



SZABO SCANDIC

Part of Europa Biosite

Produktinformation



Forschungsprodukte & Biochemikalien



Zellkultur & Verbrauchsmaterial



Diagnostik & molekulare Diagnostik



Laborgeräte & Service

Weitere Information auf den folgenden Seiten!
See the following pages for more information!



Lieferung & Zahlungsart

siehe unsere [Liefer- und Versandbedingungen](#)

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien

T. +43(0)1 489 3961-0

F. +43(0)1 489 3961-7

mail@szabo-scandic.com

www.szabo-scandic.com

[linkedin.com/company/szaboscandic](https://www.linkedin.com/company/szaboscandic) 

Disposable Collection Tubes of Virus Samples

English VER 2.0

Instruction for Use



Basic UDI 697089547SPS01VU

REF Refer to box label

PRODUCT TYPES

This instruction is available for 4 different types medium.

Type A: Sample preservation solution (Activated Medium).

Type B: Sample preservation solution (Inactivated Medium).

Type C: Sample preservation solution (PBS Medium).

Type D: Sample preservation solution (Nucleic Acid Release Reagent).

PACKAGING SPECIFICATIONS

20 Sets/Kit, 36 Sets /Kit, 50 Sets /Kit, 100 Sets /Kit, etc.

INTENDED USE

This kit is intended for collection, transport and preservation of clinical specimens to be processed with molecular diagnostic platforms. This kit is for *in vitro* diagnostic use and it's for professional use.

TEST PRINCIPLE

The main components of type A preservation solution are Hank's Balanced Salt Solution, which can help stabilize the virus. The phenol red in the solution indicates the preservation state, and antibiotics added to prevent the growth of bacteria and fungus.

The main components of type B preservation solution are guanidine salt, surfactant, buffer, etc., which can inactivate the pathogens such as viruses and bacteria in the samples, inhibit the activity of nuclease and stabilize the DNA/RNA in pathogens and human cells.

The main components of type C preservation solution are dibasic sodium phosphate, sodium dihydrogen phosphate, sodium chloride, gentamicin, etc., which can help stabilize nucleic acid.

The main components of Type D preservation solution are protein denaturants, osmotic pressure regulator, purified water, etc., which can release viral nucleic acid.

APPLICABLE SPECIMENS

Nasopharyngeal swabs

Oropharyngeal swabs

Nasal swabs

Cervical shedding cells (Only available for Type A solution)

MATERIALS PROVIDED

Tube with medium

Sterile Disposable swab/Sampler

Biosafety Bag (optional)

SHELF-LIFE

Expiration: 2 years.












Storage condition: 2-30°C







TRANSPORTATION

1. Please transport the collected sample as soon as possible.
2. In general, the sample collected by Type A solution, should be transported at 0-8 °C for virus isolation within 48 hours. For nucleic acid analysis, if the transportation cannot be guaranteed at -(20±5) °C, it should be at least at 0-8°C.
3. For sample collected by Type B, Type C and D solution, if the transportation cannot be guaranteed at -(20±5) °C, it should be at least at 0-8 °C.






OPERATION PROCEDURE

1. Fill the necessary information on the label before sampling.
2. Collecting samples according to the sample collection requirements.
3. Please refers to the table below for swab sample collection steps:

Nasopharyngeal swab sampling		Take out the swab.
		Gently and slowly insert the swab through the nostril parallel to the palate until resistance is encountered.
		Gently rub and roll the swab at least 3 times, leaving it in place for 15-30 seconds to absorb secretions. Slowly remove the swab while rotating it.
		After the sample is collected, place the swab into the tube containing the preservation solution.
		Break the swab at breakpoint, leave the swab head in the solution.
		Close the tube tightly.
Oropharyngeal swab sampling		Take out the swab
		Insert swab into the posterior pharynx and tonsillar areas, rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
		After the sample collected, insert the swab into the tube containing preservation solution.
		Break the swab at breakpoint, leave the swab head in the solution.
		Close the tube tightly.

Nasal Swab sampling		Take out the swab.
		Carefully Insert the entire swab head into one nostril no less than one inch (about 2cm) or until feel resistance.
		Slowly rotate the swab, gently pressing in a circular path against the nasal wall 5 times for at least 15 seconds, get as much nasal discharge as possible on the swab head then gently remove the swab while rotating it. Repeat above step in the other nostril using the same swab.
		After the sample collected, insert the swab into the tube containing preservation solution.
		Break the swab at breakpoint, leave the swab head in the solution.
		Close the tube tightly.

