KIT DESCRIPTION

Code	Description
230417	**UNI-TER:** **Sterile swab with plastic stick (CE 0373) + polypropylene test tube Ø 12xh140mm with AMIES with charcoal (CE IVD) transport medium**

Dimensions of kit components:

Test tube	**Diameter:**	**12,00 mm outer test tube**
	Height:	**143,50 mm outer test tube**
cap	**Diameter:**	**12,50 mm external**
	Height:	**26,00 mm external**
swab	**Length:**	**147,64 mm**
	Diameter:	**2,11 mm**

Kit packing:

Single kit in Peel pack	Inner packing Carton box	External packing Carton boxes
Peel pack printed in green color bearing: CE IVD Diagnostic medical device in vitro + CE 0373 Medical Device – Manufactured by Meus S.r.l. via Leonardo da Vinci 24/b, Piove di Sacco ITALY – STERILE R – Store at room temperature (+5/+25 C°) - lot manufacturing data (in black)	*4 carton boxes of 100 pcs of single kit – label bearing: code 230417 pcs. 100, description, lot, expiry, Manufacturer: Meus S.r.l. via Leonardo da Vinci 24/B 35028 Piove di Sacco ITALY – Contains Medical Device KIT CE 0373 (Direction 93/42/CEE) + IVD CE (Direction 98/79/CE)- Store at room temperature (+5/+25 C°) - lot manufacturing data*	*Label bearing: code REF 230417 pcs. 400, description, lot, expiry, Manufacturer Meus S.r.l. Via L. Da Vinci, 24/B 35028 Piove di Sacco (PD) ITALY – Contains Medical Device KIT CE 0373 (Direction 93/42/CEE) + IVD CE (Direction 98/79/CE)- Store at room temperature (+5/+25C°) - lot manufacturing data – bar code – sterilization seal and utilization symbols. Every carton box contains Multilanguage directions.*

Kit Sterilization:

By irradiation as per directives:
UNI EN 556-1 Requirements for medical devices carrying sterile indications,
UNI EN ISO 11137-1:2006 Sterilization of medical products – Radiation – Part 1
UNI EN ISO 11737-2 Microbiological methods – Sterility tests performed during the validation of sterilization process.

Quality system applied for the kit preparation referring to:

UNI EN ISO 9001:2000, certificate ICIM n. 4264/0 issued by ICIM S.p.a. on 18/01/2007

UNI EN ISO 13485 : 2004 certificate ICIM n. 4265/0 issued by ICIM S.p.a. on 18/01/2007
CE: production quality system guarantee approved as per Directive 93/42/CE (D.L. 46/1997 by competence of Instituto Superiore di Sanita, CE certificate no. 099 QPS 144 (23/022004) Notify Body no. 0373.

EN 375 In Vitro Diagnostic Devices – Requirements for labels and information about products related to reagents for in vitro diagnostics devices for professional use.

UNI EN 980 Symbols used for labelling medical devices.

UNI CEI EN 14971 – Application of risk management to medical devices.

Raw material kit components certifications:

All raw materials used are non toxic, food and medical certified, as per European and FDA (USA) directives.

Kit destination use:

SWAB (Medical Device: CE 0373): indicated for clinical sample collection for microbiological analysis regarding: eyes, ears, breasts, throat and nasopharynx, urogenital system, rectum and various exudates.

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TEST TUBE (CE IVD) containing transport culture: indicated for transport for safe conservation of microbe flora eventually present in the collected sample.

The KIT must be used by professionally qualified staff.

Kit use directions

1. Open the single peel-pack packing containing the swab and the test tube with transport media and remove the cap from the test tube.
2. Extract the swab taking care to handle it by the cap where the swab is attached and avoid any contact between the swab and other surfaces different from the collection area.
3. Perform the collection.
4. Introduce the swab into the test tube containing the transport media and immerse it completely into the transport media in conformity with microbiological techniques and Good Laboratory Practice. Make sure that the cap with the swab is correctly inserted into the test tube in order to guarantee the closure.
5. Identify the sample and send it quickly to the laboratory.

Part regarding Medical Devices Directive 93/42/EC

Synthetic fiber swab (RAYON) on plastic polystyrene anti-shock shaft inserted in a polyethylene cap carrying "CE 0373" imprint.

