

Stability testing of in vitro diagnostic reagents

The European Standard EN 13640:2002 has the status of a
British Standard

ICS 11.100

National foreword

This British Standard is the official English language version of EN 13640:2002.

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

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- 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.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 3 May 2002

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English version

Stability testing of in vitro diagnostic reagents

Essais de stabilité des réactifs de diagnostic in vitro

Haltbarkeitsprüfung von Reagenzien für in-vitro-
diagnostische Untersuchungen

This European Standard was approved by CEN on 27 December 2001.

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Foreword

This document EN 13640:2002 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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.

This document 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 document.

Annexes A and ZA are for information only.

This standard includes a Bibliography.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This European Standard is applicable to the stability testing of in vitro diagnostic reagents including reagent products, calibrators, control materials and kits, hereinafter called IVD reagents. It specifies general requirements for stability testing and gives specific requirements for real-time testing and accelerated testing when generating stability data in the

- determination of IVD reagent shelf-life including transport stability;
- determination of stability of the IVD reagent in use after the first opening of the primary container (e. g. on-board stability);
- monitoring of stability of IVD reagents already placed on the market;
- verification of stability after IVD reagent modifications that may affect stability.

This standard does not apply to instruments, apparatus, equipment, systems, or specimen receptacles.

2 Terms and definitions

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

2.1

accelerated stability study

stability study designed to increase the rate of chemical or physical degradation of an in vitro diagnostic reagent by using exaggerated conditions with the purpose of predicting the shelf-life

NOTE The design of an accelerated study may include elevated temperature, high humidity, light and vibration.

2.2

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

[EN 375:2001]

2.3

expiry date

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

[EN 375:2001]

2.4

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 Bibliography.

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

[EN 375:2001]