

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

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ICS 11.100

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English version

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

Dispositifs médicaux de diagnostic in vitro —
Informations fournies par le fabricant de réactifs de
coloration de diagnostic in vitro utilisées en
biologie

In-vitro-Diagnostika — Bereistellung von
Informationen durch den Hersteller von
in-vitro-Diagnostika-Reagenzien für biologische
Färbungen

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by 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of an identical text or by endorsement, at the latest by July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

Annexes A and B are given for information.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This European Standard relates to EN 375, *In vitro diagnostic systems — Requirements for labelling of in vitro diagnostic reagents for professional use* and EN 376, *In vitro diagnostic systems — Requirements for labelling of in vitro diagnostic reagents for self testing* and should be used in conjunction with these.

The use of reagents required for staining in biology as well as the specific examples of information supplied by the manufacturer for four 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 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.

1 Scope

This European 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 biology. The requirements for information supplied by the manufacturer specified in this European Standard are a prerequisite for achieving comparable and reproducible results in all fields of staining in biology.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 375, *In vitro diagnostic systems — Requirements for labelling of in vitro diagnostic reagents for professional use*.

EN 376, *In vitro diagnostic systems — Requirements for labelling of in vitro diagnostic reagents for self testing*.

ISO 31-8, *Quantities and units — Part 8: Physical chemistry and molecular physics*.

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*.

3 Terms and definitions

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

3.1

information supplied by the manufacturer

all printed, written, graphic or other information affixed to, or accompanying an in vitro diagnostic reagent

3.2

label

any printed, written or graphic information placed on a container

[EN 375]

3.3

in vitro diagnostic reagent

reagent that, used alone or in combination with other in vitro diagnostic medical devices, is intended by the manufacturer to be used in vitro for examination of substances derived from human, animal or plant sources, for providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality

3.4

staining

impartment of colour to a material by means of reaction with a stain or chromogenic reagent

3.5

dye

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

NOTE The physical origin of colour is the selective absorbance (and/or emission) in the visible region of the electromagnetic spectrum between 400 nm and 800 nm. Dyes are molecules with large systems of delocalized electrons (conjugated π -electronic system). The light absorbance characteristics of dyes are displayed by absorbance spectra, resulting from plotting absorbance of light against wavelength. The shape of the spectra and the wavelength at maximum absorbance depend on the chemical structure of the dye, the solvent, and on the conditions of the spectral measurements.

3.6

stain

solution of one or more dyes at defined concentrations in a defined solvent used for staining

NOTE The stain can be prepared by directly dissolving the dye in the solvent or by dilution of a stock solution with suitable agents.

3.6.1

stock solution of stain

stable defined solution of one or more dyes at a higher concentration than that employed for staining

NOTE Stability refers to constant properties of the dye even in the presence of other dyes.