



## INSTRUCTION FOR USE

### Sterile Nasal Specimen Collection Swabs

#### INTENDED USE

The Sterile Nasal Specimen Collection Swab is a single use, sterile device that is suitable for samples collection in the anterior nares human's nasal area. The swab is suitable for short contact and should be used as directed.

#### INTENDED USER and USE ENVIRONMENT

The swab is intended for collecting either self-sampling or healthcare professional sampling. Swab can be use at home and in healthcare organizations, always with assurance a hygienic condition.

#### TARGETED PATIENT POPULATION

Adult and pediatric patients, except children under the age of 3, can use our swab for specimen collection. Pediatric patients should be tested by an adult, especially those under 15 years of age. Individuals who are over 65 years of age should consider assistance in taking the sample.

#### CONTRAINDICATIONS

None identified

#### TEST PRINCIPLES

The swabs can be used in a standard testing procedure for general specimen collection for testing and screening of infections. Sample collection, registration or return for analysis and results communication requires an established process from an institutional testing laboratory /service provider or healthcare provider.

#### TECHNICAL NOTES

A slight yellowing of the tip is a well-known phenomenon. This could be due to many factors: to the type of raw material, to the product sterilization treatment, to the product natural aging. Therefore, product yellowing is not necessarily indicative of product deterioration. The content of the unopened and undamaged units is guaranteed to be sterile.

#### WARNINGS & PRECAUTIONS

**1.** Carefully follow the instructions for use. **2.** Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft. **3.** Use swab immediately after removing from packaging. **4.** Excessive contact between the swab and the nasal sampling area might cause the fiber to come out. **5.** Product cannot be reused or re-sterilized. Reuse may cause a risk of infection and/or inaccurate results. **6.** Do not re-pack. **7.** Do not use beyond the expiration date printed on the sealed pouch. **8.** Not suitable for any other application than intended use. **9.** The use of this product, in association with a diagnostic kit or with diagnostic instrumentation, should be previously validated by the healthcare institution/or diagnostic kit manufacturer. **10.** Do not use if the swab or package is visibly damaged (i.e., if the swab tip or swab shaft is broken/ or missed; there is evidence of damage or contamination to the product, package is open). **11.** Do not use this device by yourself if you are under the age of 15. **12.** The manufacturer cannot be held responsible for any improper or inadequate technique of device use. **13.** Do not use this device to perform test on a child under the age of 3. **14.** It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to regulations for infectious waste.

#### STORAGE

Store the swabs at temperature of 2°C -30°C (35.6°F -86°F). Keep away from sunlight. Keep dry. The test device is stable through the expiration date printed on the sealed pouch. If the product is stored at a different temperature, it might not maintain the stated performance and functionality specifications.

#### SPECIMEN COLLECTION

**Note:** Sterile gloves and protective clothing and eye wear should be worn when collecting and handling microbiology specimens. A swab sample is needed from both nostrils, and this is taken using the same swab.

# SteriPack™

CONTRACT MANUFACTURING



## Set Up

Blow nose and wash your hands or use hand sanitizer before starting.



## Open package

Remove the swab from the pouch by pulling the two ends of the pouch wrapper apart (follow the marking direction on the pouch). Do not touch the soft tip of the swab or lay the swab down on any surface.



## Sample Collection – First Nostril

Gently insert the soft tip of the swab into one nostril **no more than 3/4 of inch** (about 1.5 cm) for adults and **no more than 1/2 of inch** (about 1.27 cm) for younger children.

With children you may need to have a second person to hold the child's head while gently swabbing.

Slowly rotate the swab, gently pressing against the inside of your nostril several times.

Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab from the first nostril.



## Sample Collection – Second Nostril

By using the same swab, repeat sampling in the second nostril with the same swab tip.

After patient swabbing, process the swab in the appropriate collection device, as soon as possible. Do not place the swab back into the swab packaging sleeve after specimen collection.



## Clean Hands

Sanitize hands

## CAUTION

Seek immediate medical care from a healthcare professional if seriously ill, e.g. allergic reaction. In the case of medical emergency, contact the local medical emergency number.

## RESIDUAL RISKS/UNDERSIABLE SIDE-EFFECTS

None identified

## CUSTOMER SERVICE

For technical support please contact: swabs@steripackgroup.com, telephone 1-863-648-2333 or www.steripackgroup.com

For product complaints or medical incidents please complete questionnaire at: [www.steripackgroup.com/incident-complaint](http://www.steripackgroup.com/incident-complaint).

Please note, swabs that have been used for sample collection will not be accepted for returns.

## WASTE DISPOSAL

Disposal of used swabs should be conducted in accordance with applicable regulations.

## MANUFACTURER INFORMATION AND USED PICTOGRAMS

	MANUFACTURER SteriPack USA Ltd LLC, 4255 South Pipkin Road, Lakeland, Florida, 33811, USA		Batch code		Medical Device		Keep away from sunlight
	Authorized Representative in the EU S.M.P. Sp. z o. o., Leg, Japonska 1, 55-220 Jelcz- Laskowice, Poland		Date of manufacture		Single sterile barrier system		Temperature limit for device storage is between 2°C -30°C.
	Sterilized using irradiation		Use-by date		Caution		Paper + plastic
	Catalogue number		Unique Device Identifier		Do not re-use		Corrugated fibreboard (cardboard)
	Read electronic instructions for use <a href="http://steripackgroup.com/ifu/">steripackgroup.com/ifu/</a>		CE mark		Do not use if package is damaged		Keep dry