



# LAB 31

EDITION 2 | June 2009

## USE OF CULTURE MEDIA PROCURED READY-TO-USE OR PARTIALLY COMPLETED IN MICROBIOLOGICAL TESTING

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### CHANGES SINCE LAST EDITION

Minor changes have been made to Edition 1 in order to clarify some of the text and include new and updated references to relevant international standards

## 1 INTRODUCTION

- 1.1 Laboratories that have been assessed by UKAS as meeting the requirements of ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* may be granted UKAS accreditation. Whilst ISO/IEC 17025:2005 is the authoritative document, several guidance publications on the application of these requirements are listed under *Publications for Laboratory Accreditation to ISO/IEC 17025* on the [www.ukas.com](http://www.ukas.com) website.
- 1.2 This publication provides guidance on the application of specific requirements for laboratories carrying out microbiological testing. By following the guidance given, such laboratories will be able to demonstrate that they meet the requirements regarding the suitability of media (including diluents) procured ready-to-use or partially completed for microbiological testing purposes (ISO/IEC 17025:2005, paras 4.6 and 5.5). Alternative approaches may be used provided that they are shown to give an equivalent outcome.
- 1.3 The guidance given in this publication applies to the use of any medium procured ready-to-use or partially completed, including identification or diagnostic kits that are dependent on microbial growth. It does not cover validation of methods, such as described in ISO/IEC 16140:2003.
- 1.4 Demonstration of suitability as outlined in this publication does not replace the need for using positive and negative controls alongside testing when relevant.

## 2 DEFINITIONS

Definitions of the following and other related terms may be found in BS EN 1659:1997, BS EN 12322:1999, DD ENV ISO 11133-1:2009 and DD CEN ISO/TS 11133-2:2003.

### **Culture media**

Formulations of substances, in liquid, semi-solid or in solid form, which contain natural and/or synthetic constituents intended to support the multiplication, or to preserve the viability, of micro-organisms.

*Note:* This is taken to include diluents and other suspending fluids.

### **Ready-to-use media**

Culture media supplied in containers in ready-to-use form (e.g. Petri dishes, tubes or other carriers and including identification or diagnostic kits that are dependent on microbial growth).

### **Partially completed media**

Culture media which still require one or more additional working steps before their intended use (e.g. melting, pouring, portioning and supplementing).

### 3 EVALUATION OF SUITABILITY

- 3.1 The nature of the evaluation of suitability of ready-to-use and partially completed media for testing purposes is dependent on the source and supplier of those media. The following three categories of such media are recognised:
- (a) *Media that have been performance tested by a laboratory with accreditation to ISO/IEC 17025:2005 for the performance testing of media*  
It is the responsibility of the user laboratory to define the performance specifications against which the medium is to be tested and/or to establish that those criteria applied by the performance testing laboratory meet its requirements. Results provided for batches of media may then be used without verification in the evaluation of suitability. Any relevant factors not covered by the accredited work of the performance testing laboratory need to be tested for acceptability by the user in accordance with (c) below. This may include effects of transportation and shelf-life. Test certificates showing that the agreed performance specifications have been met should be held by the user laboratory for each batch of medium supplied. The manufacturer's release specifications are not covered by accreditation to ISO/IEC 17025:2005 and may need to be covered by an agreement. An agreement may also be needed to ensure there is prior notification of changes in testing practices, including scope of accredited testing
  - (b) *Media supplied by a manufacturer with a quality management system certificated as conforming to ISO 9002 or equivalent in the relevant areas*  
It is the responsibility of the user laboratory to commission before use all supplies in accordance with 3.2 to 3.8 below. Having established product specifications and demonstrated their suitability, the user may apply a sampling and testing rate to subsequent batches in keeping with the expectation of a consistent supply. An agreement between the user and the manufacturer should be established to ensure prior notification of changes in raw material supply, manufacturing or quality control practices. Any such change would necessitate detailed consideration of the implications, possibly leading to recommissioning. Certificates of conformance with the manufacturer's performance specifications should be held by the user laboratory for every batch of medium supplied. As with (a), any relevant factors not covered by the manufacturer's quality control practices need to be tested for acceptability by the user in accordance with (c) below.
  - (c) *Other media (including any under a or b that cannot be demonstrated to meet the requirements)*  
The user laboratory has to both define the product specifications required and verify that the media comply with them. Verification should be done by testing, before use (or at the time of use where prior testing is not possible), each batch of medium received for compliance with those specifications. Guidance on this testing is given in DD ENV ISO 11133-1:2009 and DD CEN ISO/TS 11133-2:2003 and summarised below.
- 3.2 To enable proper evaluation of suitability, acceptable media performance should be defined quantitatively, with objective parameters being set for associated criteria and taking account of shelf-life. Partially completed media should be tested or otherwise evaluated for suitability as received with full performance testing carried out after completion.

