EMswab™ – Twin Pack System (Swab in Saline with Lecithin and Polysorbate 80 + Soyabean Casein Digest Medium) II

Intended Use
Ready to use sterile (Gamma-Irradiated) ICR Dacron® swab with combo pack of swab in Saline with Lecithin and Polysorbate 80 in polystyrene tube and Soyabean Casein Digest Medium filled in polypropylene tube. 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™ Twin Pack System (Swab in Saline with Lecithin and Polysorbate 80 + Soyabean Casein Digest Medium) II, constitutes swab made of ICR Dacron® with a polypropylene applicator. ICR 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. Saline with Lecithin and Polysorbate 80 acts as neutralizers which neutralizes traces of disinfectants if present during swabbing of surface whereas 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**
Saline with Lecithin and Polysorbate 80	
Sodium Chloride	9.0
Lecithin	0.7
Polysorbate 80	5.0
Soyabean Casein Digest Medium	
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 are EMswab™ – Twin Pack System (Swab in Saline with Lecithin and Polysorbate 80 + Soyabean Casein Digest Medium) II.
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 of Swab in Saline with Lecithin and Polysorbate 80 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 Soyabean Casein Digest Medium tube.
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

Saline with Lecithin and Polysorbate 80

Appearance: Clear, colourless solution in tubes with Dacron® swab.

Cultural Response: Culture characteristics observed after recovery on Accumix® Soyabean Casein Digest Agar (201190200500), (incubated at 30°C - 35°C for 18-24 hours) for bacteria and on Accumix® Sabouraud Dextrose Agar (201190040500) (at 20°C - 25°C for 48 - 72 hours) for fungal growth.

Organism (ATCC)	**% Survival after 24 hours (Stored at 2°C - 8°C)**
Escherichia coli (8739)	≥ 100 %
Staphylococcus aureus subsp. *aureus* (6538)	≥ 100 %
Pseudomonas aeruginosa (9027)	≥ 100 %
Bacillus spizizenii (6633)	≥ 100 %
Candida albicans 3147 (10231)	≥ 100 %
Aspergillus brasiliensis WLRI 034(120) (16404)	≥ 100 %

Note: Inoculum cfu is 100-1000

Neutralizing Activity in presence of Quaternary Ammonium Compound

Neutralizing activity is tested by recovery on Soyabean Casein Digest Agar Plate. The Average number of cfu recovered from the challenged product should not be less than 70% of that recovered from the inoculum control.

Organism (ATCC)	**Neutralizing Activity for Quaternary Ammonium Compound**
Staphylococcus aureus subsp. *aureus* (6538)	Complies
Bacillus spizizenii (6633)	Complies

Note: Inoculum cfu is 100-1000

Soyabean Casein Digest Medium

Appearance: Light amber coloured, clear solution without any precipitate solution in tubes.

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**
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 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

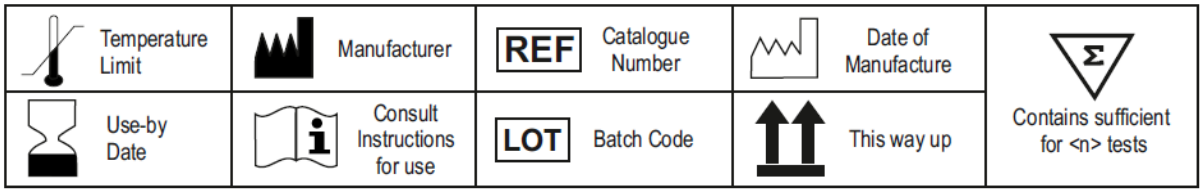
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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.	Product description	Pack Size
203050460025	Ready Prepared ICR Dacron® Swab in Saline With Lecithin and Polysorbate 80 + Soyabean Casein Digest Medium II	25 Tests (50 x 2 mL)



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.