

INTENDED USE

BactiSwab® Gel and BactiSwab® Liquid are intended for the collection and transport of biological specimens. After collection, specimens should be inoculated onto appropriate culture media as soon as possible. BactiSwab® Gel without charcoal (Amies Clear) and BactiSwab® Liquid (Amies or Stuarts) can be used when direct microscopic examination is necessary. BactiSwab® Liquid Stuarts, Wire Shaft with flexible wire is suitable for specimen collection from nasal areas.

SUMMARY AND EXPLANATION

BactiSwab® Gel and BactiSwab® Liquid are self-contained, ready-to-use specimen collection and transport systems. Each system consists of a round-bottom polypropylene tube containing one of the following transport media: Amies gel without charcoal (Amies Clear), Amies gel with charcoal (Amies Charcoal), Liquid Stuarts, or Liquid Amies each held in polyurethane foam. The tube is plugged with a high-density polyethylene plug. It also incorporates one or two plastic-shaft swabs, one minitip wire-shaft swab, or one minitip flexible wire-shaft swab, secured on a biohazard safety-skirted plug cap. The swab(s) and tube are packed in a pouch and sterilized by gamma irradiation.

PRINCIPLE

Four media formulations are available: Amies Charcoal, Amies Clear, Liquid Amies, and Liquid Stuarts. All four media are non-nutritive, highly reductive due to the presence of sodium thioglycolate, and buffered with phosphate.^{1,2} This maintains the viability of microorganisms within the specimen during transport. All four media are recommended for collection and transport of aerobic and facultative microorganisms. In the gel media (Amies Charcoal and Amies Clear), the moisture and depth of the media further provide an ideal environment for survival of anaerobic organisms.^{3,4} The charcoal in BactiSwab® Amies Charcoal neutralizes fatty acids in the specimen that may be inhibitory to fastidious organisms, including *Neisseria gonorrhoeae*. Specimens should be transported to the laboratory as soon as possible or within 48 hours of collection and inoculated onto appropriate culture media. Fastidious microorganisms should be transported within 24 hours.

REAGENTS (CLASSICAL FORMULA)*

REAGENTS	AMIES CLEAR	AMIES CHARCOAL	LIQUID STUARTS	LIQUID AMIES
Sodium Chloride	3.0 g/l	3.0 g/l	-----	3.0 g/l
Disodium Phosphate	1.15 g/l	1.15 g/l	-----	1.15 g/l
Sodium Thioglycolate	1.0 g/l	1.0 g/l	1.0 g/l	1.0 g/l
Monopotassium Phosphate	0.2 g/l	0.2 g/l	-----	0.2 g/l
Potassium Chloride	0.2 g/l	0.2 g/l	-----	0.2 g/l
Calcium Chloride	0.1 g/l	0.1 g/l	0.1 g/l	0.1 g/l
Magnesium Chloride	0.1 g/l	0.1 g/l	-----	0.1 g/l
Charcoal	-----	10.0 g/l	-----	-----
Disodium Glycerophosphate	-----	-----	10.0 g/l	-----
Agar	5.0 g/l	5.0 g/l	-----	-----

PRECAUTIONS

This product should be used by properly trained individuals (in U.S.A. - for *In Vitro* Diagnostic use only). Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully. The sterility of the unit is ensured only in unopened, intact, sealed pouches.

STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at 4-25°C until used. Do not freeze or overheat. Do not incubate prior to use.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.^{3,4} Inoculate specimens onto appropriate culture media as soon as possible after being received in the laboratory. Refrigeration at 4-6°C provides a safe and dependable method of storing many clinical specimens until they can be conveniently processed. Never refrigerate genital, eye, or ear specimens, or specimens for anaerobic culture. Follow established laboratory safety procedures to avoid potential exposure to infectious agents. Consult appropriate references for more information regarding the safe and proper handling of clinical specimens.

