PD ISO/TS 17518:2015

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

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National foreword

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Published by BSI Standards Limited 2015

ISBN 978 0 580 89925 6
ICS 11.100.01

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

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2015.

Amendments/corrigenda issued since publication

Date	Text affected

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TECHNICAL SPECIFICATION

ISO/TS 17518

First edition
2015-04-15

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

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

Reference number
ISO/TS 17518:2015(E)

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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).

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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.

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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.

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TECHNICAL SPECIFICATION ISO/TS 17518:2015(E)

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.]

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