4. Please refers to the table below for cervical shedding cell collection steps:

Cervical Shedding cells sampling	
	Expose the cervix with a vaginal dilator and wipes the secretions with a disposable swab.
	Insert the gynecologic swab/sampler into the cervix and gently rotate it for 4-5 times.
	Pull out the gynecologic swab/sampler slowly and place the swab/sampler into the tube containing preservation solution.
	Break the gynecologic swab/sampler end at the molded break point and leave the swab/sampler head in the tube.
	Close the cap, label the sample and keep the tube upright.

Notes: Samples collected are recommended to be tested as soon as possible.

PERFORMANCE CHARACTERISTICS

- Adenovirus and Human Coronavirus 229E were used to evaluate the performance of stabilizing pathogens in Type A preservation solution. The results show that both of them could be stably stored at 2-8°C for 48 hours.
- Adenovirus, Human Coronavirus 229E, *Staphylococcus aureus* and *Escherichia coli* were used to evaluate the ability of inactive pathogens such as viruses and bacteria in Type B. The results show that the inactivation rate of these pathogens were all $\geq 99.99\%$.
- Adenovirus, Enterovirus, *Staphylococcus aureus*, *Legionella*, Human Airway Epithelium and related PCR detection kit were used to evaluate the Type B performance of stabilizing the DNA and RNA in pathogens and human cells. The results show that these pathogens and human cells DNA and RNA could be stably stored at 37°C for 7 days, 2-8°C for 15 days, and $-(20\pm 5)^\circ\text{C}$ for 6 months.
Influenza A virus, Adenovirus, and the related PCR detection kit were used to evaluate the precision, limit of detection, and stability of the released DNA and RNA in Type D preservation solution. The results show that the intra-batch coefficients of variation is less than 5% and the inter-batch coefficients of variation is less than 10%, the limit of detection is 1000 copies•mL⁻¹. And the released DNA and RNA could be stably stored at 2-8°C for 15 days, and $-(20\pm 5)^\circ\text{C}$ for 1 months.

LIMITATION

- Product Performance may be impacted by extreme temperatures and repeated freeze and thaw.
- The performance should be evaluated when this product will be used to inactive and preserve other pathogens which are not mentioned in this instruction.
- The performance should be evaluated when this product will be used with any diagnostic test which are not mentioned in this instruction.















WARNING AND PRECAUTIONS

- The person who uses the kit should be trained and wear a mask, gloves, and other relevant protective equipment.
- Never touch the swab head with hands or other items when using the swab.
- The product is disposable. Never reuse it.
- Never use the product when its package is broken.
- Never use the product when the preservation solution isn't clear, or the tube is broken.
- Never use the product when it expires.
- Dispose of the waste following biosafety procedures issued by local authorities.

If there is any serious incident occurs in relation to the device, please report to the manufacturer and the competent authority in your country immediately.

Manufacturing date and expiration date: view on label

INDEX OF SYMBOLS

	Consult Instructions for Use		Contain <n> tests		Do not use if package is damaged and consult instruction for use
	In vitro diagnostic medical device		Use-by date		Authorized Representative in the European Community
	Catalogue #		Lot Number		Temperature limit 2 to 30 °C
	Manufacture Date		Manufacturer		CE conformity marking
	Unique device identifier		Do not reuse		

**Jiangsu Mole Bioscience Co., Ltd.**

6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District, 225300 Taizhou, Jiangsu
Province, P.R. China
Info@molechina.com

**Lotus NL B.V.**

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: Peter@lotusnl.com
Tel: +31644168999

Accessory	Manufacturer	EC-Representative	CE Mark
Disposable swab	Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town, Guangling District, Yangzhou 225109 Jiangsu, P.R. China	Lins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany.	
Disposable swab	Jiangsu Rongye Technology Co., Ltd. Touqiao Town, Yangzhou City 225109 Jiangsu, P.R. China	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain.	
Gynecologic sampler	Jiangsu Rongye Technology Co., Ltd. Touqiao Town, Yangzhou City 225109 Jiangsu, P.R. China	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain.	
Gynecologic swab	Shenzhen Mandelab Co., Ltd. 7F & 6F, Building#5, 10th Industrial Zone, Tianliao Community, Yutang Street, Guangming District, Shenzhen, 518000 Guangdong, P.R. China	SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.	

Number: BMA6870101
Effective Date: 2022-05-18

REVISION HISTORY

Version	Date	Description
English VER 0.0	2022-01-28	First Release
English VER 1.0	2022-05-10	Update the performance characteristics.
English VER 2.0	2022-05-18	Update the product type