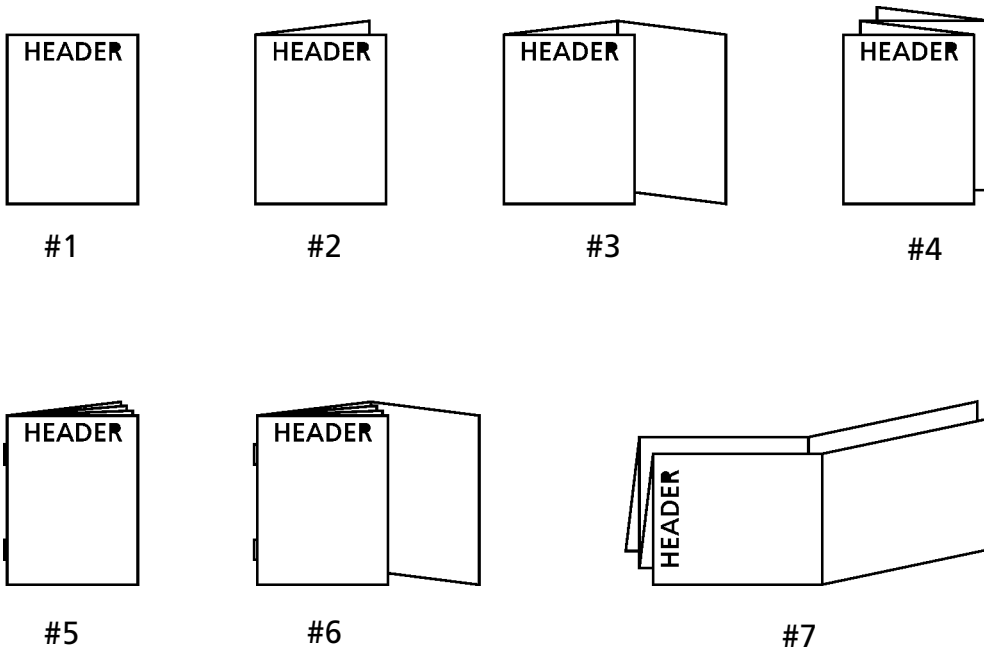


Revisions

Rev from	Rev to	ECO #
0299	0704	2996-04

Notes:

1. BD Cat. Number Various
2. Blank (Sheet) Size : Length: 11" Width: 8.5"
 Number of Pages: 4 Number of Sheets: 1
 Page Size: Length 8.5" Width 11" Final Folded Size: 5.5" x 8.5"
3. Style (see illustrations below): # 2



4. See Specification Control Number N/A for Material Information
5. Ink Colors: Printed two sides Yes No
 No. of Colors: 1 PMS# Black
6. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

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Part Number: 8809101		Category and Description Package Insert, BBL QualiSwab	Sheet: 1 of 5 <hr/> Scale: N/A	A



BD BBL™ QualiSwab™
Quality Control Culture Devices

8809101
2004/07**INTENDED USE**

BBL™ QualiSwab™ devices are for the preparation of microbial cultures employed in the quality control of microbiological media, reagents and procedures.

SUMMARY AND EXPLANATION

The quality control of microbiological reagents and procedures is an essential element of the laboratory testing process for clinical specimens. Testing laboratories are expected to maintain controls for each culture medium, reagent, biochemical reaction, and serologic determination performed. Strains chosen as quality control test organisms must exhibit predictable and reproducible reactions.¹

Reference strains have been available from several sources, including the American Type Culture Collection (ATCC™) and commercial suppliers. Commercially available disk and gel preparations have been considered advantageous because they are stable at 4°C for up to a year, require no maintenance and are relatively inexpensive.¹

QualiSwab Quality Control Culture Devices are a unique alternative to currently available culture preparations. Each device consists of a foam-tipped swab saturated with a stabilized preparation of viable microorganisms. Reconstitution in broth is not required. Cultures derived from these swabs may be used in the quality control of culture media, susceptibility and identification tests or test systems and other diagnostic products.

