Biological Testing ISO/IEC 17025 Application Document

Annex G: Media Preparation And Quality Control

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This document provides additional interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting Media Preparation and Quality Control under the fields of Biological, and Veterinary Testing.

Applicant and accredited facilities must also comply with the ISO/IEC 17025 standard and the relevant field application document and any field annexes, policies and/or technical circulars (refer to *NATA Procedures for Accreditation).*

The clause numbers in this document follow those of ISO/IEC 17025 but since not all clauses require interpretation the numbering may not be consecutive.

4 Management requirements

4.6 Purchasing services and supplies

4.6.2

Media (Solid, semi solid and diluents)

Each facility is responsible for ensuring that an appropriate level of quality control is performed on the media it uses. This is achieved through an effective media preparation and quality control program designed to suit the scope of testing.

Details of the procedures for preparation and quality control of media and diluents must be documented as part of the facility's management system consistent with the relevant current versions of the Australian Society for Microbiology (ASM) and ISO/TS 11133:

Guidelines for Assuring Quality of Food and Water Microbiological Culture Media and *ASM Guidelines for Assuring Quality of Medical Microbiological Media*

Guidelines for Assuring Quality of solid media used in Australia for cultivation of Medically important Mycobacteria.

ISO/TS 11133 *Microbiology of food and animal feeding stuffs -- Guidelines on preparation and production of culture media -*

Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory

Part 2: Practical guidelines on performance testing of culture media.

Shelf life

Shelf life of all media must be evaluated in accordance with the guidelines provided in the *ASM Guidelines for Assuring Quality of Food and Water Microbiological Culture Media, ASM Guidelines for Assuring Quality of Medical Microbiological Media and Guidelines for Assuring Quality of solid media used in Australia for cultivation of Medically important Mycobacteria* and prepared media marked accordingly.

1. Media produced in-house for distribution to satellite laboratories

In general, all facilities, including satellite laboratories receiving media from a parent facility that does not hold accreditation for media quality control (Class 8.15) will be required to carry out a full quality control evaluation on each batch of a each medium made. Alternatively, facilities preparing media for distribution to satellite laboratories are encouraged to seek NATA accreditation for media quality control.

It is, however, recognised that under special circumstances facilities may be required to produce a small amount of media in-house (e.g. specialised media used by reference laboratories). Generally, this type of media will not be available for purchase from commercial accredited manufacturers. In this situation, satellite laboratories receiving specialised media from a non-accredited parent facility will not be required to perform full QC provided the following criteria are met:

a) The parent facility carries out quality control evaluation on each batch of each medium made. A copy of the media preparation details and QC results must be made available to the satellite laboratory;

b) The receiving satellite laboratory must demonstrate that the media has not been adversely affected by transit, storage and change in environmental conditions;

c) The laboratories must be part of the one organisation; and

d) The media must not be sold or provided to other facilities outside the organisation.

If any of the above is not met, the requirement for full QC at the satellite laboratory will apply.

2. Media purchased from accredited manufacturers

Accredited media manufacturers are those holding ISO/IEC 17025 accreditation for quality control testing of media they produce. Facilities must assure themselves that such accreditation is held by checking the current scope of the manufacturer's accreditation. The scope of accreditation will specify the classes of media for which the manufacturer can issue endorsed reports or certificates.

All media must be initially assessed for suitability to the particular requirements of the facility prior to purchase. This assessment should take into account the nature of the media and the type of test for which it is used, etc. It must be assured that QC organisms testing conditions (time and incubation temperature) are relevant to the testing for which the media is to be used. Where this is not the case the facility is responsible for undertaking additional QC if this cannot be undertaken by the manufacturer.

On an ongoing basis, some media will require only visual examination whereas other types of media require the monitoring of all batches produced until sufficient data have been generated to assure the user of the reliability of the product. At such time, the frequency of testing may be reviewed and reduced.

When a manufacturer issues a product, the product must be labelled with the product name, batch number, date manufactured and expiry date. The customer must also be provided with details of:

a) name and code of media;

b) reference to test methods and sterility protocol;

c) the results of quality control (e.g. organisms, pH, recovery etc) and expected results;

d) shelf life.

The report or certificate issued by the manufacturer should include the NATA endorsement.

Media must be stored and used in accordance with the manufacturer's instructions and include inventory control.

Facilities must periodically review the reliability of purchased media against acceptance criteria and record the results of this review. Records relating to media quality control must be retained in compliance with NATA's record retention requirements.

3. Media purchased from non accredited suppliers

Facilities purchasing media from non-accredited suppliers are required to perform complete quality control testing on all media.

4. Media from suppliers holding ISO 9001 certification only

Certification of the operations of a manufacturer to ISO 9001 does not equate to technical accreditation. Facilities purchasing media from suppliers certified to the ISO 9001 series only or equivalent will be required to perform complete quality control testing on all media.

Biological consumables

Records must be kept of the date of receipt and initial use. Items should be stored according to the manufacturers' recommendations and discarded on the expiry date. Consumables used outside of the manufacturers' expiry date must be validated prior to use.

Kits

QC must be performed when commencing the use of a batch of kits with a new production lot number, using one or more of the strains of organism recommended by the manufacturer (preferably in rotation).

Reagents and standard solutions

Details of the preparation or purchase of all types of standard solutions and reagents must be recorded. The records must include the results of the standardisation, date of preparation, the identity of the preparer, and an estimate of the shelf life or acceptance/rejection criteria for the product.

Virology

The facility must test the virology culture medium to ensure:

- it supports the growth of the cell lines expected to grow;
- it supports the production of normal densities (e.g. monolayer);
- it supports growth in an appropriate time frame;

- it supports the production of normal cell morphology;
- 'cells and medium' support the growth of viruses or other intracellular pathogens of interest; and
- uninoculated and inoculated controls are used.

Different controls may be used for different viruses. The facility must be able to demonstrate that appropriate controls are being used.

Facilities must monitor the growth of viral cell lines by the following:

- recording of split ratios/seeding rates for both primary and continuous cell lines;
- testing for *Mycoplasma* yearly;
- setting up uninoculated cell cultures (cell culture only) with all viral assays. Inoculated cell cultures (cell culture with known virus) should be periodically set up with all viral assays; and
- using virus neutralisation tests (VNT) or periodic titration of a virus of known titre to monitor sensitivity.

References

Information on standard veterinary procedures (ANZSDP) and other areas that may be of interest to the veterinary testing laboratory may be accessed through the Sub-committee on Animal Health Laboratory Standards (SCAHLS) website at www.scahls.org.au

ISO/TS 11133 *Microbiology of food and animal feeding stuffs -- Guidelines on preparation and production of culture media*