INSTRUCTIONS FOR USE

TRYPTIC SOY AGAR

Ready-to-use tubes

Tryptic Soy Agar
From the left: uninoculated tube and *S.aureus*

1 - INTENDED USE

In vitro diagnostic device. General purpose medium for the cultivation and maintenance of non-fastidious and moderately fastidious microorganisms from clinical and non-clinical specimens.

2 - COMPOSITION -TYPICAL FORMULA *

Pancreatic digest of casein	15.0 g
Soy peptone	5.0 g
Sodium chloride	5.0 g
Dipotassium hydrogen phosphate	2.5 g
Glucose	2.5 g
Agar	15.0 g
Purified water	1000 mL

*the formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Tryptic Soy Agar (TSA) is one of the most widely used culture media in clinical and industrial microbiology. TSA has a multitude of uses in clinical and non-clinical laboratories including isolation, cultivation and purification of colonies of non-fastidious and moderately fastidious microorganisms and maintenance of stock cultures.[1] Tryptic Soy Agar is the medium specified as “casein soya bean digest agar” in the harmonised EP, USP, JP method.[2] Tryptic Soy Agar slant is used for the cultivation and maintenance of microbial strains.
TSA is prepared with selected casein and soy peptones: the combination of casein and soy peptones renders the medium nutritious by supplying organic nitrogen in the form of amino acids and polypeptides. Sodium chloride maintains the osmotic balance. Agar is the solidifying agent.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	pale yellow, limpid
Final pH at 20-25°C	7.3 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Tryptic Soy Agar	Ready-to-use tubes	552150	20 glass tubes with slanted medium, 17x125 mm, flat bottom, aluminium screw-cap. Packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Sterile loops, needles and swabs, incubator and laboratory equipment as required, ancillary culture media and reagents for the identification of the colonies.

7 - SPECIMENS

In clinical and non-clinical microbiology, the specimens consist of microbial colonies grown on other culture media. Tryptic Soy Agar slants should not be used for the direct inoculation of clinical specimens.

8 - TEST PROCEDURE

Allow tubes to come to room temperature.
For the subculture of colonies, by means of a sterile needle or loop, inoculate a TSA slant with a colony cultivated on another isolation medium. Usually, an incubation temperature of 35 ± 2°C for 18-24 hours is adequate for cultivation of common aerobes and facultative anaerobes.
The user is responsible for choosing the appropriate incubation time, temperature and atmosphere depending on the inoculated organism and the local applicable protocols.

9 - READING AND INTERPRETATION

After incubation, the presence of microorganisms is indicated by the appearance of colonies of various morphology and size on the medium surface. The characteristics of the growth are closely related to the type or types of cultivated microorganisms.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the 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 the quality control of un-supplemented medium.

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CONTROL STRAINS		INCUBATION T°/ t / ATM	EXPECTED RESULTS
S.aureus	ATCC 25923	35-37°C / 18-24H / A	good growth
E.coli	ATCC 25922	35-37°C / 18-24H / A	good growth

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready to use tubes of Tryptic Soy Agar and of the raw material used for the production of prepared tubes, dehydrated Tryptic Soy Agar, (Test Batch: TB), are tested for productivity by comparing the results with a previously approved Reference Batch (RB).
Productivity is tested by a quantitative test with the following strains: *P.aeruginosa* ATCC 9027, *E.coli* ATCC 8739, *B.cereus* ATCC 11778, *B.subtilis* ATCC 6633, *S.aureus* ATCC 6538, *S.aureus* ATCC 25923, *L.monocytogenes* ATCC 13932, *C.albicans* ATCC 10231, *A.brasiliensis* ATCC 16404. Tryptic Soy Agar is inoculated with decimal dilutions in saline of the colonies' suspensions and incubated at 30-35°C for 24-72 hours. The colonies are enumerated on both batches and the productivity ratio ($Pr = CFU_{TB}/CFU_{RB}$) is calculated. If *Pr* is ≥ 0,7 and if the colonies' morphology is typical, the results are considered acceptable and conform to the specifications.
Productivity is also tested by streaking the slanted surface of the medium with suitable decimal dilutions in saline of the following strains: *P.aeruginosa* ATCC 9027, *E.coli* ATCC 8739, *B.subtilis* ATCC 6633, *S.aureus* ATCC 6538, *C.albicans* ATCC 10231, *A.brasiliensis* ATCC 16404. After incubation at 30-35 °C for 24-72 hours all strains show a good growth.

12 - LIMITATIONS OF THE METHOD

- Tryptic Soy Agar slant is not suitable for the cultivation of fastidious microorganisms (e.g. *Haemophilus* or *Neisseria* spp.) and for the cultivation of strict anaerobes.
- It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed for complete identification of the cultivated colonies. If relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnostic procedures 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.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that these products do not contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use tubes be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Be careful when opening screw cap tubes to prevent injury due to breakage of glass.
- Each tube is for single use only.
- Ready-to-use tubes of Tryptic Soy Agar are subject to terminal sterilization by autoclaving.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the tubes inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- Notify Biolife Italiana Srl (complaint@biolifeitaliana.it) and the relevant Authorities of any serious incident occurring in connection with the use of the *in vitro* diagnostics.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store tubes in their original pack at 2-8°C away from direct light. If properly stored, the tubes may be used up to the expiration date. Do not use the tubes beyond this date. Tubes from opened secondary packages can be used up to the expiration date. Opened tubes must be used immediately. Before use, check the closing and the integrity of the screw cap. Do not use tubes with signs of deterioration (e.g. microbial contamination, abnormal turbidity, precipitate, drying, atypical colour).

15 – REFERENCES

1. Atlas R. Parks LC. Handbook of Microbiological Media. 2nd edition CRC Press,1997
2. European Pharmacopoeia, current edition
3.

TABLE OF APPLICABLE SYMBOLS

REF or REF — Catalogue number	LOT — Batch code	IVD — *In vitro* Diagnostic Medical Device	Manufacturer	Do not reuse	Recyclable pack; This side up
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Keep away from direct light	Fragile

REVISION HISTORY

Version	Description of changes	Date

Instructions for Use (IFU) - Revision 1	Updated layout and content in compliance with IVDR 2017/746	2021/05
Revision 2	Removal of obsolete classification	2023/04

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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