EMswab™ - Soyabean Casein Digest Medium I

Intended Use
Ready to use sterile (Gamma-Irradiated) ICR cotton swab with Soyabean Casein Digest Medium as per USP (Harmonized chapter 62) filled in polypropylene tubes. This product is used for environmental sampling in clean rooms and isolators.

Summary
Environmental and surface monitoring is a critical element in controlling the clean room and isolator area. Generally, for surface monitoring contact plates are used, however when surfaces are uneven, crevices, swabbing is employed.

Principle
Sterile EMswab™ Soyabean Casein Digest Medium, constitutes swab made of cotton with a polypropylene applicator. Soyabean Casein Digest Medium provides appropriate nutrients to maintain viability of organisms. 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

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 Cotton swab with Soyabean Casein Digest Medium.
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 cotton 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)	**Good**
Staphylococcus aureus subsp. *aureus* (6538)	Good
Pseudomonas aeruginosa (9027)	Good
Bacillus spizizenii (6633)	Good
Candida albicans 3147 (10231)	Good
Aspergillus brasiliensis 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**
Candida albicans 3147 (10231)	Good
Bacillus spizizenii (6633)	Good
Aspergillus brasiliensis WLRI 034(120) (16404)	Good

Note: Inoculum cfu 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.	Product description	Pack Size
203050230050	Ready Prepared Cotton Swab with Soyabean Casein Digest Medium I	50 Tests (50 x 2 mL)