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PROBACT AMIES COLLECTION & TRANSPORT SYSTEM

CONTENTS
Probact Amies Medium in tube with Swab applicator sealed and sterilised in peel pouch (M40-A2 compliant). This document is available in different languages, please enquire using the contact details in the header or on website for availability.

INTENDED USE
Professional use only. The Probact Amies Transport System is intended for use in the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the patient to the laboratory for gathering information once examined and/or cultured. This device provides no diagnosis only offers transport of specimens. Please read and follow the instructions in this package insert carefully and use aseptic techniques.

PACK SIZE & SHELF LIFE
100 individual pouches per box supplied. Shelf life is 24 months (2 years) from manufacture.

SUMMARY AND EXPLANATION
Clinical system for collecting and transporting bacteriological specimens routinely examined through the laboratory to aid the diagnosis of bacterial infections, especially useful for when there is a delay between specimen collection and processing.

The Probact Amies Transport System kit consists of a sterile peel-open pouch containing a swab and a sealed tube (with replaceable cap) containing 5ml of Probact Amies medium. The tube contains a semi-solid phosphate-buffered medium capable of maintaining the viability of aerobic, anaerobic, and fastidious bacteria such as *Neisseria gonorrhoeae* during transport to the laboratory. Inorganic Buffers maintains the pH, Sodium thioglycollate provides a reduced environment whilst the cations/salts help to maintain osmotic balance and maintain the membrane permeability of bacterial cells.[4,9]

Various swabs are available: Viscose, Polyester and Cotton, with and without score points to facilitate specimen collection from various sites on patients' bodies. For longer transportation, the Amies medium is supplemented with Charcoal to neutralise metabolic byproducts produced to enhance post 24hrs survival.

PRINCIPLES OF THE PROCEDURE
Once a specimen is collected with a swab, it should be placed into the transport medium immediately and processed as soon as possible to achieve optimum recovery. In cases where immediate processing (i.e., within 2-4 hours) is not possible, specimens can be stored at 4–25°C and depending on media type; samples should be processed within 24 hours (for Amies without charcoal) or within 48 hours (for Amies with Charcoal). However, *Neisseria gonorrhoeae* should be processed upto 24hrs for both. Recent independent studies suggest that the viability of certain bacteria in swab transport systems will improve when transported or stored at refrigerated temperature.[5,10,]

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REAGENTS

Approximate Probact Amies medium formulation per litre:

Sodium Chloride	3.0
Potassium Chloride	0.2
Potassium dihydrogen Phosphate	0.2
Sodium thioglycollate	1.0
Disodium Hydrogen Phosphate	1.2
Calcium Chloride	0.1
Magnesium Chloride	0.1
Purified Agar	7.5

Probact Charcoal Medium (as above) plus:

Activated Charcoal	10.0

TECHNICAL NOTES

Probact Amies medium will look cloudy/opaque. This appearance is a chemical characteristic and is normal.

MATERIALS PROVIDED

Each Probact Amies Transport System kit can be purchased in the following combinations:

Configuration		**Product Codes**	
Swab Material	**Swab Shaft**	**Amies Clear**	**Amies Charcoal**
Viscose	Polystyrene (semi flexible)	TS/5-17	TS/5-18
Viscose	Aluminium (solid shaft)	TS/5-5	TS/5-6
Cotton	Polystyrene (semi flexible)	TS/5-17A	TS/5-18A
Cotton	Birchwood (breakable)	TS/5-1	TS/5-2
Viscose	Polystyrene (breakpoint)	TS/5-9	TS/5-10
Cotton	Treated Paper (semi flexible)	N/A	TS/5-8

STORAGE

For optimum performance of the Probact devices, store at 4–25°C. Avoid freezing or excessive heat for long periods.[3,8,10]

MATERIALS NOT PROVIDED

Materials for the microscopic examination, cultivation, differentiation, and isolation of bacteria from clinical specimens are not provided. Please refer to standard laboratory procedures or referenced standards for the cultivation, isolation, and identification of bacteria from clinical specimens.[4,3,8]

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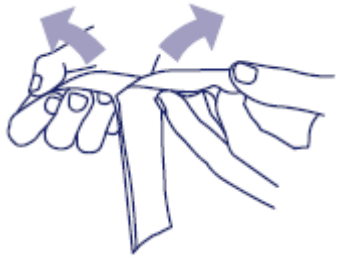
DIRECTIONS FOR USE (Keep Samples cool until sampling is performed)

STEP 1.

