AS 4659.3:2015

Australian STANDARD

Guide to determining the equivalence of food microbiology test methods

Part 3: Confirmation tests

STANDARDS Australia

This Australian Standard® was prepared by Committee FT-035, Food Microbiology. It was approved on behalf of the Council of Standards Australia on 9 December 2014.
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The following are represented on Committee FT-035:

- ACT Health
- Australian Food and Grocery Council
- Australian Institute of Food Science and Technology
- Australian Society for Microbiology
- CSIRO
- Dairy Industry Association of Australia
- Department of Agriculture (Australian Government)
- Department of Health, Vic.
- Department of Health, WA
- Food Technology Association of Australia
- Meat and Livestock Australia
- National Association of Testing Authorities Australia
- National Measurement Institute
- Queensland Health Forensic and Scientific Services
- University of Melbourne

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Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Australian Standard®

Guide to determining the equivalence of food microbiology test methods

Part 3: Confirmation tests

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PREFACE

This Standard was prepared by the Standards Australia Committee FT-035, Food Microbiology, to supersede AS/NZS 4659.3:1999, incorporating Amendment No. 1 (February 2002).

After consulting with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objectives of this revision are—

(a) to provide guidance on determining the equivalence of microbiological test methods;

(b) to explain how to determine whether an alternate method for confirmation tests using a pure culture, will yield a result equivalent to an Australian Standard method;

(c) to update the references; and

(d) to incorporate minor technical variations to emphasize the scope and limitations of the Standard.

This Standard is one of a series of guides covering determination of the equivalence of food microbiology test methods. The series now comprises the following:

AS		
4659	Guide to determining the equivalence of food microbiology test methods	
4659.1	Part 1:	Qualitative tests
4659.2	Part 2:	Quantitative tests
4659.3	Part 3:	Confirmation tests

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FOREWORD

An alternate method will be considered to be equivalent if it is shown to yield results that are not different to those obtained using the Australian Standard method.

Reference cultures specified in the relevant part of AS 5013, need to be included when performing an alternate method as specified in the relevant part of AS 5013, even after equivalence of the alternate method has been determined according to this Standard.

A minimum of 20 isolates of the target organism and 30 isolates of negative control organisms are to be tested by the alternate method and the Australian Standard method. The number of positive results is recorded and analysis performed. An equivalent number of negative control organisms are also tested. If the particular test requires a purification and/or isolation step, then it is essential that this be included in the study design.

It is not intended that this Standard be applied retrospectively to existing laboratory validation studies, nor that it replace the validation of methods performed under the auspices of organizations such as, but not limited to the Association of Official Analytical Chemists International (AOAC-International) and Association Française de Normalisation (AFNOR); or those methods validated according to ISO 16140:2003, *Microbiology of food and animal feeding stuffs—Protocol for the validation of alternative methods*.

This Standard for the determination of equivalence is intended for individual laboratories wishing to demonstrate performance of procedures that are alternatives to Australian Standard methods. It allows an equivalence determination to be performed in a single laboratory. The result of following the procedures in this Standard is the production of a report which will in some specific situations allow a laboratory and its clients to determine or agree on whether an alternative method is suitable as a substitute for a Standard method.

STANDARDS AUSTRALIA

Australian Standard

Guide to determining the equivalence of food microbiology test methods

Part 3: Confirmation tests

1 SCOPE

This Standard sets out a protocol that may be used to determine whether an alternate method will yield a result equivalent to an Australian Standard, food microbiology method (AS 5013 series), for confirmation tests using a pure culture.

As this Standard deals with pure cultures, the matrix will have no bearing on the validation of a particular test kit.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS
5013 Food microbiology (series)

3 DEFINITIONS

For the purpose of this Standard the definitions below apply:

3.1 Alternate method

The method for which equivalence is to be determined.

3.2 Equivalent

A determination according to this Standard, that two methods (the reference and alternate methods) give results that are not statistically different when confirming cultures.

3.3 False negative

When the alternate method yields a negative result the reference method yields a positive result.

3.4 False positive

When the alternate method yields a positive result but the reference method yields a negative result.

NOTE: A 'false positive' may be a true positive which was not detected by the reference method. Such occurrences need to be carefully verified. For the purpose of this Standard they will be considered false positives because the guide is aimed at demonstrating the equivalence of the two methods.

3.5 Reference method

The Australian Standard method against which the alternate method will be compared.

3.6 Target organism

The genus, species, antigenically, toxicologically or physiologically defined group of organisms which the reference method is designed to detect.