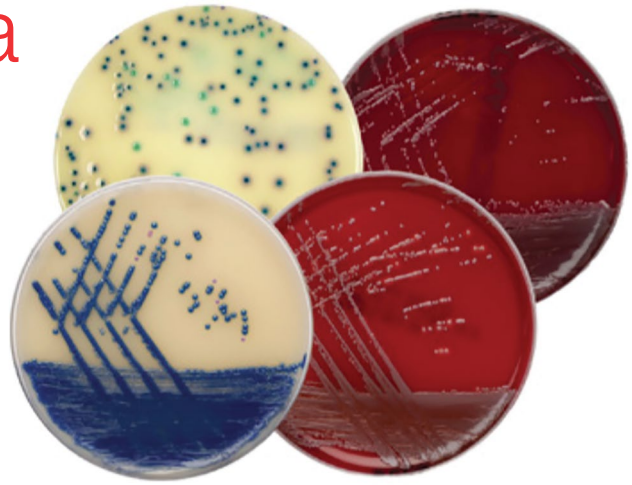
Overview Thermo Scientific Microbiological Media



The following provides general information regarding packaging, precautions, product storage and deterioration, specimen collection, transport, quality control performance, certificates of analysis, chemical hazards and safety data sheets, limitations and references. Product specifications for prepared media are also available by product code from our website www.thermofisher.com. Each product specification contains information relating to the formulation, physical characteristics and performance testing.

The packing slip delivery note, included or outside of the shipping box with every delivery of Thermo Scientific™ Oxoid™ prepared media, contains the lot number and expiration date of each product received. By retaining the delivery note, a laboratory meets guidelines for documentation of lot specific quality control of commercially prepared media. It is the responsibility of the laboratory to ensure that the products are delivered by the receiving department in a timely manner. Upon receipt in the laboratory, the technologist should visually inspect all media for damage, contamination, appearance and evidence of freezing, overheating, or other signs of deterioration. Media should continue to be monitored by the laboratory technologist and any deficiency documented. Thermo Fisher Scientific Technical Support should be notified of deficiencies so the appropriate action can be taken. In order to accurately document a deficiency, the lot number, time stamp (which is found directly after the expiration date on most plates), and expiration date of the product must be provided, as well as other information that may be requested regarding the nature of the observation.

Quality control procedures are continually updated to reflect current guidelines.

General information

Providing great service and quality are our objectives and we firmly believe every laboratory is entitled to these basic commitments from a supplier. We will endeavour to fulfil these commitments to the best of our ability, for any laboratory we are privileged to serve.

Our portfolio of products includes prepared and dehydrated media, including chromogenic media, blood culture systems, stains, reagents, identification and antimicrobial susceptibility test discs, organism identification systems, quality control organisms, animal blood products, collection and transport systems, diagnostic test kits and other related products.

Our products undergo stringent quality assurance testing, including pre-testing of raw materials, performance testing of finished goods and microbial load analysis. Performance testing of the final product complies with or exceeds relevant standards. We also hold an ISO Certificate of Registration for Quality Management System compliance with the requirements of ISO 13485:2016.

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Instructions for use

Each prepared medium formulation IFU contains information regarding intended use, principle, classical formulation, media preparation (if applicable), test procedures and interpretation, quality control and references for each product. IFUs are designed to provide a general description of the product as commonly used. Appropriate references should be consulted for detailed information regarding testing methodologies.[5-19]

IFU's can be requested via the Technical Support= team: microbiology.techsupport.uk@thermofisher.com. Our experienced microbiologists can provide you with prompt and reliable responses to your inquiries regarding appropriate product selection, test performance, expected results and quality control.

Reagents (classical formula)

The formulae used for prepared media are based on classical formulations and may be adjusted as required to meet performance standards.

Packaging

Consult the catalogue for a list of available products. Refer to the legend below for an explanation of symbols used on product labels.

Symbol legend

Symbol	Name
REF	Catalogue Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions For Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

Precautions

Prepared media products are labeled "For In Vitro Diagnostic Use Only" or "For Laboratory Use" only. Each product should be used by properly trained individuals. Appropriate safety precautions should be observed and followed for isolation of causative agents of disease. This process may require special hazard labels and containers, protective clothing and timely transport.

