AG – MUELLER HINTON AGAR - INSTRUCTIONS FOR USE

(Ready Plated Media)

INTENDED USE:

In vitro diagnostic. Culture medium for Antimicrobial Susceptibility Testing (AST) by disk diffusion method of common, aerobic, rapidly growing bacteria.

• PRINCIPLE:

Mueller Hinton Agar : P.aeruginosa ATCC 27853, ABST against 6 antibiotics

Mueller Hinton agar is considered the best medium to use for Antimicrobial Susceptibility Testing and is recommended by both CLSI and EUCAST. It is suitable and standardized by EUCAST for testing the more common rapidly growing bacteria: *Enterobacteriaceae*, *Pseudomonas* spp., *Stenotrophomonas maltophilia*, *Acinetobacter* spp., *Staphylococcus* spp., *Enterococcus* spp., *Aeromonas*, *Burkolderia pseudomallei*.

MATERIALS PROVIDED:

PRODUCT	TYPE	REF	PACK
AG – Mueller Hinton Agar Plates	Ready Plated Media	AG/MHA/22/01	10 plates in a pack

• MATERIALS REQUIRED BUT NOT PROVIDED:

Sterile loops, incubator, and laboratory equipment as required.

• SPECIMENS:

AST by disk diffusion method is designed to use with pure culture of strains isolated from clinical specimens.
A Gram stain and a preliminary bacterial identification are required for choosing the appropriate antimicrobial agents to be tested. EUCAST has published a method for rapid AST (reading at 4, 6 or 8h incubation) directly from positive blood culture bottles, validated for selected organisms; consult the EUCAST document for the test procedure, reading and interpretation of inhibition zones.

• TEST PROCEDURE, READING AND INTERPRETATION:

The test procedure and the reading and interpretation of inhibition zones here described are a summary of EUCAST documents.

- The surface of the agar should be dry before use. No drops of water should be visible on surface of agar or inside the lid.
- Use a sterile loop or a cotton swab to pick colonies from an overnight culture on non-selective media. Adjust the density of the organism suspension to 0.5 McFarland by adding saline or more bacteria. The suspension must always be used within 60 min of preparation.
- Dip a sterile cotton swab into the suspension, remove excess fluid by pressing, turning the swab against the side of the tube.
- Spread the inoculum evenly over the entire agar surface ensuring that there are no gaps between streaks.
- Allow disks to reach room temperature before opening cartridges or containers used for disk storage.
- Apply disks firmly to the surface of the inoculated agar plate within 15 minutes of inoculation. Disks must be in close and even contact with the agar surface and must not be moved once they have been applied as the initial diffusion of antimicrobial agents from disks is very rapid.
- The number of disks on a plate should be limited to avoid overlapping of zones and interference between agents.

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- Invert agar plates and make sure disks do not fall off the agar surface. Incubate plates within 15 min of disk application. If the plates are left at room temperature after disks have been applied, pre-diffusion may result in erroneously large zones of inhibition.
- Incubate at 35 ± 1°C in air for 18 ± 2 h (24 h for glycopeptides and *Enterococcus*).
- Check that inhibition zones for quality control strains are within acceptable ranges.

• USER QUALITY CONTROL:

All manufactured lots of the product are released for sale after Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Please refer certificate of analysis for quality control strains.

• LIMITATIONS OF THE METHOD:

- Incorrect inoculum concentration, improper storage of antimicrobial disks, improper storage of the plates resulting in an agar depth and pH out of specifications, excessive moisture, improper measurement of endpoints, may produce incorrect results. Therefore, strict adherence to protocol is required to ensure reliable results.
- Bacteria requiring thymine/thymidine may not grow satisfactorily on Mueller Hinton Agar.
- Mueller Hinton Agar is not appropriate for assay by disk-diffusion method with slow growing organisms, anaerobes and capnophiles.
- Consult the EUCAST and/or CLSI papers for the details of disk diffusion methodology, reading and interpretations of inhibition zones, warnings, guidance documents in susceptibility testing, guidelines for detection of resistance mechanisms, clinical breakpoints.
- Mueller Hinton Agar can be used for the determination of Minimum Inhibiting Concentrations (MICs) with strips containing antimicrobial gradients. To perform this method, it is required to follow the instructions for use of the supplier of strips and to validate the work procedure in the laboratory.
- This culture medium is intended as an aid in the treatment of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

• PRECAUTIONS AND WARNINGS:

- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose of the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available with AstraGene and can be provided on request.

• STORAGE CONDITIONS AND SHELF LIFE:

- Upon receipt, store at +2 - 8°C away from direct light in a cool, dry place. Storage below 2°C may lead to crystallization of media components due to near freezing temperature. The user is responsible for the storage method of the medium.
- For optimal usage, it is advisable to utilize the entire pack of 10 plates once they have been taken out of the packaging
- If properly stored, the product may be used up to the expiration date. Do not use it beyond the mentioned expiry date.

• SYMBOLS:

	Date of manufacture		Use-by-date		Do not use if package is damaged		Manufacturer
LOT	Batch Code		Refer to the instructions	ISO 13485:2016	ISO	GMP	GMP
IVD	*In-Vitro* diagnostic Medical devices	CE	Mark of conformity				

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