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FLOCKED SWAB SAMPLE COLLECTION KIT

Intended purpose:
Kit for the collection and transport of biological samples for subsequent microbiological analysis by *in vitro* examination by specialised health personnel under appropriate hygiene conditions. Single-use device.

Device presentation:
The kits are *in vitro* diagnostic medical devices. They consist of a swab and a transport medium. The swabs are medical devices and the tubes with transport medium are *in vitro* diagnostic medical devices. The swab sample collection kits are individually packaged. This kit can be supplied sterilised or non-sterilised. Sterile kits specify the sterilisation method on their individual packaging.

The kit does not include the material required for the isolation and cultivation of microorganisms.

*See the types of transport medium and the references included in the electronic version of these Instructions for Use.

General overview of the test:
The sterile swab sample collection kit enables the safe collection and transport of clinical samples for infection diagnosis. After sample collection, the swab is placed in the tube containing the transport medium, the function of which is to preserve the viability of the microorganisms until they reach the laboratory. The medium prevents the sample from drying out by keeping it moist and it provides suitable conditions for the microorganisms to remain stable during transport. Once the sample is received, the laboratory processes it using the appropriate techniques and resources for microbiological identification.

Use / Test procedure:
Instructions for use with graphics are included in the primary packaging.

- **Sample collection:**
  Obtain the clinical sample according to the applicable handbooks and reference guides. Ensure that the collection conditions, volume and transport time are suitable to ensure reliable results.

- **Sample handling:**
  Process and handle the samples in accordance with good clinical and laboratory practice. Avoid unnecessary delays that may compromise the viability or integrity of the microorganisms.

- **Sample transport:**
  Comply with local regulations in force for transporting biological samples. In hospital settings, additionally follow the internal procedures established by the healthcare facility.

- **Use in combination with diagnostic methods or kits:**
  If the product is used in conjunction with a specific diagnostic method or kit, the user or the manufacturer of that method/kit must verify its compatibility. Where appropriate, validate and document the acceptability of the device for use in the relevant analytical procedure.

Interpretation of the results:
The reliability of the results largely depends on the sample collection, transport and analysis operations being carried out correctly and in accordance with the established procedures. The stability and integrity of the microorganisms present in the biological sample can be influenced by a number of factors, including:

- The type of sample collected.
- The time between its collection and analysis in the laboratory.
- The storage conditions during transport, especially temperature and protection from light.
- The initial concentration of the microorganism of interest.
- The formulation and characteristics of the transport medium or system used.

These factors should be taken into account when interpreting the results during processing of the sample by the laboratory. Improper sample handling or sub-optimal transport conditions may compromise the validity of the results obtained.

Storage and stability during use:
Before use, the product should be stored in a dry place, protected from direct sunlight, at a temperature between 2°C and 30°C.
Do not use the product after the expiry date stated on the label or packaging.
Compliance with these storage conditions ensures the stability and proper functioning of the product throughout its shelf life.

For stability conditions during use, depending on the sample and the type of transport medium, please refer to the table of transport medium types on page two of these electronic Instructions for Use.

Sterility:
The product sterilisation methods are indicated on the labelling.

Warnings:
1. If the individual packaging breaks, do not use the product as there is no guarantee of sterility.
2. Do not use if any component is missing or if the printed information on the product is not displayed correctly.
3. Dispose of the device if any swab is found to be dirty, broken and/or with sharp edges or without a head.
4. Do not use after the expiry date.
5. Do not use if any alteration, dehydration or contamination of the transport medium is observed.
6. Handle with care. Although unlikely, exerting too much pressure during use could break the swab. In case of breakage, dispose of it immediately.
7. Wash or rinse with plenty of water if liquid comes into contact with skin, eyes or mouth. Do not ingest. Do not inhale.
8. For single use only; reuse of this device may lead to infection.

