LICKSON®

CE

**TECHNICAL SHEET**

# S-UVTM-K (Swab-Universal Viral Transport Medium-Kit)

**IVD in Class A, EU Reg. 2017/746**
For in vitro diagnostic use **IVD**

Collection and Transport system for Viruses, Chlamydia, Mycoplasma and Ureaplasma.

## DESCRIPTION

Collection and Transport system for Viruses, Chlamydia, Mycoplasma and Ureaplasma. The kit is compatible with viral culture, antigen detection and molecular assays. Universal Viral Transport Medium (with Phenol Red) is suitable for the collection, transport and storage of clinical specimens containing Viruses, including SARS-CoV-2 (COVID-19), Chlamydia spp., Mycoplasma spp. and Ureaplasma spp. Universal Viral Transport Medium (with Phenol Red) contains antimicrobial agents to inhibit bacterial and fungal contamination. A pH indicator (phenol red) indicates the medium integrity during the shelf life of the product.
In addition, as recommended by the CDC and FDA guidelines, the nasopharyngeal swabs used for sample collection are ultra-thi and have a breakpoint that allow, after the biological sample collection, the insertion into the test tube and captured by a particular leak-proof screw cap. The tube stands upright on the bench thanks to the sirte, flat-bottom, while the conical shape allows an appropriate centrifugation of the sample.

## NASOPHARYNGEAL SWAB

| DETAILED SPECIFICATION | |
|---|---|
| Total lenght: | 150 mm |
| The lenght for the tip: | 20 mm |
| The lenght for the breakpoint: | 80 mm |
| The diameter for the tip: | 3 mm |

## Universal Viral Transport Medium (with Phenol Red):

| COMPOSITION |
|---|
| Sucrose |
| Hanks Balanced Salt Solution (HBSS) |
| Bovine Serum Albumin (BSA) |
| HEPES Buffer |
| L-Cysteine |
| L-Glutamic Acid |
| Vancomycin |
| Colistin |
| Amphotericin B |
| Phenol Red |

**pH finale 7,3 ± 0,2 a 25°C**

## WARNING AND PRECAUTIONS

**For in vitro diagnostic use.**
Observe the precautions normally taken when handling laboratory reagents.
**Prepared Medium:** The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous.
**Safety Data Sheet** is available on request for professional users.
Disposal of waste (hazardous waste with infectious risk) must be carried out according to national and local regulations in force.

## PREPARATION

Ready to use.

## STORAGE AND STABILITY

**S-UVTM-K (Swab – Universal Viral Transport Medium – Kit):** 2-25°C

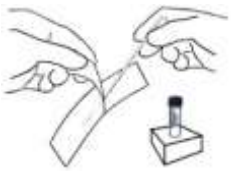
S-UVTM-K is stable until the expiration date indicated on the label under the recommended storage conditions.

## INSTRUCTIONS FOR USE

- The device must be suitable for both the selected transport medium and the defined sampling site.
- Use only for the collection and transport of human biological samples for the detection of potential pathogens such as Virus (Sars-CoV-2, etc.) Chlamydia, Mycoplasma and Ureaplasma, compatible with the type of device selected.
- Do not deviate from the intended use. Do not use the product if it is expired or the package is opened/damaged. Sterility guaranteed if unopened.
- Use the device following aseptic procedures. Single-use device; do not reuse. Reusing the device could contaminate the sample and/or the patient.
- Keep the device away from heat sources.
- The fiber is only guaranteed to adhere to the shaft for instant sampling.
- The shaft is breakable, exert moderate pressure during sample collection; do not bend the tip of the swab 90° in order to avoid breakage.
- Store in a cool, dry place at a temperature between +2°C and +25°C. Do not freeze prior to use.
- After use, the device may contain infectious microorganisms. Use appropriate PPE and dispose of the test tube and swab according to current regulations for Medical waste.

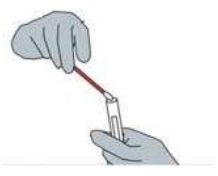
## HOW TO USE

**1)** Remove the swab and tube containing UVTM from the box.
**2)** Open the blister pack and aseptically remove the swab from the pack.



**3)** Insert the head of the swab gently into the nasopalatine part of the nasal canal, stop for a while, and then slowly rotate it to exit (or collect swab specimens according to standard technique).

**4)** Unscrew the cap and insert the swab into the test tube, being careful not tospill the liquid medium contained inside.



