

STERILE SAMPLE COLLECTION KIT WITH SWAB

Intended use:

Sterile kit for the collection and transport of biological samples for subsequent microbiological analysis through in vitro examination, to be performed by qualified healthcare professionals under appropriate hygienic conditions. Single-use product.

Presentation:

The swab sample collection kit are presented unitarily packed in a peelable peel-pouch bag, containing a swab and a tube with transport medium.

Product description:

The kits are in vitro diagnostic medical devices. They are composed of sterile surgical-type swabs and transport media. The swabs are classified as medical devices, while the tubes containing transport medium are classified as in vitro diagnostic medical devices.

The Sterile sample collection kits with swab are individually packaged.

The kit does not include the materials required for the isolation and culture of microorganisms.

Please refer to the types of transport media included in the second page of this electronic version of the Instructions for Use.

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Assay overview:

The Sterile sample collection kit with swab allows the safe collection and transport of clinical samples for the diagnosis of infections. After collection, the swab is placed into the tube containing the transport medium, which preserves the viability of microorganisms until arrival at the laboratory. The medium prevents the sample from drying out by maintaining moisture and provides suitable conditions to keep microorganisms stable during transport. Once the sample is received, the laboratory proceeds with processing using the appropriate techniques and media for microbiological identification.

Test procedure:

Instructions for use with graphics are included in the primary packaging.

• Sample collection:

Collect the clinical sample following the applicable reference manuals and guidelines.

Ensure that collection conditions, sample volume, and transport time are adequate to guarantee the reliability of results.

• Sample handling:

Process and handle samples according to good clinical and laboratory practices.

Avoid unnecessary delays that may compromise microorganism viability or integrity.

• Sample transport:

Comply with current local regulations for the transport of 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 combination with a specific diagnostic method or kit, the user or the manufacturer of such method/kit must verify its compatibility.

Where applicable, validate and document the acceptability of the product for use in the corresponding analytical procedure.

Interpretation of the results:

The reliability of the results largely depends on the correct performance of sample collection, transport, and analysis operations in accordance with established procedures.

The stability and integrity of the microorganisms present in the biological sample may be influenced by several factors, including:

- The type of sample collected.
- The time elapsed between collection and laboratory analysis.
- The storage conditions during transport, particularly 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 must be taken into account when interpreting results during laboratory processing of the sample. Improper handling of the sample or suboptimal transport conditions may compromise the validity of the results obtained.

Storage and in-use stability:

Before use, the product must be stored in a dry place, protected from direct sunlight, and at a temperature between 2 °C and 30 °C.

Do not use the product after the expiration date indicated on the label or packaging. Compliance with these storage conditions ensures the stability and proper performance 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 media types included in the second page of this electronic version of the Instructions for Use.

Sterility:

Sterilization methods are specified on the label.

Warnings:

1. Do not use the product if the individual package is damaged, as sterility cannot be guaranteed.
2. Do not use if any component is missing or if the printed product information is not clearly legible.
3. Discard the product if any swab is found to be dirty, broken, splintered, with a loose head, or missing its head.
4. Do not use after the expiration date.
5. Do not use if any alteration, dehydration, or contamination of the transport medium is observed.
6. Handle with care. Although unlikely, excessive pressure during use may cause the swab to break. In case of breakage, discard immediately.
7. Rinse thoroughly with plenty of water if the liquid comes into contact with skin, eyes, or mouth. Do not ingest. Do not inhale.
8. For single use only. Reuse of this product may cause infection.

General precautions:

1. For pediatric use, swabs with a plastic or aluminum shaft are recommended.
2. The use of the kit does not present 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 under Regulation (EU) 2017/745, a surgically invasive device intended for transient use, 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 product, its accessories and consumables:

- Each laboratory is responsible, after sample collection, for the disposal of any remaining material in accordance with the applicable local legislation and regulations on the management of biological waste.
- Used products must be decontaminated beforehand or managed as potentially contaminated healthcare waste.
- Unused swabs may be considered non-hazardous waste and disposed of in accordance with general regulations for non-special waste management.

Quality control:

All raw materials, components, and finished product batches are subjected to rigorous quality controls to ensure compliance with the established specifications. Likewise, sterilization processes are systematically validated and verified, ensuring the sterility and safety of the product throughout 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.

Ref	Description
7.012.211.110	AMIES WITH CHARCOAL -POLYSTYRENE + VISCOSE
7.012.210.110	AMIES - POLYSTYRENE + VISCOSE
7.012.220.110	STUART - POLYSTYRENE + VISCOSE

Transport medium	Recommended use	Sample storage conditions from collection to laboratory
Amies semi-solid	In this formulation, sodium, potassium, calcium, and magnesium chlorides maintain osmotic balance. Phosphates act as a buffering system. Thioglycolate provides the reducing environment, and agar-agar acts as the solidifying agent. Designed for culture in selective or differential media, as well as for antibiotic susceptibility testing.	These media allow the recovery of aerobic microorganisms, facultative anaerobes, and fastidious anaerobes for up to 48 hours at room temperature (20–25 °C), as well as fastidious bacteria such as <i>Neisseria gonorrhoeae</i> for 24 hours under refrigeration (2–8 °C).
Stuart semi-solid	In this formulation, sodium, potassium, calcium, and magnesium chlorides maintain osmotic balance. Phosphates act as a buffering system. Thioglycolate provides the reducing environment, and agar-agar acts as the solidifying agent. Designed for culture in selective or differential media. When the sample is collected with a swab, it is recommended to moisten it with an activated charcoal suspension before inserting it into the transport medium.	Aerobic microorganisms, facultative anaerobes, and strict anaerobes can survive in the medium for at least four days under refrigeration. Fastidious bacteria such as <i>Neisseria gonorrhoeae</i> remain viable for 24 h under refrigeration (2–8 °C), and a viscose swab is recommended. At room temperature, aerobes and facultative anaerobes remain viable for at least four days, while strict anaerobes remain viable for two days.

Symbol glossary:

REF Catalogue number	LOT Batch code	 Consult instructions for use on www.deltalabgroup.com/equimed-ifus	QTY Quantity	STERILE R Sterile by irradiation
IVD In Vitro Diagnostic Medical Device	 Manufacturing date	 Do not use if Package is damaged	 Do not re-use	 Storage temperature
 Keep away from sunlight	 Manufacturer	 Use-by-date	CE CE marking	 Health care centre or doctor
UDI Unique device identifier	 Unique sterile barrier system	 Patient identification	0318 Date	

en In case of a serious incident* related to the product, notify to Deltalab, S.L. as well as the competent authority of the State in which the user is established. *A "serious incident" is understood as one that entails the death, or serious deterioration of the health of the patient or user or a serious threat to public health.