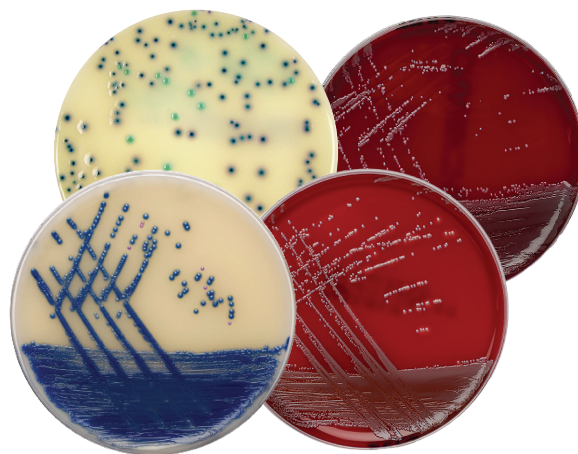


Foreword to the Technical Manual of Microbiological Media

The following provides general information regarding packaging, precautions, product storage and deterioration, specimen collection, storage and transport, quality control performance, certificates of quality, chemical hazards and safety data sheets, limitations and references. Product-specific Instructions For Use (IFU) for prepared media are also available by product code from our website www.thermofisher.com. Each IFU contains information relating to specific media use and product quality control and should be used in conjunction with this general information.

The Clinical and Laboratory Standards Institute (CLSI) has developed a standard for quality control testing of prepared cultured media¹. The CLSI M22 Approved Standard developed for quality control testing of prepared culture media lists certain prepared media as exempt meaning they did not need to be retested by the user. This exemption no longer applies. The Individualized Quality Control Plan (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) procedure which provides guidance and concepts for IQCP, and the formal representation and compilation of activities laboratories currently perform to ensure quality test results. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

For compliance, a Risk Assessment and Quality Assessment for exempt media would need to be conducted and instructions provided in a detailed Standard Operating Procedure (SOP). There is no specified way in which the laboratory must organize the risk assessment information for IQCP. For media, some laboratories have chosen to create a single IQCP that addresses all media used, while others might develop individual ones for each media type. More information on IQCP and developing procedures for the Microbiology Lab can be found at www.thermofisher.com/microiqcp.



The recommendations in CLSI Standard M22 apply to the following types of media: bacteriological, fungal and mycobacterial. These recommendations do not apply to media used for the isolation of parasites, viruses, mycoplasmas and chlamydiae. In regard to media specifically used for antimicrobial susceptibility testing, CLSI states that such media “have different quality control recommendations that are detailed in separate CLSI documents.”

The packing slip, included with every delivery of prepared media, contains the lot number and expiration date of each product received. By retaining the packing slip, a laboratory meets the CLSI guidelines for documentation of lot specific quality control of commercially prepared media. Two packing slips are included with each shipment, one for receiving and one for the laboratory. 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 breakage, contamination, proper appearance and evidence of freezing or overheating, or other signs

of deterioration following the protocol outlined in CLSI Standard M22. A space is provided on the packing slip for documenting this inspection. Media should continue to be monitored by the laboratory technologist and any deficiency documented. Thermo Fisher Scientific Technical Service 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 the most current CLSI guidelines. As new products are added to the catalog, IFUs will be prepared with usage and quality control information.

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 endeavor to fulfill these commitments to the best of our ability, for any laboratory we are privileged to serve.

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

We adhere to the current Quality Control System Regulations for Medical Devices. CFR title 21, part 820 and are routinely inspected by the United States Food and Drug Administration (FDA) for compliance.² 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 standards established by the Clinical Laboratory and Standards Institute (CLSI) or the United States Pharmacopoeia (USP) as applicable. We also hold an ISO Certificate of Registration for Quality Management System compliance with the requirements of ISO 13485:2016.

