TECHNICAL DATA SHEET

Page 21 General Catalogue 2017

Amies transport swabs, sterile

codes 300287 - 300281 - 300285 - 300281/1 - 300281TC

	code	description	case quantity	case weight (kg)	case volume (m^3)
without charcoal	300287	snappable polystyrene + viscose	6 x 100	9.33	0.060
	300281	Aluminum + viscose	6 x 100	9.08	0.056
with charcoal	300285	snappable polystyrene + viscose	6 x 100	9.37	0.058
	300281/1	Aluminum + viscose	6 x 100	9.15	0.052
	300281TC	Twisted aluminum + viscose	6 x 90	8.24	0.057

Swab for sampling: Directive 93/42/EEC. Medical Devices. MDD CE 0318, Class IIa
Tube with transport media: Directive 98/79/EC "in Vitro" Diagnostic Medical Devices.

COMPONENTS

- A 13 x 165 mm sterile round bottom tube with cap, made of non-distorting polypropylene and suitable for food use, containing the transport media.
- A swab consisting of a snappable PS or aluminium shaft, equipped with a safety cap that perfectly seals the tube (cap made of blue polyethylene).
- A label that seals the cap to the tube. The label provides space for patient's name, sample collection date and hour, number, doctor, specimen nature and hospital name. Also indicated are the expiry date, lot number, product description and brand.

- A peel-pack that contains the tube and the swab and protects them from external agents before its use. Batch number, bar code, expiry date, product code, brand and description, and instructions for use are printed on the peel-pack.
- Expiry date: 30 months from the sterilisation date. Certificate upon request.

Swabs are manufactured in a Clean Room. The CE Mark Class IIa allows their use in surgery as invasive products.

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Page 21 General Catalogue 2017

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DIMENSIONES

code	Shaft	Shaft length (mm)	Ø shaft (mm)	Ø tip (mm)	tip	length tube + cap
300287 300285	Polystyrene	150	2.5	5.0	Viscose	145 + 20
300281 300281/1	Aluminum	150	0.9	1.5	Viscose	145 + 20
300281TC	Twisted Aluminum	147	0.6	3.0	Viscose	145 + 20

Internal tube diameter: 10.94 mm
External tube diameter: 12.85 mm

AMIES TRANSPORT MEDIUM - FEATURES

AMIES is an evolution of Cary Blair medium, which in turn is of Stuart. Basically, the glycerophosphate is changed by an inorganic phosphate. In the version with charcoal, methylene blue is replaced by vegetal charcoal neutral pharmaceutical grade.

It allows the viability of many microorganisms like:
Pseudomonas aeruginosa
Haemophilus influenzae
Bacteroides fragilis
Corynebacterium sp.
Trichomonas vaginalis
Streptococcus pyogenes
Streptococcus pneumoniae
Propionibacterium acnes
Shigella flexneri
Salmonella typhi
Brucella abortus
Enterobacteriaceae
Neisseria sp.
etc.

These media allow the recovery of Aerobic, Facultative Anaerobic and Anaerobic microorganisms up to 48 hours, and 24 hour for Fastidious Bacteria like *Neisseia gonorrhoeae*, according to independent studies made following the methodology of the CLSI standard M40-A2.

In 1987, Amies suggested to modify the transport medium elaborated by Stuart in his 1946, 1954 (with Toshach and Patsula), and 1959 publications. Amies explained that the glycerophosphate that Stuart used as a buffer could favour the growth of certain Gram negative germs, so he replaced it by a buffer made of inorganic phosphates. Amies added 0,3 g % of NaCl to the medium to favour the stability of *Neisseria gonorrhoeae*, and included salts of Ca2+ and Mg2+ so as to maintain the viability of the bacterial cells.

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Amies also noticed that the gonococco was viable for a longer time in presence of vegetal charcoal, which he added onto the tip of the swabs designed for sample collection. But he soon realised that those swabs were quite unpopular, as patients disliked such bad-looking, black coloured swabs. He then decided to include the vegetal charcoal inside the transport medium and avoided the patients' opposition.
Amies also eliminated the methylene blue – unnoticeable when mixed with vegetal charcoal -and increased the quantity of agar, as vegetal alter the gelificating properties of agar.
This media assures the viability of organisms such as: Neisseria sp., Haemophilus sp., Corynebacterium sp., *Trichomonas vaginalis, Streptococcus pyrogenes, Streptococcus pneumoniae, Shigella flexneri, Salmonella typhi, Brucella abortus*, Enterobacterie, etc.
Some microorganisms can resist on the media for up to 3 days, although the recovery of microorganisms is better if cultured in the first 24 hours.

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Page 21 General Catalogue 2017

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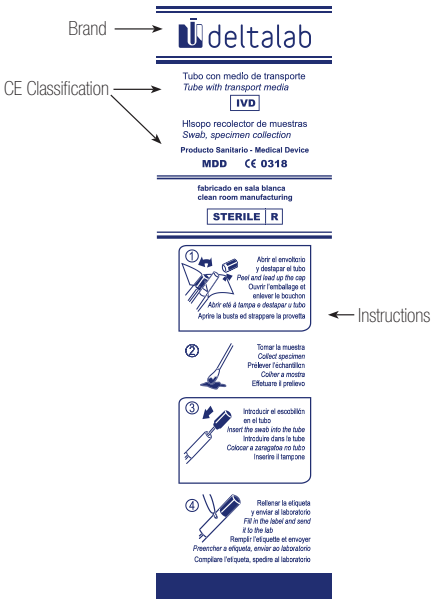
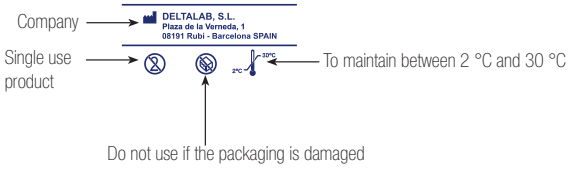
DISEÑO PEEL-PACK





INSTRUCTIONS OF USE

1. Open the pack.
2. Remove the swab to take the plug.
3. Collect the sample.
4. Insert the swab into the tube after removing the safety plug.
5. Transport to the laboratory.

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QUALITY STANDARDS AND REQUIREMENTS

Directive 93/42/EEC. Medical Devices. MDD CE 0318, Class IIa
Directive 98/79/EC "in Vitro" Diagnostic Medical Devices.

Standards For Quality System and Product:

- UNE EN ISO 9001 de Sistemas de Gestión de la Calidad.
- UNE EN ISO 13485 Sanitary Products. Systems of Quality management. Requirements for regulatory purposes.
- UNE EN ISO 14971 Sanitary Products. Application of risk on management.
- UNE EN ISO 15223 Sanitary Products. Symbols to use on labels, labeling and information to be supplied. Part 1: general requirements.
- CLSI M40-A2 Quality control of Microbiological Transport Systems.

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