PRINCIPLES OF THE PROCEDURE

Continuous subculturing of microbial cultures increases the potential for mutation, contamination and loss of viability. Alternatively, microbial cultures preserved in a stabilizing medium within the swab remain viable and stable for long periods of time.²⁻⁴

Upon breaking the ampule and wetting the swab portion of the **QualiSwab** device, fresh, pure cultures are rejuvenated and ready for use in the quality control of a variety of diagnostic reagents and procedures.

REAGENTS

QualiSwab devices are stabilized, preserved cultures of microorganisms derived from ATCC strains embedded within the swab material. Each organism swab is contained in a sealed foil pouch. Each **QualiSwab** device also contains one ampule of 0.5 mL of Stuart's Transport Medium, consisting of sodium glycerophosphate, 1.0%; sodium thioglycolate, 0.1%; calcium chloride dihydrate, 0.01%; and water which serves as a wetting agent at the time of use (approximate concentrations).

Warnings and Precautions:

For *in vitro* Diagnostic Use.

Contains living microorganisms that are potential infectious agents. For protection of personnel and the environment, this product must be handled using combinations of laboratory practices and techniques, safety equipment and laboratory facilities necessary for containment at the biosafety level (BSL). The appropriate BSL must take into consideration the laboratory activity being performed and the documented or suspected routes of transmission. For detailed information, refer to the most recent edition of Biosafety in Microbiological and Biomedical Laboratories.⁵

Disposal Procedures: All contaminated and/or expired materials are considered to be regulated medical waste and must be disposed of in accordance with applicable federal, state, or local regulations. Decontamination may be attained by autoclaving prior to disposal.

After use, **QualiSwab** devices and other contaminated materials must be sterilized by autoclaving prior to disposal.

Storage Instructions: On receipt, store swab in pouch at 2–8°C. The expiration date applies only to swabs in intact pouches stored as directed. Discard expired swabs. Discarded swabs and sheaths must be sterilized by autoclaving.

Product Deterioration: Do not use swabs from unsealed pouches or swabs that have crushed ampules or show evidence of previous hydration.

PROCEDURE

Materials Provided: Each package contains one **QualiSwab** device with a stabilized, preserved microbial control culture as labeled. Also provided is one ampule crushing unit.

Materials Required But Not Provided: Culture media and laboratory equipment as required for this procedure.

Test Procedure

1. Remove one intact foil pouch from refrigerated storage.
2. Open pouch at tear slit and remove the **QualiSwab** device.
3. Hold cap-end down. **VERIFY THAT PROTECTIVE SAFETY SLEEVE IS OVER AMPULE.** If not, reposition safety sleeve before proceeding.
4. With the **QualiSwab** device in one hand and the blue crushing unit in the other, position the **QualiSwab** ampule perpendicular to and between the serrated arms of the crushing unit. Slide the **QualiSwab** device all the way back toward the center of the unit, beyond the serrated edges, until the ampule snaps into place. Squeeze the arms of the crushing unit together to crack the ampule. Continue squeezing gently until adequate wetting of the swab is achieved. Carefully slide the crushing unit off the **QualiSwab** device.

5. Remove cap from sheath and inoculate appropriate medium (see Table 1) that has been allowed to warm to ambient temperature.* Inoculate by streaking one-half of the surface of the medium with the **moistened** swab or rolling the **moistened** swab across the surface of the medium.

Use a flamed and cooled loop or a sterile plastic loop to streak the remaining surface from the inoculated area to obtain isolated colonies following incubation.

Alternatively, a suitable broth medium can be inoculated by dipping the swab into the broth and gently rotating the swab against the side of the tube before removing.

Incubate in an appropriate atmosphere and for the recommended time appropriate for the organism (see Table 1). Suitable anaerobic, microaerophilic and CO₂-supplemented atmospheres may be obtained through the use of GasPak™, Bio-Bag™, CampyPak™ or GasPak™ EZ (Anaerobe or Campy) systems.