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

IFUs can be downloaded from www.thermofisher.com by entering the product order code into the search window of the homepage to navigate to the relevant product page. The IFU is located in the Resources section towards the bottom of the page. Alternatively, technical support is available by contacting our Technical Service Department at (800) 255-6730. Our experienced staff of 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

Media products are available in a variety of sizes, volumes and package configurations. Consult the catalog 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	Catalog 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 certain 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 (cellophane bag and box) at the appropriate temperature indicated on the product label. In order to prevent dehydration, 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 labeled 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 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. Media products stored at room temperature for daily use must be stored inside the cellophane bag, away from UV 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 expressed as YYYY-MM-DD (e.g. 2020-03-11). For those products that still carry Month-Day-Year or Year-Month formats, the expiration dates should be interpreted as expiration on the last day of the designated month.

To ensure maximum performance and recovery after inoculation, optimal environmental conditions must be followed. Aerobic incubation of product must occur under conditions appropriate to the medium, away from fans and at the proper temperature and humidity. Incubator humidity should be maintained at 70-80% and monitored on a regular basis.⁴

Product deterioration

Do not use a product if: (a) there is evidence of dehydration; (b) the product is contaminated; (c) the color 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® strains and have been found to be acceptable. These quality control organisms are listed on each IFU and strains specified in the current CLSI Standard M22 are specifically noted. 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, patient or 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 CLSI Standard M22 or other 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
- Loop sterilizing device
- 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
- Splash-proof containers, alcohol-sand flask
- Culture transfer spade, teasing needle
- Disinfectant(s)
- Autoclave, biohazard bags, sharps disposal
- Shrink seals, gas permeable and impermeable bags

Preparation of inoculum

Suspensions of control organisms should be prepared in accordance with established laboratory quality control procedures. The following instructions are consistent with the recommendations in the CLSI M22 Standard.

Preparation of cell suspension

1. Use a pure, 18-24 hour culture of the organism, suspended in sterile, non-bacteriostatic saline (0.85% w/v NaCl) and equal in density to a 0.5 McFarland standard (1×10^7 to 1×10^8 cfu/mL).
2. Alternatively, prepare a suspension by inoculating 3 to 5 colonies from an 18-24 hour culture into sterile broth. Incubate the broth for several hours until a suspension equivalent to a 0.5 McFarland standard is achieved.

Direct inoculation of media

Care must be exercised if using direct inoculation because an inoculum that is either too heavy or too light may conceal growth and/or inhibitory properties of the medium. In the event of a quality control failure using direct inoculation, repeat the testing with a standardized suspension of the organism.

Nonselective media growth performance

Plated media:

1. Dilute the cell suspension 1:100 in sterile broth or non-bacteriostatic saline.
2. Inoculate the test medium with 10 μ L of the diluted suspension using a calibrated loop or pipette. Streak the plate for isolation.
3. Incubate under conditions appropriate to the medium with the applicable incubation duration.
4. If the 1:100 dilution inoculum proves too dense, repeat using a 1:1000 dilution to produce isolated colonies.

Tube media:

1. Inoculate with 10 μ L of the undiluted 0.5 McFarland suspension.
2. Incubate under conditions appropriate to the medium with the applicable incubation duration.

Selective media growth performance

Plated media:

1. Dilute the cell suspension 1:10 in sterile broth or non-bacteriostatic saline.
2. Inoculate the test medium with 10 µL of the diluted suspension using a calibrated loop or pipette. Streak the plate for isolation.
3. Incubate under conditions appropriate to the medium with the applicable incubation duration.
4. If the 1:10 dilution inoculum proves too dense, repeat using a 1:100 dilution to produce isolated colonies.

Tube media:

1. Inoculate with 10 µL of the undiluted 0.5 McFarland suspension.
2. Incubate under conditions appropriate to the medium with the applicable incubation duration.

Interpretation of results

Nonselective media: Performance is satisfactory if the quality control organism exhibits adequate growth, expected colony size and typical colony morphology.

Selective media: Performance is satisfactory if the medium exhibits little or no growth of organisms susceptible to the inhibitory agents and growth of expected organisms with typical colony size and morphology.

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 quality

Certificates of quality 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 Quality 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 at (800) 255-6730.

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 color 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 media may inhibit some strains of the desired species or permit growth of a species they were designed to inhibit, especially if the species are present in large numbers in the specimen, or resistant to the selective agent (e.g. antibiotic, dye, alcohol).

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