General precautions:
1. The use of the kit presents no difficulty for the intended users.
2. Not suitable for any application other than its intended use.
3. The swab is a class IIa medical device according to Regulation (EU) 2017/745, surgically invasive devices intended for short-term use. It is designed for the collection of samples from external surfaces of the patient or from internal surfaces accessible through natural or surgical body orifices.

Safe disposal of the device, its accessories and consumables:
Once the sample has been collected, dispose of any surplus material in accordance with local legislation and regulations.

Each laboratory is responsible for the handling, treatment and disposal of the waste generated, following internal procedures and the applicable regulations.

Unused swabs can be considered as non-hazardous waste and disposed of in accordance with general non-special waste management regulations.

Quality control:
All raw materials, components and finished product batches are subjected to rigorous quality controls to ensure their conformity with the established specifications. Sterilisation processes are also systematically validated and verified, ensuring the sterility and safety of the device until the end of its shelf life.

References:

1. Cuñé J. et al. A superficial swab culture is useful for microbiologic Diagnosis in Acute Prosthetic Joint infections. Clin Orthop Relat Res, 467: 531-535. 2009.
2. Gil P, et al. Importancia del diagnóstico de laboratorio y la toma de muestras para el diagnóstico y tratamiento de micosis en Podología. El Peu, 29(4): 216-221. 2009.
3. García JM, et al. Recogida, transporte y procesamiento general de las muestras en el laboratorio de Microbiología. Procedimientos en Microbiología Clínica. Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica (SEIMC). 2017.

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Transport medium	Recommended use	Sample storage conditions from sample collection to the laboratory
Amies liquid medium	In this formulation, sodium, potassium, calcium and magnesium chlorides maintain an osmotic balance. Phosphates act as a buffer system. Thioglycolate provides the reducing environment. Designed for subsequent cultivation on selective or differential media by manual or automated seeding. Compatible with molecular diagnostic techniques and for direct extension on slides.	Maintains the viability of aerobic, facultative anaerobic and strictly anaerobic bacteria for up to 48 hours at ambient (20-25°C) and refrigerated (2-8°C) temperatures. Demanding bacteria, for up to 24 hours at a refrigerated temperature (2-8°C).
Cary Blair liquid medium	Suitable for transporting anaerobic microorganisms from faecal samples. Designed for subsequent cultivation on selective or differential media by manual or automated seeding. Compatible with PCR molecular diagnostic techniques and for direct extension on slides.	Viability of faecal pathogens (*Salmonella* and *Shigella*) for a minimum of 48 hours without overgrowth, at ambient (20-25°C) and refrigerated (2-8°C) temperatures.
Viral liquid medium	Its formula is chemically defined and non-nutritive, to produce a reducing, buffered and osmotically balanced environment. Designed for subsequent cultivation on selective or differential media by manual or automated seeding, compatible with molecular diagnostic techniques.	It keeps a wide variety of viruses viable for periods of more than 72 hours, both at ambient temperature (20-25°C) and refrigerated (2-8°C). It contains antibiotics that inhibit Gram-positive and Gram-negative bacteria and fungi.
MtVi medium	Its formula is chemically defined and non-nutritive. The composition of the medium ensures inactivation of viruses, inactivation of DNAases/RNAases and preservation of nucleic acids present in the sample. Designed for cell culture, performing antigenic studies for viral detection and genomic amplification techniques by PCR.	It allows viruses to be detected up to 72 hours after sampling, both at ambient temperature (20-25°C) and refrigerated (2-8°C).
ViCUM medium	Formulated with a solution of balanced salts, bovine serum albumin, HEPES buffer, antibiotics and appropriate antifungals and preservatives, with a pH that ensures the viability of viruses, *Chlamydia*, *Mycoplasma* and *Ureaplasma* species. Contains phenol red and antibiotics that inhibit the growth of bacteria and fungi, ensuring adequate sample recovery. Each tube contains glass beads to facilitate cell lysis, sample homogeneity and maximise elution. Designed for cell culture, performing antigenic studies for viral detection and genomic amplification techniques by PCR.	It allows viruses to be detected more than 72 hours after sampling, both at ambient temperature (20-25°C) and refrigerated (2-8°C).
LIM BROTH	Selective enrichment medium for group B streptococci (*Streptococcus agalactiae*). Indicated to maximise the chances of recovery of group B streptococci (*Streptococcus agalactiae*) on blood agar plates from genital and/or faecal samples. The addition of nalidixic acid and colistin sulphate is intended to inhibit the growth of gram-negative microbiota.	Once the sample has been taken, keep the swab immersed in the transport medium, preferably kept refrigerated until it is processed in the laboratory.

