

EMswab™ - Soyabean Casein Digest Medium with Lecithin and Polysorbate 80 II

Intended Use

Ready to use sterile (Gamma-Irradiated) ICR Dacron® swab with Soyabean Casein Digest Medium with Lecithin and Polysorbate 80 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™ Soyabean Casein Digest Medium with Lecithin and Polysorbate 80, constitutes swab made of Dacron® with a polypropylene applicator. Dacron®, polyester material of construction ensures no shredding of particles in the medium. Unique paddle design of swab ensures swabbing of uneven surfaces, easy to reach into crevices. Soyabean Casein Digest Medium provides appropriate nutrients to maintain viability of organisms whereas neutralizer neutralizes traces of disinfectants if present during swabbing of surface. 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
Pancreatic Digest of Casein	17.0
Papaic Digest of Soyabean	3.0
Glucose Monohydrate	2.5
Sodium Chloride	5.0
Dibasic Hydrogen Phosphate	2.5
Polysorbate 80	5.0
Lecithin	0.7

Storage and Stability

Store the product at 15°C-25°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: EMswab™ sterile Dacron® swab with Soyabean Casein Digest Medium with Lecithin and Polysorbate 80. 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: Light amber coloured, clear solution without any precipitate solution in tubes with Dacron® swab.

Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP and growth is observed after an incubation at 30°C-35°C for ≤3 days for bacteria and ≤5 days for fungi.

Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time, inoculating ≤100 cfu (at 30°C-35°C for ≤3 days for bacteria and ≤5 days for fungi).

Organisms (ATCC)	Growth
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	Good
<i>Pseudomonas aeruginosa</i> (9027)	Good
<i>Bacillus spizizenii</i> (6633)	Good
<i>Candida albicans</i> 3147 (10231)	Good
<i>Aspergillus brasiliensis</i> WLRI 034(120) (16404)	Good

Validation and Growth Promotion

(Growth Promotion is carried out after an incubation at 20°C-25°C for ≤3 days for bacteria and ≤5 days for fungi as per USP/EP/JP).

Organism (ATCC)	Growth
<i>Candida albicans</i> 3147 (10231)	Good
<i>Bacillus spizizenii</i> (6633)	Good
<i>Aspergillus brasiliensis</i> WLRI 034(120) (16404)	Good

Neutralizing Activity in presence of Quaternary Ammonium Compound

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

Key:

Test: Soyabean Casein Digest Medium with Lecithin and Polysorbate 80

Control: Soyabean Casein Digest Medium

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. 203050430050	Product description Ready Prepared Dacron® Swab with Soyabean Casein Digest Medium with Lecithin and Polysorbate 80	Pack Size 50 Tests (50 x 2 mL)
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 Temperature Limit	 Manufacturer	 Catalogue Number	 Date of Manufacture	 Contains sufficient for <n> tests
 Use-by Date	 Consult Instructions for use	 Batch Code	 This way up	

Revision: 0825/VER-03

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.