The identification of pathogenic microorganisms may require the use of safety equipment such as biological safety cabinets, splash-proof containers and appropriate disinfectants.[3] Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers and media in approved biohazard bags after use. Standards for disposal may vary per institution protocol and state, county or city regulations.

Storage

Store plated media products inside their original packaging (nylon wrap) at the temperature indicated on the product label. To prevent dehydration, the product should not be stored in close proximity to a fan, or for prolonged periods under a laminar flow hood or in a biological safety cabinet. Do not freeze or overheat the product unless specifically indicated on the package label or IFU. Media should be protected from light.

Tubed and bottled media products should be stored inside the product packaging at the temperature indicated on the package label.

An established stability program is in place to ensure performance claims are supported through assigned expiration dates for our products. The results of stability studies indicate the medium continues to meet the designated performance specifications when inoculated up to and including the labelled date of expiration and incubated for recommended incubation times as referenced in the individual product IFU.

Products should be used prior to the expiration date indicated on the package label. Any reagent requiring reconstitution should be used by the expiration date indicated in the IFU or the expiration date on the package, whichever comes first. The expiration date applies to a product in an unopened container, stored as directed.

Allow products to equilibrate to room temperature prior to use. Plated media stored at room temperature for daily use must be stored inside the nylon film away from light, not under a laminar flow hood and not for extended periods of time.

The majority of prepared media products currently follow the expiration date format Year-Month-Day. The expiration

dates should be interpreted as expiration on the last day of the designated month.

To ensure maximum performance and recovery of microorganisms after inoculation, optimal environmental conditions must be maintained. Aerobic incubation of product must occur under conditions appropriate to the medium, away from fans and at the proper temperature and humidity.

Product deterioration

Do not use a product if: (a) there is evidence of dehydration; (b) the product is contaminated; (c) the appearance has changed; (d) the expiration date has passed; (e) there are other signs of deterioration.

Specimen collection, storage, and transport

Specimens should be collected in suitable containers, transported to the laboratory without delay and protected from excessive heat or cold. If there is any delay in processing a specimen, it should be maintained in a suitable transport medium at the appropriate temperature. Consult appropriate references for recommended guidelines regarding proper specimen collection and transportation.[5-7] Certain specimens require special transport, processing and safety precautions. Refer to the product IFU and current microbiology reference manuals for proper procedures to follow for successful recovery of specific pathogens.

Quality control performance

All lot numbers of prepared media have been tested using quality control organisms derived from ATCC® and other culture collections strains that have been found to be acceptable. These quality control organisms are listed on each product specification and IFU. Additional quality control organisms are often used to further validate the performance of a specific medium.

Control organisms should be tested in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, sample results should not be reported until the discrepancy is resolved. Microorganisms used in quality control procedures should be pure and well-isolated. These organisms may be used to test for growth or selective performance of a medium. Refer to appropriate standards or procedure for detailed instruction pertaining to source, handling and storage of quality control organisms.

Materials required but not supplied

- Inoculating loops, swabs collection containers
- Disposable sterile loops
- Incubators, alternative environmental systems
- Supplemental media
- Quality control organisms
- Centrifuge
- Microscope, slides, cover slips, immersion oil
- Biological safety cabinet, safety equipment
- Gloves, personal protective equipment
- Pipettes and pipetting device
- Culture transfer spade, teasing needle
- Disinfectant(s)
- Autoclave, biohazard bags, sharps disposal
- Shrink seals, gas permeable and impermeable bags

Microbiology methods

The quality control of culture media is based on the methods detailed in ISO 11133:2014. Other international, national standards or in-house methods may be followed as appropriate for the medium.

