

Sampling procedures used for acceptance testing of in vitro diagnostic medical devices — Statistical aspects

The European Standard EN 13975:2003 has the status of a
British Standard

ICS 11.100

National foreword

This British Standard is the official English language version of EN 13975:2003.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/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.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 March 2003

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 12, 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 28 March 2003

ISBN 0 580 41510 4

English version

Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

Procédures d'échantillonnage utilisées pour l'acceptation
des essais des dispositifs médicaux de diagnostic in vitro -
Aspects statistiques

Probenahmeverfahren für die Annahmeprüfung von In-vitro-
Diagnostika - Statistische Aspekte

This European Standard was approved by CEN on 14 November 2002.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN 13975:2003) 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 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

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

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

Annex A is informative.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard relates to Annex VI "EC VERIFICATION" of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, setting out requirements for sampling procedures used for acceptance testing of in vitro diagnostic medical devices by a notified body.

In Annex VI three provisions for verification are described:

- ¾ Section 5 provides for verification by examination and testing of every finished device;
- ¾ Section 6.3 provides for verification based on statistical control by attributes and/or variables;
- ¾ Section 2.2 provides for alternative conformity assessment procedures for those situations where statistical verification as specified in Section 6.3 is considered to be not appropriate.

The first provision is not considered in the present standard since the associated sampling plan requires no statistical considerations.

The second provision is applied when sufficient certainty on the result of such verification on finished devices can be gained by a sampling plan established on a statistical basis. For this purpose existing standards on acceptance testing can be applied.

The third provision is addressed in Section 2.2 of Annex VI which states that:

"To the extent that for certain aspects the final testing according to Section 6.3 is not appropriate, adequate in-process testing, monitoring and control methods shall be established by the manufacturer with the approval of the notified body. The provision of Annex IV, Section 5, shall apply accordingly in relation to the above mentioned approved procedures."

Annex IV, Section 5, prescribes surveillance and approval of a manufacturer's quality system.

It is current state of the art that inspection and verification of the finished devices is complementary to process control and final testing performed by the manufacturer. Performance verification is generally performed by measurements on defined control materials or a defined panel of reference specimens (e.g. sera).

Valid conclusions can only be drawn from a limited number of units of the final product, if adequate in-process testing, monitoring and control procedures ensure the homogeneity of the final product batch and its components at the intermediate stage(s) of manufacture as well as the suitability of the process applied. Any sampling plan used for final testing of in vitro diagnostic medical devices is based on statistical considerations. This does not necessarily mean that a large number of units is sampled and tested. In many cases using very small sample sizes (sometimes equal to one unit) can be an acceptable approach, provided that an adequate level of conformity has been demonstrated by other appropriate means.

Following this last approach, this standard can also be used for establishing sampling procedures when annex III or IV or VII is applied.