PRODUCT DETERIORATION

This product should not be used if (1) the sterility of the unit is in question, (2) there is evidence of dehydration or contamination, (3) the expiration date has passed, or (4) there are other signs of deterioration.

MATERIALS PROVIDED

- One sterile tube with cap containing one of four transport media.
- One or two sterile rayon-tipped swab(s) with plastic shaft or one minitip swab with wire shaft or flexible wire shaft fitted into a biohazard safety plug.

MATERIALS REQUIRED BUT NOT SUPPLIED

Refer to appropriate references for necessary equipment required in specimen collection and packaging materials for transport.^{3,5}

PROCEDURE

- Peel-open the sterile pack.
- Remove plug from the tube.
- Remove the swab and collect the specimen.
- Insert the swab into the tube and push into the plug.
- Record the patient information on the label.
- Send specimen to the laboratory for immediate processing.
- Upon receipt in the laboratory, specimens should be promptly processed according to laboratory guidelines.

QUALITY CONTROL

Each lot of BactiSwab® Gel and BactiSwab® Liquid is subjected to the following quality control evaluations:

- Performance - Samples of each lot are challenged by standard microorganism inocula and tested for recovery on appropriate plated media according to current CLSI guidelines (M40-A).
- Background organisms - Microbiological staining and microscopic examination are performed on random samples. This is to ensure that there is no significant background debris or cell structure present.
- Physical appearance - Medium level, medium integrity, pouch seal, tube seal, and label information are some of the physical attributes of the product that are inspected.
- pH - Each lot number of product is checked against the standard pH of 7.25 ± 0.25.

LIMITATIONS

- Follow recommended guidelines for proper specimen collection. Consult appropriate references when necessary.^{3,4}
- Optimal recovery is achieved by direct specimen plating and smear preparation at the time of collection from the patient. Because this is not always possible, swabs provide a useful alternative for specimen collection and transport.
- Anaerobes, chlamydiae, mycoplasmas, and viruses require special transport systems. Consult appropriate references for transport of suspected potential pathogens.
- Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results.
- Transport media may maintain viability of fastidious organisms for a short period of time. Loss of viability of potential pathogens or overgrowth by commensal microbial flora may occur if transport time is excessive. Immediate culturing is recommended for *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Bordetella pertussis*, and other fastidious organisms.
- Handle specimens aseptically. Avoid contamination from indigenous flora at the site of collection, when possible.
- Never discard an unopened specimen without obtaining a new specimen or consulting with the physician, or both.^{3,4}
- BactiSwab® Liquid Stuarts will maintain and transport aerobes and facultative anaerobes that are pathogenic and normally recovered from the body.

BIBLIOGRAPHY

- Amies, C.R. 1967. Can. J. Public Health. 58:296-300.
- Starplex Scientific Internal Evaluation.
- Isenberg, H.D. 2004. Clinical Microbiology Procedures Handbook, 2nd ed. ASM Press, Washington, D.C.
- Murray, P.R., E.J. Baron, J.H. Tenover, M.L. Landry, and M.A. Pfaller. 2007. Manual of Clinical Microbiology, 9th ed. ASM Press, Washington, D.C.
- Clinical and Laboratory Standards Institute (CLSI). 2003. Quality Control of Microbiological Transport Systems; Approved Standard. M40-A. CLSI, Wayne, PA.

PACKAGING CONFIGURATIONS

Each BactiSwab® Gel includes rayon-tipped, plastic-shaft swab(s) mounted in the cap of a translucent plastic tube with spiral chamber containing gel transport medium with or without charcoal.

Each BactiSwab® Liquid includes rayon-tipped, plastic-shaft swab(s) mounted in the cap of a translucent plastic tube with spiral chamber containing a sponge impregnated with Liquid Amies or Liquid Stuarts transport medium.

Refer to individual product descriptions in the Remel catalog or visit www.remel.com for specific information about the materials supplied.

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

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