

EMswab™ – Dey-Engley Neutralizing Broth I

Intended Use

Ready to use sterile (Gamma-Irradiated) ICR cotton swab with Dey-Engley Neutralizing Broth filled in polypropylene tubes. This product is used for environmental sampling in clean rooms and isolators.

Summary

Environment and surface monitoring is a critical factor in controlling clean room and isolator area. Generally, contact plates are used for surface monitoring. In case of uneven surfaces, crevices, swabbing ensures effective environmental sampling.

Principle

Sterile EMswab™ Dey Engley Neutralizing Broth, constitutes swab made of cotton with a polypropylene applicator. Dey Engley Neutralizing Broth consists of neutralizers which neutralizes the effect of disinfectants that may be present on the surface of the sample. Also, the broth maintains the viability of the microorganisms after a sample is collected and until the sample is processed by the laboratory. Triple wrapped product subjected to adequate dose of Gamma irradiation ensures the contents are sterile thereby ensuring aseptic transfer of the product in cleanrooms/isolators.

Formula*

Ingredients	g/L
Casein Enzymic Hydrolysate	5.0
Yeast Extract	2.5
Dextrose	10.0
Sodium Thiosulphate	6.0
Sodium Thioglycollate	1.0
Sodium Bisulphite	2.5
Lecithin	7.0
Polysorbate 80	5.0
Bromocresol Purple	0.02

Storage and Stability

Store the product at 2°C-8°C. Use before expiry date on label.

Type of Specimen

Bacterial samples for culture may be used, but the survival of bacteria depends on type of bacteria, concentration and transport time.

Specimen Collection and Handling

Follow appropriate techniques for handling specimens as per established guidelines.

Directions

Materials provided are EMswab™ sterile Cotton swab with Dey Engley Neutralizing Broth. Materials required but not provided are culture media, reagents, quality control organisms and laboratory equipment.

1. Determine the surface/surfaces to be sampled.
2. Follow appropriate aseptic technique and open the outer pouch.
3. Once opened, the outer pouch should be used to maintain sterility of inner pouch and its components.
4. Unscrew and squeeze the tip of the swab against inner surface of the tube to remove excess solution.
5. Holding the cap, ensure that the premoistened swab is placed at an appropriate angle on the surface to be sampled.
6. The swab should be stroked in close parallel sweeps over the defined sample area.
7. After slowly rotating, sampling of the same area should be repeated, stroking the same swab perpendicular to the initial sweep.
8. The swab should then be placed back to the solution.
9. Immediately tighten the cap and vortex the tube to release bacteria from the swab.
10. After sampling the sample site surface should be cleaned to remove any residue.

11. The representative sample should be tested within two hours if stored at 15°C-25°C. If stored, the sample may be refrigerated at 2°C-8°C for 24 hours and then tested.

Quality Control

Appearance: Purple coloured, slightly opalescent solution with cotton swab.

Cultural Response: Cultural characteristics observed after an incubation of Dey Engley Neutralizing Broth with sterile cotton swabs inoculated with the ≤100 cfu culture suspensions and incubated at 30°C-35°C for 40-48 hours.

Organisms (ATCC)	Growth
<i>Escherichia coli</i> (8739)	Good
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	Good
<i>Pseudomonas aeruginosa</i> (9027)	Good
<i>Bacillus spizizenii</i> (6633)	Good

Growth Promotion Test in presence of Quaternary Ammonium Compound and Aldehyde

Organism (ATCC)	Test I	Control I	Test II	Control II
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	Good	No growth	Good	No growth
<i>Bacillus spizizenii</i> (6633)	Good	No growth	Good	No growth

Key:

Test: Dey Engley Neutralizing Broth

Control: Soyabean Casein Digest Medium

I: with Quaternary Ammonium Compound

II: with Aldehyde

Note: Inoculum cfu for good growth is 10-100.

Limitations

1. This product is intended only for sampling and transport of specimen collected from surface and equipments.
2. Subculture of specimens on primary isolation medium is required for identification of recovered organisms.

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. Cleanrooms and associated controlled environments. Biocontamination control – Part 1: General Principles and Methods, ISO 14698-1:2003(E).
2. WHO, Environmental Monitoring of Clean Rooms in Vaccine manufacturing facility.
3. Evaluation of the Recovery Rate of Different Swabs for Microbial Environmental Monitoring, PDA Journal, Vol.71, No.1, January- February 2017, Pg No. 33-41, Marcel Goverde, Julian Willrodt, Alexandra Staerk.
4. Releasing capacity of pre-sterile cotton swabs for discharging sampled microorganisms, European Journal of Parenteral and Pharmaceutical Sciences 2016, 21 (4): 121-127. Ravi Krishna Satyada and Tim Sandle.
5. Microbiological Culture Media, A Complete Guide for Pharmaceutical and Health Care Manufacturers. Tim Sandle, PDA, DHI Publishing, LLC. River Grove, IL, USA.
6. A Study of a new type of swab for the environmental monitoring of isolators and cleanroom. European Journal of Parenteral and Pharmaceutical Sciences 2011:16 (2): Tim Sandle.
7. United States Pharmacopoeia 38 NF 31 (2015): <71> Sterility Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
8. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.

203050170050

Product description

Ready Prepared Cotton Swab with Dey Engley
Neutralizing Broth I

Pack Size

50 Tests (50 x 2 mL)

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.
