AG – Tryptic Soy Agar (TSA) - INSTRUCTIONS FOR USE

(Ready Plated Media)

- **INTENDED USE:**

Tryptic Soy Agar (TSA) is a versatile medium for cultivating non-fastidious and moderately fastidious microorganisms, used in microbial enumeration of non-sterile pharmaceuticals and cosmetics. Supplemented with defibrinated animal blood, it supports fastidious microorganism growth and hemolysis testing in clinical specimens. Specified in EP, USP, JP, and ISO 21149 for microbial enumeration and detecting aerobic mesophilic bacteria.

- **PRINCIPLE:**

Tryptic soya Agar: *Staphylococcus aureus*

- Versatility: Widely used in clinical and industrial microbiology for isolation, cultivation, and purification of non-fastidious and moderately fastidious microorganisms.
- Stock Culture Maintenance: Suitable for maintaining bacterial stock cultures.
- Identification of Haemophilus sp.: Can identify Haemophilus by adding X (Hemin) and V (NAD) factor discs or strips.
- Reference Medium: Recommended as a reference to test the inhibition of selective media.
- Pharmaceutical and Cosmetic Testing: Specified in EP, USP, JP, and ISO 21149 for microbial enumeration and detecting aerobic mesophilic bacteria.
- Enhanced Growth: Supplementation with animal blood supports fastidious organism growth and hemolysis testing.
- Disinfectant Testing: Supplementation with lecithin and Polysorbate 80 neutralizes disinfectants, enabling sanitization efficacy testing.
- Halotolerance Testing: Addition of salt aids in determining microbial halotolerance.
- Nutritious Composition: Casein and soy peptones provide essential nutrients; sodium chloride ensures osmotic balance."

- **MATERIALS PROVIDED:**

PRODUCT	TYPE	REF	PACK
AG – TSA Agar - 90mm	Ready Plated Media	AG/TSA/22/01	10 plates in a pack

- **MATERIALS REQUIRED BUT NOT PROVIDED:**

Sterile loops, incubator, Autoclave and laboratory equipment as required.

- **SPECIMENS:**

- Unsupplemented TSA should not be used for direct inoculation of clinical samples.
- TSA is typically used for subculturing microorganisms grown on other media.
- It is also used for testing non-sterile items like pharmaceuticals and cosmetics.
- When supplemented with animal blood, TSA can be used to directly inoculate clinical samples from both sterile and non-sterile human sites.
- Always refer to the provided literature for proper specimen collection and infection-related details.
- It's best to collect samples before starting antimicrobial treatment and follow good practices for handling, transport, and storage.

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- **TEST PROCEDURE, READING AND INTERPRETATION:**
  - Allow plates to reach room temperature.
  - Ensure the TSA agar surface is smooth and moist but not excessively wet.
  - For loop inoculation: Streak the specimen across four quadrants of the plate to achieve isolated colonies, avoiding overlap between sections 1 and 4.
  - For swab inoculation: Roll the swab over a small edge area of the plate, then streak from this inoculated area using a loop.
  - Incubate plates aerobically at 35–37°C.
  - Record results after 18–24 hours. If no typical colonies are observed, re-incubate for an additional 24–36 hours (up to 72 hours total).
  - Observe and document colony morphology and color.

- **USER QUALITY CONTROL:**
  - Pale yellow, limpid/ Firm Gel.

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. Here below are listed some test strains useful for quality control.

CONTROL STRAINS	INCUBATION	EXPECTED RESULTS
Candida albicans ATCC14053	35 ± 2˚C, 24-48 hrs	Good Growth
Pseudomonas aeruginosa ATCC 9027	35 ± 2˚C, 18-24 hrs	Good Growth
Staphylococcus aureus ATCC 25923	35 ± 2˚C, 18-24 hrs	Good Growth
Escherichia coli ATCC 25922	35 ± 2˚C, 18-24 hrs	Good Growth

Key: ATCC is a trademark of American Type Culture Collection

- **LIMITATIONS OF THE METHOD:**

• As it is general purpose medium, it requires additional selective media (e.g., Chocolate Agar) for comprehensive testing of clinical specimens.

• Complete identification requires further biochemical, immunological, molecular, or spectrometry testing.

- **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. The user is responsible for the storage method (temperature) of the medium.
  - If properly stored, the product may be used up to the expiration date. Do not use it beyond the mentioned expired 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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