SLOVENSKI STANDARD

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Diagnostiļ ni medicinski pripomoļ ki in vitro ï Gojiġļ a za mikrobiologijo ï Merila za kakovost gojiġļ

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

In-vitro-Diagnostika - Kulturmedien für die Mikrobiologie - Leistungskriterien für Kulturmedien

Dispositifs médicaux de diagnostic in vitro - Milieux de culture de microbiologie - Criteres de performance des milieux de culture

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English version

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

Dispositifs médicaux de diagnostic in vitro - Milieux de culture de microbiologie - Critères de performance des milieux de culture

In-vitro-Diagnostika - Kulturmedien für die Mikrobiologie - Leistungskriterien für Kulturmedien

This European Standard was approved by CEN on 16 March 1999.

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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 Central Secretariat 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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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of an identical text or by endorsement, at the latest by October 1999, and conflicting national standards shall be withdrawn at the latest by October 1999.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).

Annexes A and 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.

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 microorganisms. 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
Microorganism used for microbial performance evaluation of culture media.

3.3
reference strain
Microorganism defined to at least the genus and species level, catalogued and described according to its characteristics.

3.4
reference stock
Lot of containers obtained in the laboratory by a single propagation from a reference strain or multiple containers from the same lot of a reference strain from a supplier.

3.5
stock culture
Subculture(s) of a reference stock.

3.6
working culture
Subculture of a stock culture.

4 Performance evaluation

4.1 General quality criteria

NOTE : This standard is not intended to give a detailed description of quality management practices for manufacturing of culture media, which are described elsewhere (see annex B, [1] to [7], [11] and [13]).

It should be noted that, according to some quality systems in use by manufacturers (e.g. according to EN ISO 9001 and EN 46001 or EN ISO 9002 and EN 46002), besides microbiological performance evaluation of culture media, performance testing shall also include testing of physical and chemical properties (see annex B, [13]), such as :

a) quantity filled ;

b) layer thickness and filling format ;

c) colour ;

d) clarity and/or optical artifacts ;

e) homogeneity ;

f) gel stability and consistency ;

g) moisture content or homogeneity of dehydrated media ;

h) appearance of specific media (e.g., blood agar) ;

i) pH value.

The quality of culture media depends on the quality of the basic ingredients, correct formulation and accuracy in preparation, adequate removal of microbial contaminants, proper packaging and storage.

Raw materials, nutritive or inhibitory supplements or miniaturized test systems for identification of microorganisms should be supplied according to the same appropriate quality procedures.

4.2 Control strains

The set of control strains shall include reference strains.

NOTE 1 : Reference strains can be obtained from service or reference collections affiliated to ECCO or WFCC (see annex B, [9] and [15]). The set of control strains can include well characterized positive (sensitive, resp. well-growing), weakly positive (weakly sensitive, resp. poor-growing), and negative (insensitive, resp. suppressed or inhibited) control strains (see annex B, [5], as well as DIN 58959-6 and DIN 58959-7). Control strains for commonly used culture media are referenced by a number of sources (see annex B [2] to [6], [9], [11] and [12], and DIN 58959-6, DIN 58959-6 suppl. 1, DIN 58959-7 , DIN 59959-9) and may be selected as appropriate. For traceability, all control strains should be available from a reference collection.

Working cultures shall be used once only. Subcultures from working cultures shall not be used for performance testing purposes or production of stock cultures.

NOTE 2 : For information on preservation, maintenance techniques and service culture collections, see annex A and annex B, [8].

4.3 Microbiological quality criteria

4.3.1 Routine quality control

4.3.1.1 Growth

4.3.1.1.1 General

For the lot-control of culture media and nutritive ingredients for culture media, as appropriate, growth shall be assessed

– either semi-quantitatively,

– or quantitatively.

Quantitative and semi-quantitative evaluations shall be performed by a validated technique (see annex B, [16]).

NOTE : Semi-quantitative evaluations can be performed by assigned growth-scores, e.g., 0 to 3+. When reading solid media, 0 corresponds to no growth, 1+ to very poor growth (< 10 colonies), 2+ to heavy growth (single colonies) and 3+ to very heavy growth (confluent colonies). When reading fluid or semi-solid media visually, 0 represents no turbidity, 1+ faint turbidity and 2+ heavy turbidity.