

Information supplied by the manufacturer with in vitro diagnostic reagents for professional use

The European Standard EN 375:2001 has the status of a
British Standard

ICS 11.100

National foreword

This British Standard is the official English language version of EN 375:2001. It supersedes BS EN 375:1992 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/69, In vitro diagnostic systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 March 2001

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 14, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

© BSI 03-2001

ISBN 0 580 37233 2

English version

Information supplied by the manufacturer with in vitro diagnostic reagents for professional use

Informations fournies par le fabricant avec les réactifs de diagnostic in vitro pour usage professionnel

Bereitstellung von Informationen durch den Hersteller von Reagenzien für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal

This European Standard was approved by CEN on 6 December 2000.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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Contents

	Page
Foreword	2
1 Scope	3
2 Normative references	3
3 Terms and definitions	3
4 Requirements for labels	5
4.1 Outer container	5
4.2 Immediate container	7
5 Requirements for instructions for use	9
Annex ZA (informative) Relationship of this document with EC Directives	12
Bibliography	14

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.

The European Diagnostic Manufacturers Association (EDMA) has contributed to its preparation.

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 2001, and conflicting national standards shall be withdrawn at the latest by July 2001.

This European Standard supersedes EN 375:1992.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

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.

1 Scope

This standard specifies the requirements for the information supplied by the manufacturer of in vitro diagnostic reagents including reagent products, calibrators, control materials and kits for professional use, which hereafter are called IVD reagents.

NOTE This standard can also be applied to accessories.

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 (including amendments).

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 standard, the following terms and definitions apply.

3.1

active ingredient

constituent that participates in the reaction used to measure or detect the analyte

3.2

batch

lot

defined amount of material, either starting material, intermediate or finished product which is uniform in its properties and has been produced in one process or series of processes

3.3

batch code

lot number

code that is a distinctive combination of numbers and/or letters which specifically identifies a batch and permits its manufacturing history to be traced

3.4

calibrator

substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an in vitro diagnostic medical device

3.5

control material

substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an in vitro diagnostic medical device

3.6

expiry date

date up to which product performance is assured by the manufacturer based on the stability of the IVD reagent

3.7

immediate container

primary container

packaging which protects the contents from contamination and/or other effects of the external environment

NOTE Examples are a sealed vial, ampoule or bottle, a foiled pouch, or a sealed plastics bag containing e. g. culture media, microtitration plates or coated tubes.

3.8

internal quality control

operational techniques and activities at the point of use that are used to fulfil requirements for quality of services

NOTE Internal quality control comprises all steps of activity for production of results from collection of sample and measurement of a measurable quantity to reporting of result of measurement.

3.9

in vitro diagnostic reagent

IVD reagent

in vitro diagnostic medical device which is a reagent, reagent product, calibrator, control material or kit

NOTE 1 For the definition of an in vitro diagnostic medical device see [13].

NOTE 2 In some cases a particular IVD reagent, as defined for use in human medicine, may serve also in veterinary medicine.

3.10

kit

set of components (reagents and/or other materials) packaged together

3.11

kit component

in vitro diagnostic medical device intended to be part of a kit

NOTE Typical kit components are e. g. antibody solutions, buffer solutions, calibrators or control materials.

3.12

label

printed, written or graphic information placed on a container

3.13

outer container

sales packaging

material used in the packaging of the immediate container(s) of (an) IVD reagent(s) consisting of a single entity or an assembly of different or identical components