Technical Circular 25 - March 2016

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Quality Control of Prepared Media and Media Preparation

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1. Introduction

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

This document replaces the *Biological Testing Annex G: Media Preparation and Quality Control* and applies to any applicant or accredited facility conducting testing that requires the use of media.

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.

Note 1: Whilst it follows the clause numbers of ISO/IEC 17025, these criteria are equally applicable to facilities using media and accredited against other international standards used in NATA's accreditation programs.

Note 2: Whilst these criteria may apply to pathology laboratories accredited under the NATA/RCPA Medical Testing Program, the criteria for media preparation and quality control are included in the Medical Testing Field Application Document for these laboratories.

4 Management requirements

4.6 Purchasing services and supplies

4.6.2

Prepared Media (Solid, semi-solid liquid)

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) Guidelines, (refer to references) and ISO 11133.

Media batches with five or less units

The requirements of the ASM Guidelines for the number of samples to be selected for quality control testing do not need to be followed when the unit number of the batch is five or less. In such cases, oneunit can be selected for testing. This acknowledges the reduced likelihood of within batch variation when batch size is small.

Shelf life

Shelf life of all prepared media must be determined in accordance with the provisions in the *ASM Guidelines* (refer to References). Prepared media shall be labelled with expiry dates as determined by this process.

Biological consumables

Records must be kept of the date of receipt and initial use. Items should be stored according to the manufacturers' recommendations. Note that consumables used outside of the manufacturers' expiry date must be verified prior to use.

Prepared Media purchased from accredited manufacturers

Accredited media manufacturers are those that hold ISO/IEC 17025 accreditation for quality control testing of the 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 prepared media for which the manufacturer can issue endorsed reports or certificates.

All prepared 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 used and 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 purchaser is responsible for undertaking additional QC if this cannot be undertaken by the manufacturer.

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

a) testing and sterility protocols including test methods, and

b) results of quality control (e.g. organisms, pH, recovery etc) for each batch produced and expected results.

Where a report or certificate is issued by the manufacturer this should include the endorsement of the accreditation body.

Prepared media must be stored and used in accordance with the manufacturer's instructions with appropriate inventory control.

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

Prepared media purchased from non-accredited manufacturers

Facilities purchasing prepared media from non-accredited manufacturers are required to perform complete quality control testing on all media. This includes performance, sterility, and physical testing parameters on every batch received.

Prepared media produced in-house for distribution to satellite laboratories

In general, all facilities, including satellite laboratories receiving prepared media from a parent facility that does not hold accreditation for media quality control (Class 8.15) will be required to carry out full quality control (physical, sterility, performance) on each batch of 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 for each batch of medium produced 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.

Prepared 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. This includes performance, sterility, and physical testing parameters on every batch received.

Quality control undertaken as a third party activity

A manufacturer of prepared media may utilise the services of another facility to perform quality control testing. Where this occurs, the manufacturer must use a facility that is accredited to ISO/IEC 17025 for media quality control. The testing facility must undertake all quality control tests as required for media preparation and test reports must include the results of all testing undertaken.

Virology media

In addition to the above issues, virology culture medium must be tested 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; and
- 'cells and medium' support the growth of viruses or other intracellular pathogens of interest.

Uninoculated and inoculated controls are to be used. Different controls may be used for different viruses. The appropriate use of controls must be able to be demonstrated.

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

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

ASM Guidelines for Assuring Quality of solid media used in Australia for cultivation of medically important Mycobacteria
ISO 11133: Microbiology of food, animal feed and water -- Preparation, production, storage and performance testing of culture media

AMENDMENTS

The table below provides a summary of changes made to the document with this issue.

Section	Amendment
	First issue, amendments refer to changes from Annex G to the Biological Testing Application Document.
Title	Change to Quality Control of prepared media and media preparation.
4.6.2	'Prepared' added throughout the document.
4.6.2	Inclusion of liquid media in title.
4.6.2	Clarification that quality control includes physical, sterility and performance.
4.6.2	Requirements for media batches with 5 or less units.
4.6.2	Quality control undertaken as a third party activity criteria added.