Each test is controlled using a non-selective control medium (reference medium) either Tryptone Soya Agar or Sabouraud Dextrose Agar. Other culture media may be used for specific products as required for example Legionella BCYE agar when testing media used for the isolation of *Legionella* species. The control media allow assessment of the inoculum. The inoculum must be within specification and these counts are used to calculate productivity and/or selectivity of the test medium. The colony counts, i.e. of the test and control media appear on the Quality Certificate which is available from thermofisher.com

As well as testing for growth the media are observed for the appropriate morphology and the correct diagnostic reactions. Any other tests appropriate to the application of the medium are also carried out for example antimicrobial sensitivity testing.

The majority of products are tested using quantitative methods. In general productivity testing is assessed using positive test strains at an inoculum of 10 to 100 or 50 to 120 colony forming units (cfu) and inhibition is tested using negative strains at 10^4 to 10^6 cfu.

Selectivity i.e. log reduction is tested using negative strains at 10^3 to 10^4 cfu. Selectivity is used for those media where a reduction in growth, but not complete inhibition, is expected from high inocula. This follows the principles in ISO 11133:2014. Inoculation is carried out using an automated spiral plater. This ensures that inoculation is consistent across our laboratories and removes variation which could be caused by the technician. This automated inoculation system is used by all Thermo Scientific European prepared media production sites.

Productivity

Solid media

Defined test organisms from international culture collections for example. ATCC® and NCTC, are inoculated onto test and standard solid culture media (plates). The inoculum level is in accordance with the specification. Inoculation is carried out using a spiral plater.

A specific non-selective control or reference medium (Nc) is inoculated and compared with the performance of the test medium (Nt).

The productivity ratio (PR) is determined as follows:

PR = x 100
Where:
Nt = Test medium colony count (cfu)
Nc = Control medium colony count (cfu)

The productivity ratio for a non-selective medium is at least 70% for positive strains when compared to the control/ reference medium. The growth recovery for a selective medium varies and depends upon the product. This will be in accordance with the specification.

Liquid Media

Defined test organisms from international culture collections, for example ATCC and NCTC are inoculated into the test and standard liquid culture media. The inoculum level is in accordance with the specification.

Growth after incubation is recorded as graded turbidity (+/++/+++) against a turbidity standard.

Certain media (selective enrichment media) may also be sub-cultured onto solid media to allow assessment of the colony count, i.e. the number of cfu/ml after incubation. This is recorded as a log increase, i.e. the increase in cfu/ml in the test medium after incubation when compared to the original inoculum.

In the example below there is a 5 log increase in the number of cfu/ml in the test medium i.e. the increase in cfu/ml after incubation.

5E + 06/ml	-	4E + 01/ml = 5 log increase
(Colony count/ml in the test medium after incubation)		(Colony count/ml when inoculated assessed using the control medium)

Note: for the purposes of the certificate of analysis exponential counts are expressed as follows: 1E + 04 = 1 x10^4 or 10000. Exponential notation or E notation is used as superscripted exponents such as 10^4 cannot always be conveniently displayed by calculators and computers.

Selectivity is assessed as either complete inhibition against a high inoculum, i.e. 1E + 04 to 1E + 06 (10^4 to 10^6) cfu or as partial inhibition i.e. log reduction against specified inoculum 1E + 03 to 1E + 04 (10^3 to 10^4) cfu. In each case the inoculum is assessed using either a McFarland turbidity standard (high inocula) or by using a control medium. The test, standard and non-selective control media are inoculated with a specified inoculum using a spiral plater. Additional dilutions may be inoculated onto the control medium to allow a colony count to be performed and the inoculum level to be assessed.

Complete inhibition is recorded as no growth/ inhibition from an inoculum of 1E + 04 to 1E + 06 (10^4 to 10^6) cfu.

Partial Inhibition is recorded as a log reduction. The colony count on the test medium is assessed and compared to the original inoculum i.e. the colony count on the control/ reference medium.

In this example there is a 2 log reduction in the number of cfu/ml in the test medium i.e. the reduction in the number of cfu/ml after incubation.

5E + 04 cfu	-	2E + 02 = 2 log reduction
(Control medium cfu)		(Test medium cfu)

Colony morphology and diagnostic reactions are also recorded.