- 3.3 A documented plan is necessary for sampling of units for testing which enables suitable comment on the whole batch.
- 3.4 Where control media are used for comparative evaluation of performance, they should be prepared independently of the media under test and should be demonstrated to be suitable for control use, in that they are shown to provide consistency of appropriate performance. Conformance with ISO/IEC 17025:2005 necessitates control strains (i.e. reference materials) being traceable to certified materials, where possible. Using cultures obtained from a recognised national culture collection or from a reference materials producer accredited to ISO Guide 34:2000 (PD6532-5:2000) would provide a suitable level of assurance. In-house maintenance of control cultures must guard against contamination and deterioration. Guidance on the preservation and handling of control strains may be found in DD ENV ISO 11133-1:2009. If microbiological certified reference materials are used, they should comply with the definition for CRMs given in ISO Guide 30:1992 (PD 6532-1:1993) and need to contain an appropriate assigned number of organisms.
- 3.5 Assessment of the performance of solid media used for isolation and for enumeration of colonies and of liquid media used in conjunction with membranes in colony count procedures needs to include recovery of target organisms and, in the case of selective media, suitable inhibition of non-target organisms.
- 3.6 Liquid media used in procedures for the detection of micro-organisms, including those used for Most Probable Number determinations, should be assessed for suitability in terms of limit of detection of target organisms and growth inhibition of non-target organisms.
- 3.7 Any differential or diagnostic attributes associated with media should be assessed objectively and relevant physical attributes of media need to meet specified and suitable criteria. Such attributes may include sterility, pH (of the finished medium), volume or quantity, depth, colour, clarity and/or any optical artefacts and gel strength.
- 3.8 Media designed for the preservation or maintenance, of micro-organisms, including diluents and other suspending fluids, should be shown under conditions of use not to alter significantly the viability or recoverability of micro-organisms, or any other relevant property.

## 4 BIBLIOGRAPHY

BS EN 1659:1997. *In vitro diagnostic systems - Culture media for microbiology - Terms and definitions.*

BS EN 12322:1999. *In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media.*

DD ENV ISO 11133-1:2009. *Microbiology of food and animal feeding stuffs - Guidelines on quality assurance and performance testing of culture media - Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory.*

DD CEN ISO/TS 11133-2:2003. *Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 2: Practical guidelines on performance testing of culture media.*

PD 6532-1:1993, ISO Guide 30:1992 *Reference materials. Guide to the contents of certificates of reference materials. Guide to terms and definitions used in connection with reference materials.*

ISO 9002:1994. *quality systems - Model for quality assurance in production, installation and servicing, second edition.*

ISO Guide 30:1992. *Terms and definitions used in connection with reference materials.*

ISO Guide 34:2000 (PD 6532-5:2000). *General requirements for the competence of reference material producers*

ISO/IEC 16140:2003. *Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods*

ISO/IEC 17025:2005. *General requirements for the competence of testing and calibration laboratories.*