



## INSTRUCTIONS FOR USE

### TRYPTIC SOY AGAR WITH POLYSORBATE 80 AND LECITHIN (TSA-TL)

#### PRODUCTS

AS-228 Tryptic Soy Agar with Polysorbate 80 and Lecithin (TSA-TL)

1 plate / pkg

#### INTENDED PURPOSE

TruPRAS™ Anaerobic Culture Media is intended for the transport, preservation, or cultivation of a wide variety of microorganisms from specimens to aid in the isolation of bacteria for in vitro diagnostic and / or research / general laboratory purposes.

#### INTENDED USERS

Scientists, laboratory, and healthcare professionals trained in anaerobic microbiology techniques working in areas such as clinical, research, industrial, pharmaceutical and veterinary applications.

#### FORMULATION\*

TSA-TL is an enriched, nonselective medium used for the growth of microorganisms, including yeasts and molds. The nutritive base consists of casein and soy peptones, while sodium chloride maintains osmotic balance. TSA-TL contains neutralizers polysorbate 80 and lecithin, which are commonly used to inactivate residual disinfectants during sample collection. Lecithin neutralizes quaternary ammonium compounds, and polysorbate 80 neutralizes substituted phenolic disinfectants. TSA-TL is suitable for use in environmental air sampling protocols. This medium is prepared, dispensed, and packaged under oxygen-free conditions using TruPRAS™ Technology to prevent the formation of oxidized products prior to use. This product is supplied ready to use, with no pre-reduction step required.

Pancreatic digest of casein	15.00	g
Soy peptone	5.00	g
Sodium chloride	5.00	g
Agar	15.00	g
Polysorbate 80	5.00	mL
Lecithin	0.70	g
DI Water	1.00	L

\*Approximate formula. Adjusted and/or supplemented as required to meet performance criteria.

Final pH: 7.3 ± 0.3 at 25°C

Final weight: 25.0 g ± 2.5 g

#### PRECAUTIONS

For IN VITRO DIAGNOSTIC USE only. Utilize approved biohazard precautions and aseptic technique when using this product. This product is for use by properly trained and qualified personnel only. Sterilize all biohazard waste prior to disposal. This product is manufactured as a single use device.

Report serious incidents that occur in direct relation to this product to [tech@biolog.com](mailto:tech@biolog.com). As necessary, report serious incidents to the regulatory authority in which the user is established.



This product may contain components of animal origin. All components of animal origin have been sourced from Bovine Spongiform Encephalopathy- (BSE-) free and Transmissible Spongiform Encephalopathy- (TSE-) free countries. Certified knowledge of the origin of animal derived components does not guarantee the absence of transmissible pathogenic agents. It is recommended that Universal Precautions be observed.

When working with anaerobic culture media, the potential for ergonomic hazards may exist due to repetitive motions, awkward postures, improper bench/chair heights or poor lighting. Although it is beyond the scope and provision of products by Anaerobe Systems, it should be recognized and mitigated by the end user in the laboratory environment.

## STORAGE AND SHELF LIFE

**Storage:** Upon receipt, store at room temperature (15 – 25°C) in original package until used. Avoid overheating or freezing. Do not use media if there are signs of deterioration (shrinking, cracking, or discoloration due to oxidation of media) or contamination. The expiration date applies to the product in its original packaging and stored as directed. Do not use product past the expiration date shown on the label.

**Shelf Life:** 6 months from the date of manufacture.

## PROCEDURE

**Specimen Collection:** Protect specimens for anaerobic culture from oxygen during collection, transportation, and processing. Consult appropriate references for detailed instructions concerning collection and transportation of anaerobes. The selection of specimens for culture is made by physicians or scientists collecting the sample.

**Methods for Use:** Refer to the most recent editions of relevant reference materials for recommended procedures.

## MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, saline blanks, slides, staining supplies, microscope, incinerator / autoclave, incubators, anaerobic chamber / anaerobic jars, disinfectant, other culture media, and serological / biochemical reagents.

## INTERPRETATION OF RESULTS

TSA-TL supports robust growth of a wide range of microorganisms, including yeasts and molds.

## LIMITATIONS

TSA-TL does not provide complete information for the identification of microorganisms, including yeast and mold isolates. Additional test procedures and media are required for full identification. Additionally, this medium may not support the growth of all clinically significant anaerobes. Consult appropriate reference materials for further guidance.

## QUALITY CONTROL

The following organisms are routinely used for quality control testing at Anaerobe Systems using the specifications outlined in the CLSI document M22-A3: Quality Control for Commercially Prepared Microbiological Culture Media.

Organism Tested	ATCC® #	Results
<i>Saccharomyces cerevisiae</i>	7754	Growth
<i>Candida albicans</i>	11006	Growth
<i>Proteus mirabilis</i>	12453	Growth
<i>Enterococcus faecalis</i>	29212	Growth



Escherichia coli	25922	Growth
Staphylococcus aureus	25923	Growth
Staphylococcus epidermidis	14990	Growth
Bacillus subtilis	6051	Growth
Pseudomonas aeruginosa	27853	Growth

**User Quality Control:** The final determination to the extent and quantity of user laboratory quality control must be determined by the end user.






**Physical Appearance:** TSA-TL should appear opaque light-yellow in color.

ATCC® is a registered trademark of American Type Culture Collection.

## REFERENCES

1. CLSI. *Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard- Third Edition*. CLSI document M22-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.
2. Weber, G.R. and L.A. Black. 1948. Soap and Sanit. Chem. 24:134-155.
3. Brummer BA. Influence of possible disinfectant transfer on *Staphylococcus aureus* plate counts after agar contact sampling. *Appl Environ Microbiol*. 1976;32(1):80-84.
4. The United States Pharmacopeia-National Formulary. 2024. Issue 1. United States Pharmacopeial Convention, Rockville, MD.
5. U.S. Department of Agriculture, Animal and Plant Health Inspection Service. *Animal Health Status of Regions*. Published March 12, 2025. <https://www.aphis.usda.gov/regionalization-evaluation-services/region-health-status>
6. European Commission. *Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3)*. Published March 5, 2011. <https://op.europa.eu/en/publication-detail/-/publication/3392e464-ba89-4ae4-955c-a07f617c8e06/language-en>

## GLOSSARY OF SYMBOLS

SYMBOL	TITLE	DESCRIPTION	STANDARD	REF#
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.1
	Lot number/ Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.4
	Authorized Representative	Indicates the Authorized Representative in the identified country or jurisdiction.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.2
	Do not re-use/ Single use only	Indicates a medical device that is intended for one single use only.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.2



	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.3
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.7
	In vitro diagnostic medical device	Indicates that a medical device is intended to be used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.5.1
	CE Mark European Conformity	Designates that the product labeled is authorized for sale in European countries.	EU IVDR (EU) 2017/746	

**AUTHORIZED REPRESENTATIVE INFORMATION**



**REVISION 2**

Additions: Intended Use, Intended Users, Animal Origin Statement, Ergonomics Precautions, Serious Incident Report Contact Information, Glossary of Symbols

Changes: Title change from Product Insert to Instructions for Use. Room temperature from 20 – 25°C to 15 – 25°C. References updated. Contact information.

Deletions: None