Technical Data Sheet

Neutralizer A – Contact - ICRplus

Ordering number: 1.46697.0020 / 1.46697.0200

Neutralizer A Contact - ICR+ is designed for the determination of the total aerobic microbial count on dry, sanitized surfaces and personnel in Isolators and Clean Rooms.

Ten lockable contact plates each with a diameter of 55 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 (Soybean-Casein Digest Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.12.; JP, 4.05 and USP, 61) and supplemented with neutralizers.

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. 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 efficacy of the neutralizer mixture "A" for disinfectants containing the following active agents:

- Alcohol (ethanol or isopropyl alcohol)
- Aldehyde
- Glucoprotamine
- Hydrogen Peroxide
- Peracetic acid
- Phenols (low pH value)
- Quaternary ammonium compounds
- Polyhexamethylene biguanides

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

Typical Composition

Casein Peptone	15 g/l
Soy Peptone	5 g/l
NaCl	5 g/l
Neutralizer A (mixture)	
Agar	15 g/l
Supplements	

The appearance of the medium is clear and yellowish. The pH value is in the range of 7.0-7.4. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

The plates are introduced into clean rooms 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 825 (corresponds to article 146697); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiry 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.

According to ISO 14698 the plates are opened and the agar surface is pressed on the dry surface to be tested for some seconds with a steady pressure. Similar recommendations are included in the PDA technical report No.13. Afterwards the plates are closed and transferred to an incubator. To protect the plates from secondary contamination during transport and incubation outside of the clean room zone, sterile transport bags (article number 146509) may be used. Residues of culture medium should be removed from the surface after sampling.

In addition, the plate model (plus or „+“) is supplied with a lockable lid. For safe transport after sampling without the risk of losing the lid as well as for aerobic incubation the plates should be locked in the “CLOSED”-position (turn the lid clockwise). For anaerobic or microaerophilic incubation the “VENT”-position (turn the lid counter-clockwise) is mandatory because this lid-position provides sufficient gas exchange with the atmosphere in the incubation chamber. Aerobic incubation while turning the lid in “VENT”-position is also possible but may increase the desiccation of the agar plates during incubation.

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
Pseudomonas aeruginosa	9027	10-100	20-24 h at 30-35 °C	50-200
*Bacillus subtilis (spore suspension)**	6633	10-100	20-24 h at 30-35 °C	50-200
Bacillus subtilis in the presence of 25 µl Klercide-CR Biocide Quat/Biguanide (Biocide A) *(spore suspension)**	6633	10-100	20-24 h at 30-35 °C	50-200
Candida albicans	10231	10-100	44-48 h at 30-35 °C	50-200
Aspergillus brasiliensis (spore suspension)	16404	10-100	44-48 h at 30-35 °C	50-200

Please refer to the actual batch related Certificate of Analysis.

* Growth promotion tests are performed with a spore suspension of *Bacillus subtilis* 6633 and *Aspergillus brasiliensis* 16404.

Literature

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

European Pharmacopoeia 10.0 (2019): 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: Clean Rooms 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 42 NF 37 (2019): <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
Neutralizer A - Contact Agar - ICR+	1.46697.0020	20 x 55 mm plates
Neutralizer A - Contact Agar - ICR+	1.46697.0200	200 x 55 mm plates
Transport Bags, sterile	1.46509.0125	25 x 5 bags

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