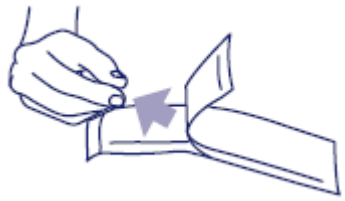
Identify the area to be sampled, ensuring the correct kit has been chosen (see Materials provided table and Precautions & Limitations).

STEP 2.



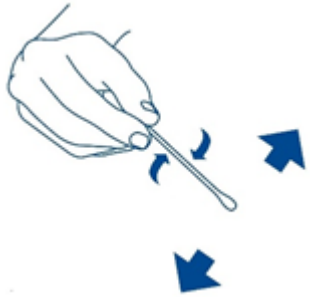
Peel open the pouch using the pull tabs located at one end of the pouch.

STEP 3.



Remove the swab and tube from the peel pouch keeping the transport tube within reach. **Discard the peeled pouch.**

STEP 4.



Swab the area to the sampled. Check Precautions & Limitations regarding certain swab types.

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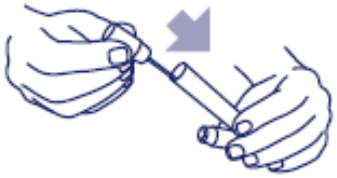
STEP 5.



When sampling is completed, insert the swab into the transport tube until the cap sit flush with the top of the tube.

STEP 6.

Write the patient details onto the tube label and send to the laboratory immediately for processing.

SPECIMEN COLLECTION, STORAGE & TRANSPORT

Proper specimen collection from the patient along with storage is critical for successful isolation and identification of infectious organisms. To maintain optimum organism viability, the specimens collected using Probact Amies System should be sent to the laboratory within 4 hours of collection. Specimens should be processed as soon as they are received into the laboratory using a protective and safe environment including suitable PPE (for example laminar flow cabinet, Lab coat, safety glasses).

For specific guidance regarding specimen collection procedures, consult published reference manuals.[1,2,3,10] If immediate delivery or processing is delayed, then specimens should be refrigerated at 4-8°C or stored at room temperature (20-25°C) processing Amies Clear within 24 hours, and Amies Charcoal within 48 hours. The only exception is suspected *Neisseria gonorrhoeae* which should be processed within 24 hours irrelevant of media type.

<u>Direct microscopic examination</u>

The Gram stain procedure can be performed and is used in laboratories for direct microscopic examination of patient clinical samples with Amies Clear being preferred. The procedure can be a useful tool that allows the laboratory personnel to assess the quality of the specimen and provide additional information to the physician managing the patient therefore assisting diagnosis and treatment.[10,11]

For further information or guidance on the preparation of specimen slides for microscopic analysis, for information on Gram staining procedures and the interpretation and reporting of microscopic analysis, consult published laboratory reference manuals.[1,2,3,8,10]

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Specimen cultures in the laboratory

Probact Amies System specimens should be processed for bacteriological culture using recommended culture media and laboratory techniques which will depend on the specimen type and the potential organism under investigation. For recommended culture media and techniques for the isolation and identification of bacteria from clinical swab specimens refer to published microbiology manuals and guidelines.[1,2,8,10,12]

QUALITY CONTROL

All raw materials used in the manufacture of Probact Amies Transport System are tested and qualified before use. Every batch of Probact Amies Transport System is tested prior to release for sterility, pH, and bio-burden levels. Representative samples of each batch are further evaluated for their ability to maintain the viability of selected micro-organisms over the predefined time periods.

All bacterial test isolates and testing procedures were established using the criteria outlined in the Clinical and Laboratory Standards Institute's M40-A2 document.[12]

PRECAUTIONS & LIMITATIONS

All clinical specimens should be considered biohazards and handled with care. Wear appropriate personal protective equipment and follow laboratory and biosafety guidelines when handling clinical specimens.

