BRITISH STANDARD

BS EN
12322:1999
Incorporating
Amendment No. 1

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

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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.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 10, an inside back cover and a back cover.

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Amendments issued since publication

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12322

April 1999

+A1

October 2001

ICS 07.100.10

English version

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)

This European Standard was approved by CEN on 16 March 1999. Amendment A1:2001 was approved by CEN on 30 September 2001. 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 biographical references concerning such national standards may be obtained on application to the Central Secretariat 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 Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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