**5)** Break the swab in the test tube by placing the "breakpoint" indicated on the shaft of the swab against the edge of the test tube. Tilt it 180°, using moderate pressure. Discard the broken part of the shaft in accordance with current regulations for medical waste.

**6)** Firmly tighten the cap onto the test tube and shake gently. Label the test tube with the patient's data. Specimens may be dispatched at ambient (10-25°C) or refrigerated temperature (2-8°C) to arrive at the laboratory for processing within 48 hours. If a delay in testing or shipping is expected, specimens should be frozen at -70°C or below. When the cap is removed, the swab will also automatically be removed. Analyze the sample by performing standard clinical laboratory procedures.

## QUALITY CONTROL (Universal Viral Transport Medium)

**Appearance:** clear, light orange-red.

In accordance with the predefined Company Quality System, each lot of **S-UVTM-K** is tested against predetermined specifications to ensure consistent product quality.

**REFERENCES**


- World Health Organization (2020). https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance
- Center for Disease Control and Prevention (2020). Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19). https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
- Gruppo di Lavoro ISS Diagnostica e sorveglianza microbiologica COVID-19: aspetti di analisi molecolare e sierologica. Raccomandazioni ad interim per il corretto prelievo, conservazione e analisi sul tampone rino/orofaringeo per la diagnosi di COVID-19. Versione del 29 maggio 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 11/2020 Rev. 2).
- Circolare Ministero della Salute del 25/02/2020 – OGGETTO: richiamo in ordine a indicazioni fornite con la circolare del 22 febbraio 2020.
- Ministero della Salute – Circolare COVID – 2019. Nuove indicazioni e chiarimenti 22 Febbraio 2020.
- Mawaddah A, Gendeh SH, Lum SG, Marina MB. Upper respiratory tract sampling in COVID-19. Malays J Pathol. 2020; 42(1):23-35.
- UNI EN ISO 11137-1:2020 - Sterilizzazione dei prodotti sanitari - Radiazione - Parte 1: Requisiti per lo sviluppo, la convalida e il controllo sistematico del processo di sterilizzazione per i dispositivi medici
- UNI EN ISO 11135-1:2008 - Sterilizzazione dei prodotti sanitari - Ossido di etilene - Parte 1: Requisiti per lo sviluppo, la convalida e il controllo sistematico di un processo di sterilizzazione per dispositivi medici.


| PRESENTATION | Packaging | REF. |
|---|---|---|
| **S-UVTM-K (Swab Universal Viral Transport Medium)** | **100 pcs** | **32202** |

**The kit includes:**
**n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 1 mL of UVTM;**
**n. 100 Nasopharyngeal Swab (sterile, in single blister);**
**n. 100 Labels for a correct identification of the sample.**

| | | |
|---|---|---|
| **S-UVTM-K (Swab Universal Viral Transport Medium)** | **100 pcs** | **32208** |

**The kit includes:**
**n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 1,5 mL of UVTM;**
**n. 100 Nasopharyngeal Swab (sterile, in single blister);**
**n. 100 Labels for a correct identification of the sample.**

| | | |
|---|---|---|
| **S-UVTM-K (Swab Universal Viral Transport Medium)** | **100 pcs** | **32218** |

**The kit includes:**
**n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 2 mL of UVTM;**
**n. 100 Nasopharyngeal Swab (sterile, in single blister);**
**n. 100 Labels for a correct identification of the sample.**

| | | |
|---|---|---|
| **S-UVTM-K (Swab Universal Viral Transport Medium)** | **100 pcs** | **32204** |

**The kit includes:**
**n. 100 Tubes (16x100 mm, with internal shaped conical bottom and screw cap, sterile) containing 3 mL of UVTM;**
**n. 100 Nasopharyngeal Swab (sterile, in single blister);**
**n. 100 Labels for a correct identification of the sample.**

| REF. | CND | BD/RDM |
|---|---|---|
| **REF. 32202** | **W0104010203** | **2028427** |
| **REF. 32208** | **W0104010203** | **2119910** |
| **REF. 32218** | **W0104010203** | **2208328** |
| **REF. 32204** | **W0104010203** | **2028417** |

**SYMBOLS**

**Read the instructions**

**Biological hazard**

**CE Mark (product complies with the requirements of Regulation (EU) 746/2017)**

**Temperature limitation**

**Use by**

**IVD** **For in vitro diagnostic use**

**Manufacturer**