- Not suitable for self-testing and must be used by qualified healthcare professional.
- Do not push device through packaging – use the peel function. Otherwise the device will be damaged.
- Do not use the device beyond the expiration date printed on the label or pouch.
- Do not use the device if the peel pouch seal or the tamper seal on the tube is damaged or has been unintentionally opened before use.
- Do not use the device if the media or swab or any of the components appears discoloured, faulty/missing, tainted or the presentation affected in any form.
- Only use components contained within the same pouch or tube to maintain device compatibility and function. Any unauthorised or external additions will jeopardise performance and give spurious results.
- The breakpoint swab provided in certain kits is scored at a specific point to allow for easy breakage after transferring the swab tip to an external vial for easier processing. However, whilst collecting specimens from patients it is the responsibility of the professional user to ensure care is taken not to use excessive force, pressure, twist, angling or lose sight of the bud that might lead to premature breakage of the swab shaft requiring medical intervention to resolve.
- It is the responsibility of the user to ensure the appropriate device is used for the application.
- Do not ingest (or attempt to ingest) any part of the device.

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- Ensure any used devices are processed using local Health & Safety and biohazard controls. After analysing, decontaminate device and dispose of according to biohazard waste disposal regulations.
- Do not ingest Probact Amies medium.

Reliable specimen collection and transport depends on many factors, including collection and handling techniques, initial specimen condition and volume, and timing. Best results are achieved when specimens are processed shortly after the time of collection. Refer to the corresponding reference standard and procedures for optimum collection techniques.[8,10]

- Viability of other microorganisms in the Probact Amies System other than the ones shown in the Performance Characteristics section have not been established.
- The performance of the Probact Amies System for storage time over 48 hrs has not been evaluated.
- Extreme temperatures should be avoided during transportation of the collection system.
- Use of the Probact Amies System in conjunction with rapid diagnostic kits and instruments must be validated prior to use by the user.
- Breakpoint swab are unsuitable for certain sample areas (body cavities, twists, bends or where poor visibility is experienced) due to the breakpoint activating before desired.
- Probact Amies Transport System is recommended for aerobic, anaerobic, and fastidious organisms. Viruses, Chlamydiae, mycoplasmas, and ureaplasmas require a transport medium formulated specifically for use with these organisms.[12,13,14]

PERFORMANCE CHARACTERISTICS

The performance characteristics of Probact Amies Transport System were determined using the procedures outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A2 document.[12] A variety of aerobic, anaerobic, and fastidious organisms were included in this study. The test organisms comprised of the ten ATCC strains that are recommended in the CLSI

M40-A2 document for determining performance characteristics of swab transport systems.[12] To determine the performance characteristics of the Probact Amies Transport System, bacterial viability studies were performed. These studies were conducted at two different temperatures to reflect refrigerated (4-8°C) and room temperature (20-25°C) conditions. The swabs from each transport system were inoculated in duplicate with a specified volume of select bacterial concentrations. These swabs were then placed in their respective transport vial and held for 0, 24, and 48 hours; at the designated time intervals the swabs were removed and processed. These studies were conducted using both the Roll-Plate and Swab Elution Methods.

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Organisms Evaluated:

ORGANISM	STRAIN
Pseudomonas aeruginosa	ATCC BAA-427
Streptococcus pyogenes	ATCC 19615
Streptococcus pneumoniae	ATCC 6305
Haemophilus influenzae	ATCC 10211
Bacteroides fragilis	ATCC 25285
Peptostreptococcus anaerobius	ATCC 27337
Fusobacterium nucleatum	ATCC 25586
Propionibacterium acnes	ATCC 6919
Prevotella melaninogenica	ATCC 25845
Neisseria gonorrhoeae	ATCC 43069

Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A2 were followed using the Roll-Plate Method. For the viability to be considered acceptable, there shall be ≥5 CFU following the specified holding time from the specific dilution that yielded zero-time plate counts closest to 300 CFU. The results of the study by Roll-Plate Method are presented in the Tables below. The results demonstrate the ability of Probact Amies Transport System to sustain the viability and recovery of test bacteria within acceptance criteria for at least 48 hours at refrigerated (4-8°C) and room (20-25°C) temperatures.[12]

