BD Sterile Pack Swab

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INTENDED USE

The BD™ Sterile Pack Swab is a ready-to-use sterile swab in a pre-filled tube of rinse solution for surface and equipment sampling.

SUMMARY AND EXPLANATION

Surface and equipment sampling is routine practice in hospitals, pharmaceutical and food industries as part of infection control, environmental monitoring and hygiene control programs. Collection of samples from the same area before and after cleaning and/or treatment with a disinfectant permits the evaluation of the efficacy of the sanitary procedures. Each BD Sterile Pack Swab unit is ready-to-use and comprised of a peel open pouch containing a sampling swab in a tube with approximately 10 mL rinse solution. The BD Sterile Pack Swab is designed to sample a variety of surface textures and equipment with the advantage of sampling hard-to-reach areas such as equipment crevices and inside pipe work. The pre-filled rinse solution is a general-purpose isotonic solution with neutralizing agents for the maintenance of microorganisms and the neutralization of disinfectants. The double pouch design is gamma-irradiated.

PRINCIPLES OF THE PROCEDURE

The swab tip is made of Dacron™ fiber on a polypropylene applicator within a polypropylene flat bottomed tube. The rinse solution is a balanced isotonic solution to maintain organism viability. Four neutralizers are incorporated to inactivate a variety of disinfectants and antiseptic chemicals. Sodium thiosulfate inactivates working concentrations of stabilized blends of hydrogen peroxide and peracetic acid. Lecithin inactivates quaternary ammonium compounds; and polysorbate 80 inactivates substituted phenolic disinfectants.[1-3] Engley and Dey reference the neutralizer sodium thioglycollate for inactivation of mercurials.[4] Sodium pyruvate helps recover injured microorganisms.

Because the doubled-bagged product is subjected to a sterilizing dose of gamma radiation, the contents inside the outer bag are sterile.[5] This allows the outer bag to be aseptically removed and its contents to be brought into an environmentally controlled area without introducing contamination. Since this product has been sterilized after packaging, the presence of microbial growth after sampling and incubation can be relied upon to represent the presence of environmental contaminants and not pre-existing microorganisms in the product that may have been introduced during manufacture.

REAGENTS

BD Sterile Pack Swab Rinse Solution

Approximate Formula* Per Liter Purified Water

Sodium Chloride	3.0 g	Lecithin	1.3 g
Potassium Chloride	0.2 g	Sodium Thiosulfate	1.1 g
Calcium Chloride	0.1 g	Sodium Thioglycollate	0.75 g
Sodium Bicarbonate	0.05 g	Sodium Pyruvate	1.1 g
Polysorbate 80	3.0 g		

*Adjusted and/or supplemented as required to meet performance criteria.

Precautions: For Laboratory Use.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, contaminated materials should be sterilized by autoclaving. Applying excessive pressure during sampling may cause the applicator to break. Inside of the unit, it is possible to find detached swab fibers. Some pieces of fiber may detach from the swab during sampling.

Storage Instructions: Store at 5 to 25 °C. Avoid freezing or overheating. Do not open until ready to use. Minimize exposure to light.

Product Deterioration: Do not use if this product shows evidence of damage or microbial contamination.

SPECIMEN COLLECTION AND HANDLING

Samples suitable for culture may be obtained using various techniques. Samples should be transported in the appropriate manner. Bacterial survival in the rinse solution depends upon a series of factors such as bacteria type, bacteria concentration in the sample and transport time.

PROCEDURE

Material Provided: BD Sterile Pack Swab.

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Instructions: The pouches may be opened by peeling apart or by cutting open with sterile scissors. If the sterility of the inner pouch and swab units are of importance for your procedure, open the outer pouch using aseptic technique. Once the outer pouch is opened, appropriate measures should be used to maintain the sterility of the inner pouch and its contents.

Determine surfaces to be sampled. Using aseptic technique, remove the cap containing the swab. Holding the cap, swab the surface at approximately a 30° angle. Wipe the swab over the sample area in a back and forth motion several times, rotating the swab while wiping. Return the swab to the rinse solution and tighten cap. After sampling, transport the sample to the laboratory for analysis within 4 hours at ambient room temperature. Samples can be refrigerated at 2 to 8 °C for 24 hours before laboratory analysis.

In the laboratory, vortex the unit and remove the volume of rinse solution required for your enumeration method (i.e. spread plate, pour plate or membrane filtration method). The selection of the appropriate aliquot of rinse solution and the enumeration method may be dependent on the expected microbial load. Plate onto appropriate nutritive agar to obtain an estimate of the viable microbial load from the sampled surface.[6]

User Quality Control:

1. Examine the product for signs of deterioration as described under "Product Deterioration."
2. Check performance by inoculating a representative sample of swab units with pure cultures of stable control microorganisms that give known, desired reactions.

The following test strains are recommended.

TEST STRAIN	EXPECTED RESULT
Staphylococcus aureus ATCC® 6538	Viable
Escherichia coli ATCC 25922	Viable

RESULTS

Seeded culture studies were performed using eight bacterial strains and one yeast strain (source: ATCC) traditionally considered common environmental contaminants to establish product transport and recovery claims. All microorganisms tested demonstrated satisfactory recovery at the transport times and conditions previously described.

After incubation on a primary isolation medium, it is desirable to have isolated colonies of microorganisms from the sample. Subculture colonies of interest so that positive identification can be made by means of biochemical testing and/or microscopic examination of microorganism smears.[7-9]

LIMITATIONS OF THE PROCEDURE

The BD Sterile Pack Swab is intended for the sampling and transport of specimens collected from surfaces and equipment. Use of the BD Sterile Pack Swab for other applications should be confirmed using established procedures.

Subculture of specimens onto primary isolation media is required for identification of any recovered microorganisms. Appropriate texts should be consulted for further information on microorganism identification. [7-10]

AVAILABILITY

Cat. No.	Description
220518	BD™ Sterile Pack Swab, Carton of 200.

REFERENCES

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