*NOTE: For optimal recovery, a nonselective plating medium is recommended for *Campylobacter* species, with incubation at 35–37°C. Incubation at 42°C is **NOT** recommended.

Table 1
Suggested Subculturing for QualiSwab™ Cultures

Organism Type	Plating Medium	Incubation Conditions
Nonfastidious gram-positive or gram-negative aerobes and facultative anaerobes (e.g., <i>Staphylococcus</i> spp., <i>Enterobacteriaceae</i> and nonfermentative bacilli)	Trypticase™ Soy Agar with 5% Sheep Blood (Cat. No. 221239, 221261)	Aerobic, 35–37°C, 24–48 h.
<i>Neisseria</i> , * <i>Haemophilus</i> and <i>Moraxella</i> (<i>Branhamella</i>) spp.	Chocolate II Agar (Cat. No. 221169, 221267)	5–10% CO ₂ , 35–37°C, 24–48 h.
<i>Campylobacter</i> spp., including <i>C. jejuni</i> subsp. <i>jejuni</i> *	Chocolate II Agar (Cat. No. 221169, 221267)	Microaerophilic (5–12% CO ₂ , 5–15% O ₂), 35–37°C, 4–72 h. (NOT 42°C)
<i>Gardnerella</i> spp.*	V Agar (Cat. No. 221874, 221875) HBT Agar (Cat. No. 297884)	5–10% CO ₂ , 35–37°C, 24–48 h.
Anaerobic bacteria*	CDC Anaerobe Blood Agar (Cat. No. 221733, 221734) or Trypticase Soy Agar with 5% Sheep Blood (Cat. No. 221239, 221261)	Anaerobic, 35–37°C, 24–72 h. * <i>Porphyromonas gingivalis</i> takes 5–7 days for mature growth.
Yeasts	Sabouraud Dextrose Agar (Cat. No. 221180, 221278) Trypticase Soy Agar with 5% Sheep Blood (Cat. No. 221239, 221261)	Aerobic, 24–30°C 24–72 h.

*NOTE: For fastidious and anaerobic organisms, pre-warming of inoculating plates to 35–37°C will aid in the release of the microorganisms from the embedded stabilizing medium and enhance recovery.

6. Disposal Procedures: All contaminated and/or expired materials are considered to be regulated medical waste and must be disposed of in accordance with applicable federal, state, or local regulations. Decontamination may be attained by autoclaving prior to disposal.

User Quality Control: Examine swabs for signs of deterioration as described under "Product Deterioration." Using these control cultures, follow the quality control recommendations for the media, reagents and procedures being employed.

RESULTS

QualiSwab devices, when properly restored, should yield viable pure cultures of the desired strains providing correct results when utilized in properly performed procedures with reagents of satisfactory quality.

Refer to specific product inserts for pertinent reactions.

LIMITATIONS OF THE PROCEDURE

Some cultures may exhibit a prolonged lag phase upon inoculation onto growth media and should be incubated for twice the recommended incubation time before discarding as nonviable.

If the cultures perform incorrectly, the entire procedure should be checked; incorrect results may be due to the swab, preparation of the inoculum, product being tested, procedure being followed or other factors.

Performance depends not only on the proper handling of the swab, but on use of appropriate media and conditions for restoration and cultivation of microbial strains.

PERFORMANCE CHARACTERISTICS

In order to assure satisfactory performance of organism type as identified in Table 1 over its intended shelf life, an internal study was conducted to assess performance by: (1) determining purity of the organism on the swab; (2) determining colony recovery; (3) Gram stain; (4) biochemical identification using an automated identification system and/or standard biochemical tests; and (5) satisfactory performance on growth medium.⁵ All organism types exhibited satisfactory performance in the five areas identified above over the shelf life of the product.⁵

AVAILABILITY

Organism swabs are provided in sealed foil pouches. Refer to the BD Diagnostics Product Catalog for a list of the available cultures and catalog numbers.

REFERENCES

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