Dimensions of device:		
Cap	**Diameter:** **Height:**	**12,50 mm external** **26,00 mm external**
Swab	**Length:** **Diameter:**	**147,64 mm** **2,11 mm**

Device material composition:	
Cap	**Swab**
Polyethylene	**Rayon tipped applicator on plastic polystyrene anti-shock shaft suitable for use in medical procedures**

Device destination use:
SWAB suitable for clinical sample collection for microbiological analysis regarding: eyes, ears, breasts, throat and nasopharynx, urogenital system, rectum and various exudates. **The KIT must be used by professionally qualified staff.**

Part regarding In Vitro Diagnostic Medical Device Directive 98/79/CE

Test tube (CE IVD) with transport media:

Material composition:		
Test tube	**Cap**	**Transport media**
Polypropylene	**Polyethylene**	**Amies with charcoal**

Dimensions e specifications:

Test tube	**Diameter:** **Height:**	**12,00 mm outer test tube** **143,50 mm outer test tube**
	White self-adhesive paper label 75x25 mm, breaking line between cap and test tube - printed: STERILE, date, room, id n°, name, test, CE IVD, Sterile R, MEUS S.r.l. Piove di Sacco - Italy, lot, exp, type of media + sensible data + utilization symbols "for in vitro diagnostic use only"	
Blue cap	**Diameter:** **Height:**	**12,50 mm external** **26,00 mm external**
Transport media:	**Amies with charcoal**	

COMPOSITION* per liter of distilled water (conductibility < 3µS)	g/l
Sodium thioglycolate	**1**
Sodium chloride	**3**
Potassium chloride	**0,20**
Calcium chloride	**0,10**
Magnesium chloride	**0,10**
Potassium phosphate monobasic	**0,20**
Potassium phosphate dibasic	**1,15**
Agar	**5**

pH 7.2 ± 0.3

**Base formula on which some changes may be performed in order to optimize the media performance.*
No other components or presevatives not listed in the composition are added.

DESTINATION OF USE

Sterile culture media ready to use in test tube for safety transport and the conservation of aerobic and anaerobic microbic flora.

This product must be used by professionally qualified staff only.

DESCRIPTION

The transport media has the function to maintain alive the micro-organisms for a period of time long enough to allow the transport of the sample from collection site to the lab where the culture test will be performed.
The composition of the media allows the preservation of aerobic and anaerobic micro-organisms (even if the survival time of anaerobic ones is necesserally shorter than the other bacteria).
The semisolid media is not nutritive and the presence of buffered saline solution, substituting the sodium glycerophosphate Stuart media, avoids excessive development of contaminant flora allowing a better isolation of pathogenies.

This media allows a good preservation for at least:

48-72 hours Streptococci, intestinal pathogens (as: Salmonella spp, Shigella Spp., E.coli,…) and Staphylococci;
24 hours Neisseria gonorrhoea;
12-24 hours Haemophilus influenzae, Bordetella pertussis, Gardnerella vaginalis.

MODALITY OF USE

See kit utilization modalities.

METHOD LIMITS

The media is not suitable to transport samples for VIRUS or CLAMIDYA research.

Time limits for a good preservation of bacteria in transport media are listed in the description. However must be considered that the survival of bacteria is influenced by several factors (example: bacteria charge, temperature of preservation, modalities of transport, vitality of bacteria) and it is recommended to transport as soon as possible the samples at the lab.

QUALITY CONTROL

Inoculate the swab with bacteria strain and subsequent immersion into transport media. Preservation at room temperature (15-25ºC) for 12-48 hours depending on bacteria strain and subsequent subculture in proper media.

Neisseria gonorrhoea	**ATCC 19424**	Growth after 24 hours
Haemophilus influenzae	**ATCC 10211**	Growth after 12 hours
Streptococcus pneumoniae	**ATCC 6305**	Growth after 48 hours
Streptococcus pyogenes	**ATCC 19615**	Growth after 48 hours

Further controls could and should be done in function of domestic and European directives.

PERFORMANCE

The performances of every manufactured lot, referring to the ATCC strains indicated, are listed in the internal Control Quality Sheet which generates the Conformity Certificate delivered on Client request.

The performance evaluation of the product as related to raw materials used and suitability of the production process applied, have been made using several strains both of ATCC or clinical origin. The tests carried confirmed the suitability of the media for the applications above listed. All strains used have maintained a good survival for periods over 24 hours.

PRECAUTIONS FOR USE

Manipulation of samples, inoculated media and bacterial cultures have to be done by qualified and equipped staff in function of the risks relative to the handling of potentially infective materials. It References: NCCLS M29-A2 "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Second Edition".

PRESERVATION

Preserve at **5-25°C avoid from light** until expiry date indicated on each single packaging.

The quantity of media present in the tube is approximately **4 ml**.

Shelf life of the kit duly preserved: **560 gg** from production date.

DISPOSAL MODALITIES

Before the use the kit must be considered as non hazardous: CER 18 01 07 "chemical substances different from those stated in field 18 01 08"

After use the product is medical waste potentially hazardous and infective: CER 18 01 03* "waste that must be collect and disposed applying particular precautions mto avoid infections."