CUSTOMER INFORMATION PACKET

BD STERILE PACK SWAB

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Sparks, MD 21152
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1 INTRODUCTION

As the leader in Industrial Microbiology, BD Diagnostic Systems continues to apply its product-offering portfolio in order to satisfy the varied and increasing needs of our regulated QA/QC Microbiologists and Environmental Monitoring professionals.

The utilization of the BD Sterile Pack Swab is dependent upon compliance with regulatory requirements and we hope this documentation assists you in meeting those requirements. Should you have additional questions after reading this material, you will find detailed contact information at the end of this package.

This packet contain:

- A verification summary of the BD Sterile Pack Swab test methods and results
- Information on the Certificate of Analysis
- Information on the Automated Change Notification Program

BD takes seriously our responsibility for helping our customers meet their regulatory documentation needs, and appreciates your use of our products and services. BD facilities are FDA-registered and certified to ISO 9000 Quality Systems.

2 BD STERILE PACK SWAB VERIFICATION SUMMARY

2.1 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.

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 comprised of a peel-open pouch containing a sampling swab in a tube with approximately 10 mL rinse solution. It 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.[1, 2] 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 swab tip is made of Dacron ™ fiber [2] 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.[3] 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.[4-6] Engley and Dey reference the neutralizer sodium thioglycollate for inactivation of mecurials.[7] Sodium pyruvate helps recover injured microorganisms.

The BD Sterile Pack Swab has a double-bagged design that is gamma-irradiated. Because the doubled-bagged product is subjected to a sterilizing dose of gamma radiation, the contents inside the outer bag are sterile.[8] 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. Quarterly dose audits on the BD Sterile Pack Swab are conducted following the sterilization dose auditing procedures outlined in the ANSI/AAMI/ISO 11137 – 1994 document.[9] The audit is used to reaffirm the sterilization dose. During the sterilization dose audit procedure, samples are tested for microbial bioburden. In addition, samples are irradiated at the verification dose level and tested for sterility to confirm adequate response of any bioburden to gamma irradiation.

Dacron is a registered trademark of DuPont for its polyester fibers.

2.2 PRECAUTIONS

For Laboratory Use.

All microbial cultures are potentially infectious and should be treated with universal precautions. Please refer to CDC manual *Bio-safety in Microbiological and Biomedical Laboratories,* 1988, as well as other recommended literature.

2.3 SWAB VERIFICATION DESCRIPTION

The purpose of this verification was to evaluate methods for determining the BD Sterile Pack Swab performance requirements and the swab's performance with these methods to ensure a safe and effective product throughout its shelf life.

Three lots of BD Sterile Pack Swab were tested for viable organism recovery and neutralization efficacy. The verification was conducted according to approved BD Diagnostic Systems R&D protocols.

The ability of the swab product to support viable organism recovery and neutralize disinfectants efficaciously was based on microbial growth determinations on BBL™ Trypticase™ Soy Agar (TSA).

The swab lots were tested at two storage parameters: refrigerated storage conditions of 2-8 ^{o} C and room temperature storage conditions of 25-30 ^{o} C.

2.4 DOCUMENTATION

The viable organism recovery and neutralization efficacy documentation has been generated for each lot as part of the validation of the BD Sterile Pack Swab.
All of our products are manufactured in compliance with BD policies/procedures, FDA cGMP and ISO 9000 standards.
Prior to testing, your facility should review and approve a qualification or validation plan for the BD Sterile Pack Swab.

2.5 RELEASE CRITERIA

As part of the validation of the BD Sterile Pack Swab, the identified processes and monitoring results are reviewed for conformance to predetermined validation criteria and product specifications. If all specifications are met, the product is released for sale.

For this study the release criteria for the viable organism recovery is:

- 70% to 130% recovery for all organisms on TSA from the tube of rinse solution held at room temperature compared to the same tube sampled immediately after inoculation.
- 70% to 130% recovery for all organisms on TSA from the tube of rinse solution held at refrigerated temperature compared to the same tube sampled immediately after inoculation.

The release criterion for the neutralization efficacy is:

- Greater than or equal to 80% recovery of the organism on TSA from a tube of rinse solution inoculated with disinfectant and organism compared to a tube of rinse solution only inoculated with organism and to a tube of normal saline inoculated with disinfectant and organism.

As part of your qualification or validation of the BD Sterile Pack Swab, the identified tests and results should be reviewed for conformance to your predetermined qualification or validation criteria and specifications.