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References	Description	CE marked
304225F	AMIES 1ML FLOCKED SWAB NASOPH. 100MM FLOW	IVD CE 0318
304227KF.SA	AMIES 2ML FLOCK. SWAB ST BP80 C/NO GRIP FLOW	
304222KF	AMIES 1ML FLOCKED SWAB URETRAL 80MM FLOW	
304221KF	AMIES 1ML FLOCKED SWAB STANDARD 80MM FLOW	
304221KF.TM	AMIES 1ML FLOCK SWAB ST 80MM FLOW MAUVE CAP	
304223KF	AMIES 1ML FLOCK.SWAB NASOPH. 80MM FLOW	
304224KF	AMIES 1ML FLOCK.SWAB MINITIP 80MM FLOW	
304260KF	CARY BLAIR 2ML FLOCK.SWAB ST. 80MM FLOW	
304305KF	VIRUS 3ML FLOCK SWAB NASOPH. 80MM FLOW	
304243KF	VIRUS 3ML FLOCK SWAB STANDARD 80MM FLOW	
304227KF	AMIES 2ML FLOCKED SWAB STANDARD 80MM FLOW	
304305KF.2S	VIRUS 3ML FLOCK SWAB STD 80MM+NAS80MM FLOW	
304305KFI	INACT. VIRUS 3ML FLOCK SWAB NAS. 80MM FLOW	
304227KP.3S	AMIES 2 ML FLOCK NASO 80+STD 80+URET 80 PEEL	
304243KFI	INACTIVANT VIRUS 3ML FLOCK.SWAB ST 80MM FLOW	
304230KF.2S	VICUM 2ML FLOCK SWAB STD80MM+NASOPH 80MM FLOW	CE IVD
304234KF	VICUM 2ML FLOCKED SWAB NASOPH. 80MM FLOW	
304236KF	VICUM 2ML FLOCK SWAB URET. 80MM FLOW	
304213KF	LIM BROTH 2ML FLOCK SWAB STD 80MM FLOW	
304238KF	VICUM 2ML FLOCK SWAB STD 80MM FLOW	
304233F	VICUM 3ML FLOCK SWAB STD 100MM FLOW	
304239KF	VICUM 2ML FLOCK SWAB MINITIP 80MM FLOW	
304233.I	VICUM 3ML FLOCK SWAB STD 100MM	

Glossary of symbols:

REF	Catalogue number	LOT	Batch number	deltalabgroup.com/eifus	For the instructions for use, see *www.deltalabgroup.com/eifus*	QTY	Quantity	STERILE R	Sterilised by irradiation
IVD	In vitro diagnostic medical device		Date of manufacture		Do not use if the packaging is damaged		Do not reuse	2°C 30°C	Storage temperature
	Keep away from sunlight		Manufacturer		Expiry date	CE 0318	CE marked		Medical centre or doctor
UDI	Unique device identifier		Unique sterile barrier system	MD	Medical Device		Patient identification	31	Date

In the event of a serious incident* related to the device, notify both Deltalab, S.L. and the competent authority of the State in which the user is established. *"Serious incident" means an incident that leads to death or serious deterioration of the patient's or user's health or a serious threat to public health.

Sterile kit: IVD CE 0318 Non-sterile kit: CE IVD

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