LICKSON®

CE

TECHNICAL SHEET

CHAOTROPIC LYSIS BUFFER WITH SWAB

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

Chaotropic Lysis Buffer with Swab is intended for the stabilization, transportation and inactivation of an unprocessed upper respiratory clinical specimen suspected of containing RNA and DNA of Viruses (Sars-CoV-2, etc.), Bacteria, Chlamydia, Trichomonas vaginalis, and Mycoplasma.
It is intended for use with compatible molecular assays.

DESCRIPTION

Kit consisting of a nasopharyngeal swab and a test tube containing **Chaotropic Lysis Buffer.** The "Chaotropic Lysis Buffer" medium is formulated in order to inactivate the samples and to preserve the integrity of the nucleic acids of clinical samples during transport and storage. The medium contains guanidine thiocyanate, which is a potent nuclease inhibitor (RNase and DNase), as well as a protein denaturing agent to prevent microbial proliferation, so Chaotropic Lysis Buffer is not intended for use in culture-based techniques or antigen tests.
Chaotropic Lysis Buffer is intended for use with compatible molecular assays, NAAT (Nucleic Acid Amplification Test).
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 lenght:	150 mm
The lenght for the tip:	20 mm
The lenght for the breakpoint:	80 mm
The diameter for the tip:	3 mm

Chaotropic Lysis Buffer:

COMPOSITION
Guanidine thiocyanate
Tris-EDTA
HEPES
Detergent

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: contains **guanidine thiocyanate**. During handling, wear protective gloves, protective clothing, eye protection, face protection. Avoid direct contact between guanidine thiocyanate and sodium hypochlorite or other highly reactive reagents such as acids and bases. These mixtures could release harmful gases.
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

CHAOTROPIC LYSIS BUFFER WITH SWAB

2-25°C

CHAOTROPIC LYSIS BUFFER WITH SWAB is stable until the expiration date indicated on the label under the recommended storage conditions.

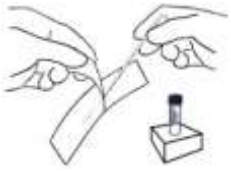
INSTRUCTIONS FOR USE

- The device must be suitable for both the selected transport medium and the defined sampling site.
- Chaotropic Lysis Buffer is intended for the stabilization, transportation and inactivation of an unprocessed upper respiratory clinical specimen suspected of containing RNA and DNA of Viruses (Sars-CoV-2, etc.) or other important clinically fastidious microorganisms.
- 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

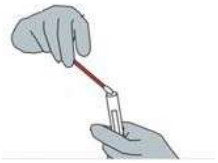
1) Remove the swab and tube containing Chaotropic Lysis Buffer from the box.

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 room (10-25°C) or refrigerated temperature (2-8°C) to arrive at the laboratory for processing within 24 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 (Amies Transport Liquid Medium)

Appearance: clear to slightly opalescent solution.

In accordance with the predefined Company Quality System, each lot of **CHAOTROPIC LYSIS BUFFER WITH SWAB** is tested against predetermined specifications to ensure consistent product quality.

REFERENCES

- RNA Methodologies - A Laboratory Guide for Isolation and Characterization - 4th Edition Robert E. Farrell , Jr., Ph.D . The Pennsylvania State University York, PA. AMSTERDAM • BOSTON • HEIDELBERG • LONDON • NEW YORK OXFORD • PARIS • SAN DIEGO • SAN FRANCISCO • SINGAPORE SYDNEY • TOKYO Academic Press is an imprint of Elsevier.
- Clinical and Laboratory Standards Institute 2005. Collection, transport, preparation, and storage of specimens for molecular methods; approved guideline. MM13-A CLSI, Wayne, PA.
- J. Michael Miller, Shelley A. Miller, 2017. A Guide to Specimen Management in Clinical Microbiology, Third Edition. ASM, Washington DC.
- 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.
CHAOTROPIC LYSIS BUFFER WITH SWAB	**100 pcs**	**32220**

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

REF.	CND	BD/RDM
REF. 32220	**W0104010203**	**2248219**

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