2.6 PROCEDURE AND TESTING

2.6.1 VIABLE ORGANISM RECOVERY [1]

2.6.1.1 METHOD

Individual tubes of each lot of BD Sterile Pack Swab were inoculated with 1000 colony-forming units (CFU)/ milliliter (mL) of the following working cultures:

Bacillus subtilis ATCC™ 6633 [c]
Candida albicans ATCC 10231 [a, e]
Escherichia coli ATCC 25922 [e]
Escherichia coli ATCC 8739 [b]
Micrococcus luteus ATCC 9341 [c]
Pseudomonas aeruginosa ATCC 9027 [a]
Salmonella typhimurium ATCC 14028 [e]
Salmonella typhimurium ATCC 13311
Staphylococcus aureus ATCC 6538 [a]
Staphylococcus epidermidis ATCC 12228 [d, e]

ATCC is a trademark of the American Type Culture Collection.
[a, b, c, d] USP recommended test organisms.[10, 11]
[e] NCCLS recommended test organisms.[12]

The tubes were sampled in duplicate immediately after inoculation as a baseline sample and again at two-hour time intervals up to 24 hours. Each sample was plated[3] on TSA for growth promotion using a quantitative spread plate method.[13] Sampling was designed to deliver approximately 100 CFU/plate with the expected recovery range to be 25 to 250 CFU [14] of appropriate microorganisms on TSA after incubation. The inoculums of 25 to 250 CFU/plate were targeted to reduce random sampling error and crowding effects on the TSA.

The plates were incubated at 35 $\pm$ 2°C in air and colonies counted after 16 to 18 hours of incubation. Incubation time was extended to 24 hours for *Candida albicans* and *Micrococcus luteus*. The duplicate plates were counted for each microorganism from each lot of BD Sterile Pack Swab rinse solution and the average result per microorganism was calculated.

The average recoveries from the two-hour timed samples were compared to the average recovery from the baseline samples to verify that the microorganism seeded in the tube remained static at its original inoculum concentration. The percent recovery was calculated by dividing the average timed plate count by the average baseline plate count for each microorganism.

The acceptable recovery range of the microorganisms from the timed samples was 70% to 130%[15] of the recovery from the same tube at the baseline sampling.

2.6.1.2 RESULTS

All microorganisms demonstrated satisfactory recovery within 2 hours at ambient room temperature and satisfactory recovery within 24 hours at refrigerated temperature. Additionally, 8 of the 10 microorganisms demonstrated satisfactory recovery within 4 hours at ambient room temperature.

2.6.2 NEUTRALIZATION EFFICACY

The purpose of a neutralizing efficacy study is to demonstrate the ability of the system to adequately neutralize the disinfectant agent, allowing unrestrained microbial growth. [16] Effectiveness of the neutralizer must be assayed in a way to show that:

- The neutralizer being assayed must not show inhibitory effects against the microorganism used in the assay.
- The neutralizer should overcome the disinfectant.
- The neutralizer plus the disinfectant plus the microorganism should result in consistent viable organism recovery.

The inclusion of suitable controls will give information on the possible toxicity of neutralizer, effectiveness of disinfectant and a microorganism viability/concentration check.[17]

2.6.2.1 METHOD

Three lots of the BD Sterile Pack Swab were verified for neutralization efficacy against benzalkonium chloride (Aldrich Chemical, Milwaukee, WI), phenol (Aldrich Chemical, Milwaukee, WI), and Spor-Klenz ® disinfecting solutions. A rinse solution inoculation step was followed by the spread plate method onto TSA.

In the inoculation step, individual tubes of the BD Sterile Pack Swab rinse solution were inoculated with various concentrations of disinfectant, mixed 10 times by inverting [18] then allowed to stand for one hour. The ratio of 1 to 50, disinfectant to rinse solution, was chosen so as not to dilute-out the rinse solution ingredients. Rinse solution without disinfectant was used as a neutralizer toxicity check and an inoculum confirmation. BBL Normal Saline with added disinfectant was used as a control to check the efficacy of the disinfectant, expecting no growth results. Normal saline without disinfectant was used as a microorganism viability check

For the spread plate method, all of the individual tubes of each lot of BD Sterile Pack Swab were inoculated with 1000 colony-forming units (CFU)/ milliliter (mL) of the following working cultures, [19] inverted 10 times and allowed to stand for 30 minutes.

