INSTRUCTIONS FOR USE

Rhinostics Standard Swab

INTENDED USE

The Rhinostics Standard Swab is intended for use by clinicians to collect an anterior nares (nasal) swab or other swabbed sample types in the clinical setting.

SUMMARY AND EXPLANATION

Specimens collected using the Rhinostics Standard Swab are transported at ambient temperature for testing at a qualified testing laboratory. Testing is limited to in vitro diagnostic tests that are authorized for use with the Standard Swab or validated by the laboratory under their designation for its high complexity assays.

MATERIALS PROVIDED

The PG-100001 Rhinostics Standard Swab includes:

- 1 sterile polypropylene swab[1]

The PG-100011 Rhinostics Standard Swab Collection Device includes:

- 1 sterile polypropylene swab (Rhinostics Standard Swab)[1]
- 1 capped and unlabeled transport tube (CE nonsterile)[2]

PRECAUTIONS

- All clinical specimens should be considered biohazards and handled with care. Wear appropriate personal protective equipment and follow laboratory and biosafety guidelines when handling clinical specimens.
- Do not use the collection device if the sterile package containing the swab is damaged or not sealed completely. Do not use if the swab is visibly damaged.
- Do not use the device beyond the expiration date printed on the label.
- This product is for single use only; reuse may cause a risk of infection and inaccurate results.

COLLECTION DEVICE STORAGE

For optimum performance, store at 2-25 °C. Avoid freezing and excessive heat.

LIMITATIONS

Reliable specimen collection and transport depends on many factors, including collection and handling techniques, specimen condition and volume, and timing. Best results are achieved when specimens are processed within 72 hours after the time of collection.

The Standard Swab is designed for dry shipment. Shipment in viral transport media (VTM) may dilute sample, cause variable results, and potentially leak during shipment. Use of the Rhinostics Standard Swab in conjunction with rapid diagnostic kits and instruments must be validated prior to use by the user.

[1]The device is certified under Medical devices Regulation (MDR) (EU) 2017/745 (CE 2460). The swabs are Class I sterile and the MDR certification covers the swabs and the sterile barriers.

[2]The device is not under Medical devices Regulation (MDR) (EU) 2017/745 (CE 2460). The transport tubes are Class A devices conforming to in vitro Diagnostic Medical Devices under Regulation (IVDR) (EU) 2017/746.

PN: IFU00EN_Standard Swab_001_Rev F

RHINOSTICS
Revolutionizing Laboratory Workflows

Standard Swab Family

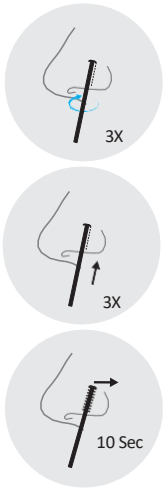
PG100001 / PG100011 Rhinostics Standard Swab

COLLECTION OF AN ANTEROR NARES SAMPLE

The Rhinostics Standard Swab can be used to collect anterior nares (nasal) samples following the instructions below.

STEP 1

Take Sample



1. Carefully remove the swab portion for sample collection from the package without touching the collection end of the swab.
2. Hold the collection portion of the swab on the shaft and collect the sample as follows:

   a. Insert the tip of the swab into one (1) nostril until pressure is felt in the nose. The swab should be placed just inside your nostril.

   b. Rotate the swab around the inside of the nostril three (3) times being sure you are making firm contact with the inside of your nose.

   c. Gently slide the swab up and down against the inside of the nose one time.

   d. Firmly hold the swab against the inside of the nostril for ten (10) seconds.

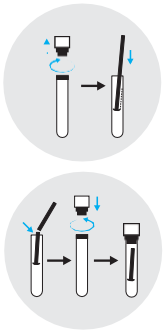
STEP 2

Repeat

3. Repeat collection steps (a-d) in the second nostril using the same swab.

STEP 3

Seal



4. Remove the cap from the tube but keep the cap safe for recapping. Place collection end of the swab in the tube. Bend the swab so that the tip snaps off, leaving the swab in the collection tube. Discard the shaft of the swab.
5. Replace the cap into the collection device. Make sure the cap is completely closed to ensure that the swab does not come out.

QUALITY CONTROL

Each lot of the Rhinostics Standard Swabs is sterilized with gamma irradiation. A representative sample of each lot is evaluated for bioburden and all testing procedures are established per the definitions in Clinical Laboratory Standards Institute M40-A2.

PATENTS AND TRADEMARKS

Rhinostics®

Patent applications 63/051,263, 63/019,620 and 29/737,922

RHINOSTICS
Revolutionizing Laboratory Workflows

SYMBOLS

Table of Label Symbols					
	Manufacturer		Temperature Limit 2-25 °C		Do Not Reuse
	Catalogue Number		European Uniion Conformity		Do Not Use If Packaging Is Damaged
	Use By Date		Medical Device		Protect From Direct Sunlight
	Lot Number		Serial Number		Consult Instructions For Use
	Sterile Barrier		Do Not Re-Sterilize		Sterilization By Gamma Radiation

BASIC UDI-DI

0850042963STA4L

CONTACT INFORMATION

UK REP

International Associates Limited
Centrum House, 38 Queen Street, Glasgow, Lanarkshire,
G1 3DX, UK
UKRP@ia-uk.com

EC REP

International Associates Auditing & Certification Limited The
Black Church, St Mary's Place,
Dublin 7, D07 P4AX Ireland
EUAR@ie.ia-net.com

Rhinostics Inc.

411 Waverley Oaks Road, Suite 118

Waltham, MA 02452

(877) 746-6789

(877) RINOSTX

RHINOSTICS

Rhinostics Inc.

quality@rhinostics.com www.rhinostics.com

PN: IFU00EN_Standard Swab_001_Rev F