

In vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media

The European Standard EN 12322:1999, with the incorporation of amendment A1, has the status of a British Standard

ICS 07.100.10

National foreword

This British Standard is the English language version of EN 12322:1999, including amendment A1:2001.

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.

The UK submitted a negative vote to prEN 12322 but the standard received an overall positive vote from CEN Member Bodies and the UK comments were not accepted. The reasons for UK disapproval were as follows.

Clause 4, Performance evaluation. It is not clear how the requirements are to be verified, contrary to the ISO/IEC Directives Part 3:1997.

Clause 4.1, General quality criteria. It is expected that manufacturers will use appropriate European and international quality systems standards in conjunction with EN 12322, so inclusion by cross reference is unnecessary. The verbal form “shall”, used to describe the requirements of a quality assurance scheme, cannot be taken as normative as the standard relates to culture media and not to quality systems, which are outside its scope.

Cross-references

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

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Summary of pages

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In vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media

(includes amendment A1:2001)

Dispositifs médicaux de diagnostic in vitro —
Milleux de culture de microbiologie — Critères
de performance des milieux de culture
(inclut l'amendement A1:2001)

In-vitro-Diagnostika — Kulturmedien für die
Mikrobiologie — Leistungskriterien für
Kulturmedien
(enthält Änderung A1:2001)

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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 October 1999, and conflicting national standards shall be withdrawn at the latest by October 1999.

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).

Annex A and Annex B are for information only.

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.

Foreword to amendment A1

This amendment EN 12322:1999/A1:2001 to the EN 12322:1999 has been prepared by Technical Committee CEN/TC 140, In vitro diagnostic medical devices, the Secretariat of which is held by DIN.

This amendment to the European Standard EN 12322:1999 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2002, and conflicting national standards shall be withdrawn at the latest by April 2002.

This amendment to the European Standard EN 12322:1999 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.

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Introduction

In the microbiology laboratory many tests and procedures depend on culture media being consistent and providing reproducible results. Several hundreds of formulae of dehydrated culture media are commercially available, and many more designed for specific growth responses or purposes are described in the literature. In addition, in clinical and industrial laboratories, the main objectives are growth and rapid and sensitive detection of micro-organisms. The requirements for media are specific to both the sample and the organism(s) to be detected. Standardized culture media are therefore a prerequisite for any reliable microbiological work (see Annex B [1]), and it is of primary importance to define the major objectives and criteria related to how a culture medium is supposed to perform. Determining the performance characteristics of culture media is necessary for commercially prepared culture media. For in-house prepared culture media the internal quality control is carried out by the user.

Performance criteria for culture media are necessary for obtaining comparable products of the same medium type, regardless of source. In addition these criteria may be used by all microbiology laboratories for the evaluation of nutritive and/or selective properties of (new) culture media.

Uniform performance criteria should therefore result in the manufacture of “standardized” products, and limit the amount of testing of commercial culture media in microbiology laboratories.

1 Scope

This European Standard specifies requirements for the performance of culture media. It is concerned with the traceability, comparability, reproducibility and suitability of culture media used in microbiological laboratories. These characteristics are achieved by applying the quality criteria outlined in this standard.

This European Standard is applicable to:

- a) commercial organizations distributing media to microbiology laboratories in ready-to-use form, as dehydrated media or as semi-finished media (see 2.5 in EN 1659:1996);
- b) non-commercial organizations that distribute media to satellite locations;
- c) laboratories that prepare culture media for their own use.

Cell culture media are not covered by this standard.

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 1659:1996, *In vitro diagnostic systems — Culture media for microbiology — Terms and definitions*.

EN ISO 8402:1995, *Quality management and quality assurance — Vocabulary. (ISO 8402:1994)*

3 Definitions

For the purposes of this standard, the definitions given in EN 1659:1996 and in EN ISO 8402:1995 apply, together with the following.

3.1

batch of culture media; lot of culture media

fully traceable unit referring to a defined amount of bulk, semi-finished product or end product, which is consistent in type and quality and which has passed the requirements of production (in-process control) and quality assurance testing, and which has been produced within one defined production period having been assigned the same lot number

3.2

control strain

micro-organism used for microbial performance evaluation of culture media