Technical Data Sheet

ReadyPlate™
Tryptic Soy Agar
acc. ISO, FDA-BAM, EP +USP
Ordering number: 1.46431.0020 / 1.46431.0100

ReadyPlate™ TSA is a universal culture media free from inhibitors and indicators for a wide spectrum of applications.

The medium exceeds the test parameters for Reference medium set in EN ISO 11133.

Mode of Action

Tryptic Soy Agar (TSA, Soybean Casein Digest Agar) is a complex medium for cultivation and isolation of a wide range of bacteria, yeasts and molds.

Typical Composition

Specified by EP, USP, JP		Specified by BAM M152		ReadyPlate™ TSA	
Pancreatic Digest of Casein	15 g/l	Trypticase Peptone	15 g/l	Pancreatic Digest of Casein	15 g/l
Papaic Digest of Soya Bean	5 g/l	Phytone peptone	5 g/l	Papaic Digest of Soya Bean	5 g/l
Sodium Chloride	5 g/l	NaCl	5 g/l	Sodium Chloride	5 g/l
Agar	15 g/l	Agar	15 g/l	Agar-Agar*	15 g/l
Water	1000 ml/l	Water	1000 ml/l	Water	n/a
pH at 25 ℃	7.3 ± 0.2	pH at 25 ℃	7.3 ± 0.2	pH at 2 5 ℃	7.3 ± 0.2

* Agar-Agar is equivalent to other different terms of agar.

The appearance of the medium is clear and yellowish-brown.

Application and Interpretation

Depend on the purpose for which the media are used.

Each plate is provided with a label including a data matrix code for paperless plate identification. The code consists of a two-dimensional 20-digit serial number, which harbors the following information:

digits 1-3: here code 749 (corresponds to article 146431); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiration date (YY/MM/DD).

Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.

Incubation: 24 hours at 35 ℃ aerobically, for *Candica albicans* and *Aspergillus niger* up to 5 days at 35 ℃.

For total aerobic microbial count on non-sterile pharmaceutical samples, incubation at 30-35 ℃ up to 3-5 days.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +4 ℃ to +12 ℃.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 ℃, disinfect, incinerate etc.).

Quality Control

Function	Control strains	Incubation	Reference media	Method of control	Expected results
Productivity	*Bacillus cereus* ATCC® 11778	21-27 h at 36-38 ℃	Media batch TSA already validated	Quantitative	Characteristic colony according to each species
	Bacillus subtilis ATCC® 6633				
	Escherichia coli ATCC® 25922				
	Escherichia coli ATCC® 8739				
	Listeria monocytogenes 4b ATCC® 13932				
	Staphylococcus aureus ATCC® 25923				
	Staphylococcus aureus ATCC® 6538	24 h at 30-35 ℃	Blood Agar	Quantitative	-
	Bacillus subtilis ATCC® 6633				
	Escherichia coli ATCC® 8739				
	Pseudomonaas aeruginosa ATCC® 9027				Green colonies

Function	Control strains	Incubation	Reference media	Method of control	Expected results
Productivity	*Candida albicans* ATCC® 10231	≤ 5 days at 30-35 °C	Sabouraud Dextrose Agar		-
	Aspergillus brasiliensis ATCC® 16404				Recovery ≥ 50 %
	Bacillus cereus ATCC® 11778	21-48 h at 29-31 °C	Media batch TSA already validated	Quantitative	Recovery ≥ 70 %, characteristic colony according to each species
	Bacillus subtilis ATCC® 6633				
	Escherichia coli ATCC® 25922				
	Escherichia coli ATCC® 8739				
	Staphylococcus aureus ATCC® 25923				
	Listeria monocytogenes 4b ATCC® 13932	40-48 at 36-38 °C	Media batch TSA already validated	Quantitative	

Please refer to the actual batch related Certificate of Analysis.

The performance test is in accordance with the current version of EN ISO 11133 and EP + USP.

A recovery rate of 70 % is equivalent to a productivity value of 0.7.
A recovery rate of 50 % is equivalent to a productivity value of 0.5.

Literature

EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.

European Pharmacopeia 8.0 (2013): Chapter 2.6.12 and 2.6.13 B (harmonized Method).

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.

Hawkey, P.H., McCormick A. and Simpson, R.A. (1986): Selective and differential medium for the primary isolation of members of the proteae. J. Clin. Microbiol. **23**: 600-603.

ISO 11133:2014: Microbiology of food and animal feed and water – Preparation, production, storage and performance testing of culture media.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

United States Pharmacopoeia 38 NF 31 (2015): <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.

Ordering Information

Product	Cat. No.	Pack size	Other pack sizes available
ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	1.46431.0020	20 x 90 mm	100 x 90 mm
GranuCult™ Tryptic Soy Agar EP, USP, JP, ISO FDA-BAM	1.05458.0500	500 g	5 kg

Merck KGaA, 64271 Darmstadt, Germany
Fax: +49 (0) 61 51 / 72-60 80
mibio@merckgroup.com
www.merckmillipore.com/biomonitoring

Find contact information for your country at:
www.merckmillipore.com/offices
For Technical Service, please visit:
www.merckmillipore.com/techservice