Liquid Media

Selectivity is assessed as either complete inhibition against a high inoculum, i.e. 1E + 04 to 1E + 06 (10^4 to 10^6) cfu or as partial inhibition, i.e. log reduction against specified inoculum 1E + 03 to 1E + 04 (10^3 to 10^4) cfu.

In each case the inoculum is assessed using either a McFarland turbidity standard (high inocula) or assessing the inoculum using a control medium.

The test liquid medium is inoculated with a specified inoculum; this is also inoculated onto a solid control medium using a spiral plater. Additional dilutions may be inoculated onto the control medium to allow a colony count to be performed and the inoculum level to be assessed.

Complete inhibition is recorded as no growth/ inhibition i.e. no turbidity, from an inoculum of 1E + 04 to 1E + 06 (10^4 to 10^6) cfu.

Partial inhibition is recorded as a log reduction. The test liquid medium is sub-cultured onto a non-selective solid medium after incubation and a colony count is performed. This is then calculated as cfu/ml of the test medium when inoculated and after incubation. The log reduction calculation is then performed with reference to the original inoculum as determined on the control medium.

In the example below there is a 2 log reduction in the number of cfu/ml in the test medium i.e. the reduction in the number of cfu/ml after incubation.

5E + 04 cfu	-	2E + 02 /ml = 2 log reduction
(Inoculum cfu/ml)		(cfu/ml after incubation i.e. on subculture)

Biochemical performance

1. Follow instructions listed on the product IFU or established laboratory procedures.
2. Always use a fresh, pure subculture of the test organism.
3. Inoculate the surface of the medium by stabbing, streaking and/or agitating the inoculum in or on the medium.
4. Incubate in the appropriate atmosphere, with applicable incubation duration.
5. Observe medium for desired biochemical reaction.
6. Specific instructions for mycology and mycobacteriology biochemical performance may apply. Consult established laboratory procedures or appropriate reference manuals for further instruction.

Quality control organisms used to validate growth, selectivity and biochemical reactions for certain fungal and mycobacteriology media should be derived from an actively growing culture. These organisms either require direct inoculation to the medium being tested or a dilution equal to 0.5 or 1.0 McFarland turbidity standard or equivalent, prepared in sterile water, saline or appropriate medium with subsequent transfer of the medium being tested. Some exceptions may apply. The product IFU and appropriate reference manuals should be consulted for guidance in selecting organisms to use as quality control organisms.

Certificates of analysis

Certificates of analysis certify that specific lot numbers of products have met all performance and quality criteria for the product. For the purpose of quality assurance documentation, Certificates of Analysis are available from the website at www.thermofisher.com.

Chemical hazards and Safety Data Sheets

Products ordered from Thermo Fisher Scientific are intended for use by qualified laboratory professionals who are trained in appropriate laboratory procedures and aware of potential hazards. Safety Data Sheets (SDS) are prepared in accordance with the OSHA.

Hazard Communications Standard and are available for specified products upon request and from the website at www.thermofisher.com. SDS not found on the website may be obtained by contacting Technical Support.

Limitations

1. The use of prepared and dehydrated culture media is only part of the overall scheme for identification of microorganisms. Variations in results may occasionally be observed.
2. Slight to moderate colour variations of broth media may occur and do not affect performance.
3. While every process is established to minimize the potential, nonviable organisms may be seen when Gram staining some broth culture media resulting from their presence in various media components.
4. A pure culture of the organism is recommended for biochemical, serological and other confirmatory tests for identification of the organism. Organisms vary in their requirements for temperature, humidity and atmospheric conditions. Optimal environmental conditions must be determined and followed for each organism being tested. Consult appropriate references for further information.[5-19]
5. A single medium is rarely adequate for detecting all organisms of potential significance in a specimen due to the degree of selectivity or non-selectivity of the medium. A specimen grown on a selective medium should be compared with a culture of the same specimen grown on a nonselective medium to obtain additional information about potential pathogens.
6. The agents in a selective medium may inhibit some strains of the desired species or permit growth of a species they were designed to inhibit, especially if present in large numbers in the specimen, or resistant to the selective agent (e.g. antibiotic, dye, alcohol).

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