

## LIQUID AMIES COLLECTION SWAB

**IVD in Class A, EU Reg. 2017/746**

 For in vitro diagnostic use **IVD**

Collection and Transport system for Viruses, aerobic, anaerobic and fastidious microorganisms.

### DESCRIPTION

Collection and Transport system for Viruses, aerobic, anaerobic and fastidious microorganisms. The kit is compatible with molecular assays.

**Amies Transport Liquid Medium** is suitable for the collection and storage of clinical specimens containing viruses, including SARS-CoV-2 (COVID-19) and clinically important fastidious microorganisms, such as *Neisseria gonorrhoeae*.

In addition, as recommended by the CDC and FDA guidelines, the nasopharyngeal swabs used for sample collection are ultra-thin 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 length:	150 mm
The length for the tip:	20 mm
The length for the breakpoint:	80 mm
The diameter for the tip:	3 mm

#### Amies Transport Liquid Medium:

##### COMPOSITION

Sodium chloride  
Sodium hydrogen phosphate  
Potassium dihydrogen phosphate  
Potassium chloride  
Sodium thioglycollate  
Calcium chloride  
Magnesium chloride

**pH finale 7,2 ± 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

#### LIQUID AMIES COLLECTION SWAB

2-25°C

LIQUID AMIES COLLECTION SWAB 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

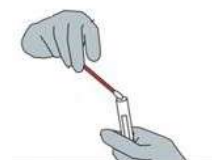
- 1) Remove the swab and tube containing Amies Transport Liquid Medium from the box.
- 2) Open the blister pack and aseptically remove the swab from the pack.



- 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).



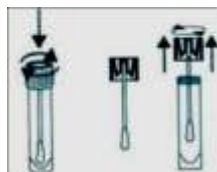
- 4) Unscrew the cap and insert the swab into the test tube, being careful not to spill the liquid medium contained inside.



- 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 refrigerated temperature (2-8°C) to arrive at the laboratory for processing within 48 hours. When the cap is removed, the swab will also automatically be removed. Analyze the sample by performing standard clinical laboratory procedures.



### QUALITY CONTROL (Amies Transport Liquid Medium)

**Appearance:** clear to slightly opalescent solution.

In accordance with the predefined Company Quality System, each lot of **LIQUID AMIES COLLECTION SWAB** is tested against predetermined specifications to ensure consistent product quality.

### REFERENCES

- World Health Organization (2019). Appendix A: SARS-CoV-2 Laboratory testing information.
- 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.
- Evaluation of Swabs, Transport Media, and Specimen Transport Conditions for Optimal Detection of Viruses by PCR. Julian Druce, Katherine Garcia, Thomas Tran, Georgina Papadakis, and Chris Birch. Journals. ASM.org.
- Amies, C. R. 1967. A modified formula for the preparation of Stuart's transport medium. Can J. Public Health 58:296-300.
- Miller, J. M., and H. T. Holmes. 1995. Specimen collection, transport and storage, p. 19-31. In P. R. Murray, E. J., Baron. M. A. Pfaller, F. C. Tenover, and R. H. Tenover (ed.), Manual of clinical microbiology, 6th ed. American Society of Microbiology, Washington, D.C.
- 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.
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**LIQUID AMIES COLLECTION SWAB** 100 pcs **32216**

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

**LIQUID AMIES COLLECTION SWAB** 100 pcs **32206**

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

REF.	CND	BD/RDM
<b>REF. 32216</b>	<b>W0104010203</b>	<b>2190494</b>
<b>REF. 32206</b>	<b>W0104010203</b>	<b>2082244</b>

### SYMBOLS

- Read the instructions
- Biological hazard
- CE Mark (product complies with the requirements of Regulation (EU) 746/2017)
- Temperature limitation
- Use by
- For in vitro diagnostic use
- Manufacturer