Escherichia coli ATCC 11229
Pseudomonas aeruginosa ATCC 15442
Staphylococcus aureus ATCC 6538

The tubes were sampled in duplicate. Each sample was plated on TSA for growth promotion using a quantitative spread plate method.[13] Sampling was designed to deliver approximately 100 CFU/plate with the expected recovery range to be 25 to 250 CFU [14] of appropriate microorganisms on TSA after incubation.

A point to keep in mind when testing neutralization efficacy is that disinfectants are less effective against higher numbers of microorganisms used in the laboratory challenge tests than the numbers found in the clean rooms. Inocula from a log growth phase that are employed in the laboratory are more resistant than those from a static or dying or stressed organism in the environment.[19]

The plates were incubated at 35 $\underline{+}$ 2^{o}C in air and colonies counted after 16 to 18 hours of incubation. The duplicate plates were counted for each microorganism from each lot of BD Sterile Pack Swab rinse solution and the average result per microorganism was calculated.

The average recoveries from the tubes containing rinse solution and disinfectant were compared to the average recovery from the tubes containing only rinse solution to verify that the microorganism seeded in the tube with disinfectant remained static at its original inoculum concentration. The percent recovery was calculated by dividing the average rinse solution with disinfectant plate counts by the average rinse solution plate counts for each microorganism.

The concentration of disinfectant at which neutralization by the rinse solution was achieved was when consistent recovery of the microorganism from rinse solution with disinfectant was equivalent to the rinse solution alone. The lower recovery limit was 80%.

Also, the normal saline tube with disinfectant would result in no growth of any of the microorganisms assayed compared to the normal saline tube without disinfectant.

2.6.2.2 RESULTS

The BD Sterile Pack Swab neutralization efficacy of specific concentrations of the different disinfectants varied depending on the microorganism assayed.

Neutralization efficacy was achieved at benzalkonium chloride dilution ranges of 1/15,000 for *Staphylococcus aureus,* 1/1,000 for *Escherichia coli* and 1/750 for *Pseudomonas aeruginosa.*

Neutralization efficacy was achieved at phenol dilution ranges of 1% for *Staphylococcus aureus* and *Escherichia coli* and 0.5% for *Pseudomonas aeruginosa.*

Neutralization efficacy was achieved at all working concentrations of Spor-Klenz Ready-to-Use for *Staphylococcus aureus, Escherichia coli* and *Pseudomonas aeruginosa.*

The percent recoveries from the rinse solution without disinfectant control tubes were satisfactory showing no toxicity effect to the microorganisms. The salines with disinfectant control tubes were satisfactory showing no growth results in all dilutions with the microorganisms.

2.6.3 PERFORMANCE QUALIFICATION [15, 20]

A Performance Qualification is designed to ensure that the system performs as specified using selected compendia organisms for routine batch testing of product**.** To qualify the performance characteristics of BD Sterile Pack Swab for use in your facility, it may be necessary to meet certain performance requirements for reproducibility and accuracy. Approaches to testing reproducibility and accuracy are outlined in *The United States Pharmacopoeia*. It is recommended that each facility validate the BD Sterile Pack Swab independently given that each facility's quality and regulatory requirements, personnel, and working environment will vary.

2.7 PROBLEM REPORTING AND CORRECTIVE ACTION

Documented procedures are established to ensure that nonconforming material is prevented from unintended use. Product that fails to meet established specifications or standards or was not manufactured in accordance with all appropriate manufacturing procedures is investigated in detail. Our Quality Management and Regulatory

Compliance Departments are responsible for establishing and implementing a documented system for control and resolution of nonconforming materials.

If the test conducted in your facility during qualification or validation should fail, the failure should be investigated in detail. A written record of the investigation, including conclusions and corrective action should be made.

2.8 CUSTOMER REVIEW

BD Sterile Pack Swab is manufactured in compliance with BD polices/procedures, FDA cGMP and/or ISO 9000 standards. BD welcomes customer review of our adherence and compliance to these standards.

2.9 TOOLS, TECHNIQUES AND METHODOLOGIES

The validation plan and acceptance criteria are based on approved R&D protocols that incorporate referenced materials. (Refer to REFERENCES)

Your qualification or validation plan and acceptance criteria should be based on your facility's approved protocols.

2.10 RECORDS COLLECTION, MAINTENANCE AND RETENTION

All BD Sterile Pack Swab product documentation is located in the Quality Assurance Department. Documentation will be retained for the life of the products.

