**BBL™ CultureSwab™ Plus**: are sterile ready-to-use systems intended for the collection, transport and preservation of clinical specimens for bacteriological examination.

**SUMMARY & PRINCIPLES:**
One of the routine procedures in the diagnosis of bacterial infections involves the collection and safe transportation of a clinical specimen from the patient to the laboratory. This can be accomplished using the BBL CultureSwab™ Plus collection and transport device. Each BBL CultureSwab™ Plus unit is comprised of a sterile peel pouch containing a rayon-tipped swab applicator used to collect the sample and a tube containing transport medium into which the swab applicator is placed after sampling.

The BBL CultureSwab™ Plus are available with Amies Medium Without Charcoal and Amies Medium With Charcoal. These transport media are non-nutritious, buffered with phosphate and provide a reduced environment, due to their formulation with sodium thioglycollate. Organisms in the sample material are protected from drying by moisture in the transport medium. The medium is designed to maintain the viability of organisms during transit to the laboratory. Survival of fastidious bacteria such as *Neisseria gonorrhoeae* can be prolonged due to the presence of charcoal in Amies Medium With Charcoal. BBL CultureSwab™ Plus pouches are made of a plastic film which retards the penetration of atmospheric air into the product.

**REAGENTS:**
The nominal formula for each L of Amies Transport Medium Without Charcoal:

<table>
<thead>
<tr>
<th>Sodium Chloride</th>
<th>3.0 g</th>
<th>Monopotassium Phosphate</th>
<th>0.2 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium Chloride</td>
<td>0.2 g</td>
<td>Disodium Phosphate</td>
<td>1.15 g</td>
</tr>
<tr>
<td>Calcium Chloride</td>
<td>0.1 g</td>
<td>Sodium Thioglycollate</td>
<td>1.00 g</td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>0.1 g</td>
<td>Bacteriological Agar</td>
<td>7.5 g</td>
</tr>
</tbody>
</table>

Amies Transport Medium With Charcoal is same formulation as above with addition of 10.0 g of charcoal. **Precautions**: For *in vitro* Diagnostic Use.

It must be assumed that all specimens contain infectious microorganisms; therefore, all specimens should be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

**BBL CultureSwab™ Plus** is for single use only; reuse may cause a risk of infection and/or inaccurate results.

**Storage**: Store BBL CultureSwab™ Plus at 5–25°C.
**Product Deterioration**: Contents sterile if unopened or not damaged. Do not use if they show evidence of damage, dehydration or contamination. Do not use past expiration date.
SPECIMEN COLLECTION & HANDLING:

The BBL CultureSwab™ Plus systems are available with different applicator shafts which facilitate the collection of specimens from various sites of the patient. For specific recommendations about collection of specimens for microbiological analysis and primary isolation techniques, consult the following references: Cumitech 9, Manual of Clinical Microbiology and Clinical Microbiology Procedures Handbook.

Once a swab sample is collected, it should be placed in the tube of medium, transported to the laboratory as soon as possible and cultured onto appropriate primary isolation media.

PROCEDURE:
Materials Provided: Fifty (50) units of sterile BBL™ CultureSwab™ Plus devices contained in each Vi-Pak Pouch.

Materials Required But Not Provided: Appropriate materials for isolating, differentiating and culturing aerobic and anaerobic bacteria. These materials include culture media plates or tubes and incubation systems, gas jars or anaerobic workstations.

DIRECTIONS for USE:

1. Peel open the BBL™ CultureSwab™ Plus pouch.
2. Remove cap from transport tube.
3. Remove applicator swab and collect specimen.
   During specimen collection, the applicator tip should only touch the area where the infection is suspected to minimize potential contamination.
4. Place applicator swab in transport tube.
5. Record patient’s name and information on tube label.
6. Send specimen to the laboratory for immediate analysis.

Directions, with diagrams, for use are printed on each BBL CultureSwab™ Plus unit.

EXPECTED RESULTS:
The survival of bacteria in a transport medium depends on many factors. These include the type of bacteria, duration of transport, storage temperature, concentration of bacteria in the sample and formulation of the transport medium. BBL CultureSwab™ Plus will maintain viability of many microorganisms for 24–48 hr. For fastidious bacteria such as Neisseria gonorrhoeae and Streptococcus pneumoniae and anaerobes, swab specimens should be plated directly onto culture medium or transported immediately to the laboratory and cultured within 24 hr.
LIMITATIONS OF THE PROCEDURE:

BBL™ CultureSwab™ Plus Amies Medium without Charcoal and Amies Medium with Charcoal are intended for the collection and transport of bacteriological samples only. Preferred samples for anaerobic investigations are: tissue samples obtained during surgical procedures, biopsies from tissue or bone, fluid, pus, or aspirates collected using a syringe. For detailed information and recommendations for transporting fluid and tissue specimens for anaerobic culture, refer to specific publications. Samples containing viruses or chlamydia should be collected and transported using alternative specific transport systems.

Transport media, staining reagents, immersion oil, glass slides and specimens themselves may sometimes contain nonviable organisms visible upon Gram staining. Caution should therefore be used when interpreting Gram stains from either sterile body fluids or specimens from normally sterile body fluids.

PERFORMANCE CHARACTERISTICS:

Recovery studies were performed using BBL™ CultureSwab™ Plus Amies Medium Without Charcoal and Amies Medium With Charcoal products with a variety of aerobic and anaerobic organisms. Swabs were dosed with inoculum and inserted into the transport tube containing medium. The tubes were stored at room temperature prior to subculturing onto appropriate media.

Aerobic/Faculative anaerobes organisms evaluated were Escherichia coli (NCTC 9001 and ATCC™ 25922), Haemophilus influenzae (ATCC 19418), Neisseria gonorrhoeae (ATCC 43069), Neisseria meningitidis (NCTC 10025 and ATCC 13090), Pseudomonas aeruginosa (NCTC 9332 and ATCC 27853), Staphylococcus aureus (NCTC 5532 and ATCC 25923), and Streptococcus pyogenes (ATCC 19615).

Anaerobic organisms evaluated were Bacteroides fragilis (ATCC 25285), Bacteroides levii (ATCC 29147), Bacteroides thetaiotaomicron (ATCC 29741), Bacteroides vulgatus (ATCC 8482), Clostridium difficile (ATCC 9689), Clostridium perfringens (ATCC 13124), Clostridium sporogenes (ATCC 3584), Clostridium tertium (ATCC 19405), Fusobacterium necrophorum (ATCC 25286), Fusobacterium nucleatum (ATCC 25586), Peptostreptococcus anaerobius (ATCC 27337), Peptostreptococcus magnus (ATCC 29328), Porphyromonas gingivalis (ATCC 33277), Prevotella melaninogenica (ATCC 25845), and Propionibacterium acnes (ATCC 6919).

All organisms tested remained viable for more than 24 hr when maintained at room temperature.

REFERENCES:


ATCC™ is a trademark of the American Type Culture Collection. NCTC are National Collection of Type Cultures operated by Public Health England.