken for examination, study or analysis of one or more quantities or properties to determine the property of the whole

[SOURCE: ISO 18113-1:2009, 3.54, Non-relevant notes to entry have been deleted.]

3.24
product certification
third-party attestation that specified requirements relating to a product are fulfilled

[SOURCE: ISO/IEC 17000:2004, 5.5, Definition has been made specific for the product.]

3.25
product certification body
third-party organization that performs conformity assessment services and provides attestation related to products

[SOURCE: ISO/IEC 17000:2004, 2.5 and 5.5]

3.26
product qualification
process of demonstrating whether a product is capable of fulfilling specified requirements

[SOURCE: ISO/IEC 12207:2008, 4.22, Definition has been made specific for the product.]

3.27
professional use
designation that an IVD medical device is intended for personnel who are qualified to perform IVD examinations through special education and training

[SOURCE: ISO 18113-1]

3.28
safety data sheet
SDS
material safety data sheet
MSDS
document prepared in accordance with regulatory requirements for occupational safety to convey information about a hazardous chemical substance

Note 1 to entry: A safety data sheet typically describes physical properties, health hazards, toxicity, fire and reactivity properties, and provides storage and handling precautions.

Note 2 to entry: Safety data sheets are not considered part of IVD medical device labelling.

Note 3 to entry: A globally harmonized system of classification and labelling of chemicals (GHS) contains classification criteria and hazard communication elements. [20, 21]

[SOURCE: ISO 18113-1:2009, 3.38, The preferred term "*safety data sheet*" and Note 3 to entry have been added.]