Neisseria gonorrhoeae results support acceptable recoveries up to 24 hours as recommended in the CLSI guidance M40-A2 document.[12]

Viability performance studies also included an assessment of bacterial overgrowth at the refrigerated temperature. Overgrowth assessment as defined in CLSI M40-A2 guideline is greater than 1 $\log_{10}$ increase in CFU between zero-time and the holding time point for certain ubiquitous organism(s). There was no increase in bacterial count when the samples were stored at 4-8°C for 48 hours and analysed by the Roll-Plate Method.[12]

Representative data of bacterial recovery results for Amies with and without Charcoal using the Roll Plate Method at Room and Refrigerated Temperature is available on request for each lot produced.

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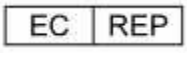
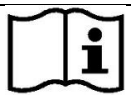
SYMBOLS EXPLAINED (not limited to):

Symbol	Brief Description
	Manufacturer
	Unique reference associated to product
	Product Reference
	Sterilised by Gamma Irradiation
	Storage Conditions (defined max/min limits added to lines)
	If Packaging or device damaged do not use
	Not Reusable/Single use only
	Expiry
	Indicates conformity to the general safety and performance requirements set out in the European directive and/or regulations.
1639	Notified Body number the CE conformity is approved through. Must be adjacent to CE symbol.
	Authorised Representative in the European Community
	In Vitro Diagnostic symbol used with CE Mark.
	Consult Instructions For Use
	Caution, see instructions
	Electronic Instruction For Use indicator

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UKCA	United Kingdom (UK) Conformity Assessment Mark.
UDI	Unique Device Identifier
MD	Medical Device

REFERENCES

1. Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry, D.W. Warnock. 2011. Manual of Clinical Microbiology, 10th ed. American Society for Microbiology. Washington, DC.
2. Balows, A., W.J. Hausler Jr, K.L. Herrmann, H.D. Isenberg, H.J. Shadomy. 1991. Manual of Clinical Microbiology, 5th ed. American Society for Microbiology. Washington, DC.
3. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, R.H. Yolken. 1995. Manual of Clinical Microbiology, 6th ed. American Society for Microbiology. Washington, DC.
4. Amies CR. 1967. A modified formula for the preparation of Stuart's medium. Can J Public Health 58:296–300.
5. Serra-Pladevall Judit; Gulin Blanco Carlos; Vila Olmo Neus; Arjona Camacho Pilar; Andreu Domingo Antonia. Preservation of *Neisseria gonorrhoeae*: should swabs be refrigerated or not?: *Neisseria gonorrhoeae* preservation.
6. Sewell, D.L. 1995. Laboratory-associated infection and biosafety. J Clin. Microbiol. Rev 8:398–405. American Society for 8 Microbiology. Washington, DC.
7. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risk related exposure to biological agents at work. Official Journal of the European Communities. L 262/21–45.
8. Miller, J.M. 1996. A guide to specimen management in clinical microbiology. American Society for Microbiology. Washington, DC.
9. Wikipedia. https://en.wikipedia.org/wiki/Thioglycolate_broth
10. Oxoid Online Manual, Amies Transport Media. CM0425.
11. Spiegel, C.A., R. Amsel, K.K. Holmes. 1983. Diagnosis of bacterial vaginosis by direct gram stain of vaginal fluid. J. Clin. Microbiol. 18:170–177.
12. Clinical and Laboratory Standards Institute. 2014. Quality Control of Microbiological Transport Systems; Approved Standard-Second Edition. M40-A2, vol. 34, no. 9.
13. V Fiacco, M J Miller, E Carney, and W J Martin. 1984. Comparison of media for isolation of Ureaplasma urealyticum and genital Mycoplasma species. J Clin Microbiol. Nov; 20(5): 862–865.
14. D L Barnard, K Farnes, D F Richards, G F Croft, and F B Johnson. 1986. Suitability of new chlamydia transport medium for transport of herpes simplex virus. J Clin Microbiol. Nov; 24(5): 692–695.