INSTRUCTIONS FOR USE –



AGAR PLATES

CE

TSA W/ LECITHIN & POLYSORBATE RODAC

REF 1095

SPML manufacture and supply a range of Pre-prepared media for the culture of microorganisms such as bacteria yeasts and moulds. SPML offer a range of media pre-poured culture media to meet the needs of its customers across a range of industries that include Clinical, food, water, pharmaceutical, and many more.

SPMLSELECT

The range of plates cover selective and non-selective media and plate sizes and are intended for the use by professional parties in the isolation of microbial organisms.

INTENDED USE

These media are recommended for the detection and enumeration of microorganisms present on surfaces of sanitary importance. Prepared plates are provided for environmental monitoring. Sterile Pack and Isolator Pack RODAC[™] prepared plates are particularly useful for monitoring surfaces in clean rooms, Isolator Systems and other environmentally-controlled areas and are also recommended for use in air sampling equipment such as the Surface Air System. Finger Dab[™] Sterile Pack and Isolator Pack plates are intended for sampling gloved hands.

• Micro Organism Reactions pH: 7.10 -7.50

	Organisms	Result, Colour of Colony
	S. Pyogenes	Moderate; Colourless colony
P	S. Aureus	Good; white colony
	E. Coli	Good; cream colony

TECHNIQUE

Using a sterile loop inoculate the medium with 4±5 colonies and t Incubate all plates at 35-37°C for 48 hours, and 25°C for 7 days or as required.

As methods and media preference may vary as to media types and test method due to jurisdictions, and personal preferences the customer should use the plates in accordance with their organisations stated methods and procedures however SPML product brochure does provide further product information

The end user should however take into consideration that selective media should, therefore, be compared with specimens/samples

cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens and other significant organisms

PRECAUTIONS

IVD. For professional use only.

Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

Consult In house instructions to ensure correct application of product use is observed. Ensure GLP and aseptic handling procedures are followed, used plates should be treated as biohazards, and disposal of used product should be treated as such, and disposed of in accordance with local /national regulations.

STORAGE AND SHELF LIFE

On receipt, store plates in the dark at 2 to 8° C, in their original sleeve wrapping until just prior to use. Avoid freezing and overheating. The plates may be inoculated up to the expiration date (see package label) and incubated for the recommended incubation times.

Plates from opened stacks of 10 plates can be used for one week when stored in a clean area at 2 to 8° C.

QUALITY CONTROL

SPML undertake batch release for all media checking pH, sterility, Inhibition and enhancement testing of all media batches based on the EN12322:19991¹, M22-A3², and ISO11133³, For clinical purpose the product is CC marked in accordance with the requirements of 97/79/EC IVD Directive and registered with the Competent Authority MHRA in the United Kingdom. SPML is ISO9001:2008 certified

FURTHER INFORMATION

For further information please contact your local SPML representative.Saudi Prepared Media Laboratory Company LtdTelephone:+966 11 4767931, 11 4773697FAX:+966 1 4778313E-mail: media@spml.com.saWeb Site:http://www.spml.com.sa

References.

¹EN 12322:1999 - In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media.

² *Clinical and Laboratory Standards Institute. 2004. Approved standard: M22-A3, Quality control for commercially prepared microbiological culture. media, 3rd ed*

³ISO11133 <u>Microbiology of food, animal feed and water — Preparation, production storage and performance testing of culture media</u>



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Symbols Definition

· · · · · · · · · · · · · · · · · · ·	
REF	Product Reference Number
IVD	For in vitro diagnostic use
	Do not use if damaged
STERILE	Sterile by Moist / Dry heat
NON	Non Sterile
\otimes	Single Use
· · · · · · · · · · · · · · · · · · ·	Manufacturer
LOT	Lot Number
X	Bio hazardous material
CE	CE Mark – Against the European In Vitro Diagnostic Medical Device Directive 98/79/EC
ł	Storage temperature limitation
\sim	Manufacture date
Ĩ	Consult Instructions for use
淡	Avoid direct sunlight
	Keep Dry
X	Expiration Date
EC REP	EU Representative
\square	WARNING – Consult IFU