Your qualification or validation information should be filed in the Quality Department of your facility.

2.11 REVALIDATION

BD Diagnostic Systems revalidation studies will be conducted prior to implementation of major product changes that could affect the design and/or function of the BD Sterile Pack Swab. Any significant changes in process or product specifications will be documented following the BD Change Notification system. Further, the change will be validated prior to implementation into production for routine release of products. Refer to the AUTOMATED CHANGE NOTIFICATION PROGRAM section of this document for more information.
When process changes occur in your facility, review and evaluate the process and perform revalidation where appropriate. Any significant changes in your process or product specifications should be documented.

2.12 STUDY LIMITATIONS

The results of this study are only valid for the conditions evaluated in the study.
The BD Sterile Pack Swab is intended for the sampling and transport of microorganisms from surfaces. Each application by the end user must be independently qualified or validated for the specific application employed.

This validation summary information provided here can be used as a tool in qualifying or validating the use of the BD Sterile Pack Swab with your specific application(s).

For identification of any recovered isolates, subculture onto primary isolation media is required. Appropriate texts should be consulted for further information on microorganism identification. [21-24]

2.13 REFERENCES

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3 CERTIFICATE OF ANALYSIS

For your convenience, a Certificate of Analysis is included in each BD Sterile Pack Swab package. The Certificate of Analysis provides customers with a summary of QC tests performed and acceptance criteria for the tests that are lot specific.

Certificates of Analysis and Certificates of Origin are also available via our documentation service.

Certificate of Analysis

Sterile Pack Swab, Carton of 200, Catalog No. 220518

Physical Characteristics

Appearance:	Clear; opalescent or light precipitate is acceptable
pH at 25°C:	7.00 ± 0.50
Fill:	10 mL ± 1.0 mL

Biological Performance

Lot have been tested with the following organisms:

Culture	ATCC™	Result
Candida albicans	10231	Viable
Salmonella choleraesuis ssp. choleraesuis	13311	Viable
Staphylococcus aureus	6538	Viable
Escherichia coli	25922	Viable

Sterilization

Irradiation exposure is cerified to be no less than 25 kGy.

Results reported were obtained at time of release.

Microb. Quality Assurance

Lot Number will be perforated in this space

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

4 AUTOMATED CHANGE NOTIFICATION PROGRAM

BD Diagnostic Systems manufactures products for use in both the clinical laboratory and industrial laboratory. BD industrial products are used in fermentation applications, pharmaceutical production, quality control testing, and food/dairy/beverage testing.

BD recognizes that FDA and USDA regulated customers must provide certain types of change notification to regulatory agencies, as well as, to their own customers regarding changes to products. We have designed an automated notification system to provide assistance in meeting these requirements. This program assists the regulated customer in assuring the FDA and USDA that BD is providing notification regarding suppliers' product changes.

It is our policy to notify all customers of certain changes to any and all BD Diagnostic Systems products for any customers who require notification of changes above and beyond these changes, or by notification methods different from standard methods, BD has developed the Automated Change Notification Program. This program is available to all customers for most Difco™ and BBL brand culture media and other microbiology and cell culture products. In order to participate in this program, BD requests that the customer enter into a Change Notification Agreement with BD Diagnostic Systems.

5 CONTACT INFORMATION

Thank you for taking the time to review this package. If you have any questions regarding this document, please contact one of the following:

- Your BD Sales Representative in the USA at 1-800-219-7174.
- BD Technical Assistance: 1-800-638-8663, selection 2
- BD Customer Service: 1-800-675-0908
- 7 Loveton Circle
  Sparks, Maryland 21152 USA
  Worldwide to the USA: 1-410-316-4000
- **http://www.bd.com/diagnostics/support/**

- **APPENDIX 1: BD FUNCTIONAL AREAS**

FUNCTIONAL AREA	DESCRIPTION OF RESPONSIBILITY
Quality Management Regulatory Compliance (QM/RC)	Quality Assurance and Compliance: • Product Release • Scheduling of quality testing • Assuring that all product specifications are met • Approving qualification/validation protocols • Monitoring of validation runs • Preparation of summaries
Operations	Scheduling and production of project and production lots.
Research and Development	• Writing qualification/validation protocols • Product development/feasibility • Product reliability, stability and special testing
Technical Services	Customer facing and response to technical inquiries
Marketing	Customer notification