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EN

STERILE SWAB SAMPLE COLLECTION KIT

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

Device presentation:
The kits *in vitro* diagnostic medical devices. They consist of sterile swabs and transport medium. The swabs are medical devices and the tubes with transport medium *in vitro* diagnostic medical devices. The sterile swab sample collection kits are individually packaged.

*See the types of transport medium and the references included on page two of these Instructions for Use.

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

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 swabs are found to be dirty, broken and/or with splinters and/or with the head not compacted and/or missing.
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. For paediatric use, it is recommended to use the swab with the plastic or aluminium holder.
2. The use of the kit presents no difficulty for the intended users.
3. Not suitable for any application other than its intended use.
4. 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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References	Description
300280	CARY BLAIR WOOD+COTTON
300281	AMIES SWAB ALUMINIUM+VISCOSE
300285	AMIES+CHARCOAL SWAB PS+VISCOSE
300287	AMIES SWAB PS+VISCOSE
300290	STUART SWAB WOOD+COTTON
300291	STUART SWAB ALUM+COTTON
300295	STUART 13X165MM PS W/VISCOSE
300298	VIRUS 2ML PS+VISCOSE
300280.2	CARY BLAIR SWAB PS+VISCOSE
300281/1	AMIES CHARCOAL SWAB WIRE+VISCOSE
300284.SE	AMIES SWAB LIQUID PS+VISCOSE NO SPONGE
300299.SE	CHLAMYDIA SWAB PS+POLYESTER NO SPONGE

Transport medium	Recommended use	Sample storage conditions from sample collection to the laboratory
Amies semi-solid 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 and agar-agar the solidifying agent. Designed for subsequent culture on selective or differential media, antibiogram testing.	These media allow recovery of demanding aerobic, facultative anaerobic and anaerobic microorganisms for up to 48 hours at ambient temperature (20-25°C), as well as demanding bacteria such as *Neisseria gonorrhoeae* for 24 hours under refrigerated conditions (2-8°C).
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)
Amies semi-solid medium with charcoal	In this formulation, sodium, potassium, calcium and magnesium chlorides maintain an osmotic balance. Phosphates act as a buffer system. Thioglycolate provides the reducing environment and agar-agar the solidifying agent. Charcoal helps neutralise toxic substances present in the sample and improves the recovery rate of *Neisseria gonorrhoeae* and *Vibrio cholerae*. Designed for subsequent cultivation on selective or differential media.	These media allow recovery of demanding aerobic, facultative anaerobic and anaerobic microorganisms for up to 48 hours at ambient temperature (20-25°C), as well as fastidious bacteria such as *Neisseria gonorrhoeae* for 24 hours under refrigerated conditions (2-8°C).
Chlamydia semisolid medium	Nitrogen-free medium, containing glutamate and 1% bovine albumin in buffered saline at pH 7. It contains antibiotics that inhibit Gram-positive and Gram-negative bacteria and fungi. Recommended transporting samples containing *Chlamydia*. Also for transporting *Rickettsia*, *Mycoplasma* and for some viruses, such as Herpes virus. Culture in cell lines such as adaptation to ELISA immunological techniques.	Isolation is optimised if samples are kept refrigerated immediately after collection at a temperature between 2 and 8°C and kept refrigerated during transport to the laboratory. The time between sample collection and processing in the laboratory should be less than 48 hours.
Stuart semi-solid 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 and agar-agar the solidifying agent. Designed for subsequent cultivation on selective or differential media.	When the sample is taken with a swab, it is advisable to impregnate it with a suspension of activated charcoal before placing it in the transport medium. Aerobic, facultative anaerobic and strictly anaerobic microorganisms can resist in the medium for a minimum of four days under refrigerated conditions. Fastidious bacteria such as *Neisseria gonorrhoeae* survive for 24h under refrigerated conditions (2-8°C) and the use of viscose swabs is recommended. At ambient temperature, aerobic and facultative anaerobic bacteria resist for a minimum of four days, while strictly anaerobic bacteria resist for two days.
Cary Blair semi-solid medium	Suitable for transporting anaerobic microorganisms from faecal samples. In the formulation, sodium, potassium, calcium and magnesium chlorides maintain an osmotic balance. Phosphates act as a buffer system. Thioglycolate provides the reducing environment and agar-agar the solidifying agent. Designed for subsequent cultivation on selective or differential media.	Storage temperature: · Ambient temperature (15-25°C): suitable for faecal samples in general. · Refrigeration (2-8°C): recommended especially if *Campylobacter jejuni* is suspected or if transport exceeds 24 hours. · Vaginal samples with anaerobes: should be transported at 4°C for better recovery. Maximum storage time: · Ideal: transport the sample to the laboratory within 4-6 hours, maximum 24 hours. · Acceptable: up to 4 days after sample collection if kept under appropriate conditions. Note: Some research studies have described longer survival times for certain pathogens (e.g. *Shigella* and *Salmonella* up to 49 days, *Vibrio cholerae* up to 22 days and *Yersinia pestis* up to 75 days under controlled conditions). However, such extended periods are not recommended in routine practice as they may compromise the viability of more sensitive microorganisms. For optimal results, samples should always be processed as soon as possible.

Glossary of symbols:

REF	Catalogue number	LOT	Batch number	deltalab.es/eifus	For the instructions for use, see *www.deltalab.es/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		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.

DELTALAB, S.L.
Plaza de La Verneda 1, Pol. Ind. La Llana,
08191 Rubí, Barcelona. España/Spain.
info@deltalabgroup.com - www.deltalabgroup.com

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