Technical Data Sheet

Vegetable Pepton Agar + LTHThio-Sedi. ICRplus

Ordering number: 1.46804.0020 / 1.46804.0120

Vegetable Pepton Agar + LTHThio – ICR+ in 90 mm plates is designed for the determination of the total aerobic and anaerobic microbial count in air via active or passive air monitoring as well as fingerprints of personnel in **I**solators and **C**lean **R**ooms.

Ten lockable settle plates each with a diameter of 90 mm are triple-bagged in transparent, hydrogen peroxide impermeable sleeves. The product is gamma-irradiated in the final packaging at a dose of 9-20 kGy. The sleeves consist of polypropylene with a barrier of PE-EVOH-PE.

The formulation of the basic medium (Vegetable Peptone Agar, VPA) is prepared based on the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.12.; JP, 4.05 and USP, 61) for Soybean-Casein Digest Agar and supplemented with neutralizers, but contains peptones of non-animal origin only. The exclusive use of raw materials of non-animal origin allows the elimination of a potential contamination risk of the environment with TSE/BSE agent.

Further plate design is available with the identical media formulation:

- Vegetable Pepton Agar + LTHThio – Contact ICR+ (article number 146803): 55 mm lockable contact plates, triple-bagged, gamma-irradiated; intended for microbial monitoring of dry, sanitized surfaces and personnel in cleanrooms and isolators. The plate design allows aerobic, microaerophilic and anaerobic incubation.

Mode of Action

Vegetable Peptone Agar is a complex medium for cultivation and isolation of a wide range of bacteria, yeasts and molds without a potential contamination risk of the environment with TSE/BSE. The medium is supplemented with pyruvate in order to provide an efficient neutralization of hydrogen peroxide for use in isolators. Internal studies confirmed the neutralization efficiency of the neutralizers lecithin, polysorbate (Tween®) 80, histidine and sodium thiosulfate added to TSA or VPA for disinfectants containing the following active agents:

- Alcohol (70 % ethanol or isopropyl alcohol)
- Aldehyde
- Dichloroisocyanurate
- Hydrogen Peroxide
- Peracetic acid
- Phenols (low and high pH value)

The neutralizing efficiency towards residues of disinfectants in use should be validated at the application site.

Typical Composition

Peptone (non-animal origin)	20 g/l
NaCl	5 g/l
Lecithin	0.7 g/l
Polysorbate (Tween®) 80	5 ml/l
Histidine	0.5 g/l
Sodium Thiosulfate	0.05 g/l
Agar	15 g/l

The appearance of the medium is clear and yellowish. The pH value is in the range of 7.1-7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

The plates are introduced into cleanrooms grade A or B by removing one bag in each material lock. For use in isolators the inner bag has a hole in the sealing to hang up the bag during decontamination. Do not leave plates which are unprotected (unwrapped) in an isolator during decontamination.

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 893 (corresponds to article 146804); 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.

The plates may be used for passive or active air monitoring as described in USP chapter <1116> or ISO 14698. For active air sampling please follow the guidance of the air sampler. Typically, 1000 liter of air are sampled for quantification of CFU. The exposure time of opened settle plates should be validated with respect to the environmental conditions of the sampling area such as flow rates, temperatures and relative humidity to preclude desiccation. Afterwards the plates are closed and transferred to an incubator. To protect the plates from secondary contamination during transport and incubation outside of the cleanroom zone, sterile transport bags (article number 146509) may be used.

Several recommendations are given by different guidelines for incubation: according to USP <1116> the plates used for environmental monitoring should be incubated between 20 and 35 °C for not less than 72 hours. According to the FDA Aseptic Guide the plates for determination of the total aerobic bacterial count should be incubated at 30 to 35 °C for 48 to 72 hours, while the plates for determination of the total yeast and mold count should be incubated at 20 to 25 °C for 5 to 7 days. Individual incubation conditions can be chosen and should be validated at the application side.

Finally, the number of CFU per plate is examined.

Grown colonies are recommended to be identified.

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 +15 °C to +25 °C.

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 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Result Recovery in %
Staphylococcus aureus	6538	10-100	20-24 h at 30-35 °C	50-200
Staphylococcus aureus in the presence of 120 µl Cutasept F	6538	10-100	20-24 h at 30-35 °C	50-200
Pseudomonas aeruginosa	9027	10-100	20-24 h at 30-35 °C	50-200
Bacillus subtilis	6633	10-100	20-24 h at 30-35 °C	50-200
Clostridium sporogenes	11437	10-100	44-48h at 30-35 °C anaerobic	50-200
Candida albicans	10231	10-100	44-48 h at 30-35 °C	50-200
Aspergillus brasiliensis	16404	10-100	44-48 h at 30-35 °C	50-200

Please refer to the actual batch related Certificate of Analysis.

Literature

EMA/410/01 rev.3 and European Pharmacopoeia 8.0, Chapter 5.2.8: Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

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

European Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).

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

ISO 14698-1:2003: Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods.

Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test.

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

United States Pharmacopoeia 38 NF 33 (2015): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.

Ordering Information

Product	Cat. No.	Pack size
Vegetable Pepton Agar + LTHThio -Sedi. ICR+	1.46804.0020	20 x 90 mm plates
Vegetable Pepton Agar + LTHThio -Sedi. ICR+	1.46804.0120	120 x 90 mm plates
Vegetable Pepton Agar + LTHThio - Contact ICR+	1.46803.0020	20 x 55 mm plates
Vegetable Pepton Agar + LTHThio – Contact ICR+	1.46803.0200	200 x 55 mm plates
Transport Bags, Sterile	1.46509.0125	25 x 5 bags

Lit. No. MK_TN5880EN00