INSTRUCTIONS FOR USE

RHINOstic® Automated Swab

INTENDED USE

The RHINOstic® Automated Swab is intended to collect a swab sample at home or in any healthcare setting by patients or medical professionals. Samples that can be collected with the automated swabs include anterior nares (nasal), buccal cells, vaginal, penile, anal, wounds, and other types of biological swab samples. Samples collected using the RHINOstic® Automated Swab are transported dry at ambient temperature for testing at a qualified testing laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Testing is limited to in vitro diagnostic tests that are authorized for use with the RHINOstic® Automated Swab or validated by the laboratory under their CLIA designation for its high complexity assays.

SUMMARY AND EXPLANATION

The RHINOstic® Automated Swabs were developed during the COVID-19 pandemic to bring improved materials and remove laboratory workflow bottlenecks for swab samples when they reach the laboratory. By combining a swab with a cap that is enabled for automated, robotic decapping, the RHINOstic® Automated Swab lowers the time and cost significantly for diagnostic assays that need swab samples. The swabs can be used with a wide variety of sample types where the assay is validated by qualified testing laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

The Rhinostics automated swabs bring easy-to-manufacture materials with properties that allow for dry shipment and sample concentration in addition to automation and rapid accessioning to allow for home collection as well as increase laboratories' throughput and lower costs. The RHINOstic® Automated Swab collection device consists of a hydrophobic polymer swab with a threaded lid attached for transport in a 1 ml transport tube. Once the sample is collected, the swab is screwed securely into the transport tube,
so the threaded lid aligns with the threading on the open portion of the transport tube. The thread swab cap is screwed shut onto the transport tube. The transport tube can then be transported to the testing laboratory under ambient temperatures. Testing will be performed in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories. When the automated swab collection device is delivered to an approved testing site, the technician reconstitutes the sample in accordance with the provided instructions.

MATERIALS PROVIDED

The RH-S000111 RHINOstic® Automated Swab includes:
1 sterile polypropylene swab[1]

The RH-S000001 RHINOstic® Automated Swab collection device includes:
1 sterile polypropylene swab (RHINOstic® Automated Swab)[1]
1 capped and unlabeled transport tube (CE nonsterile)[2]

The LV-2D1D002 RHINOstic® Automated Swab collection device includes:
1 sterile polypropylene swab (RHINOstic® Automated Swab)
1 uncapped clear barcoded transport tube[2]

The LV-2D1D003 RHINOstic® Automated Swab Kit includes:
1 sterile polypropylene swab (RHINOstic® Automated Swab)[1]
1 uncapped black barcoded transport tube[1]

[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.

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 automated swab 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.

The swab should be screwed tightly into the transport tube to ensure it stays in the tube during transport to the laboratory for testing.

AUTOMATED SWAB AND COLLECTION DEVICE STORAGE

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

SAMPLE, AUTOMATED SWAB, COLLECTION DEVICE DISPOSAL

Dispose of the use automated swab and collection device materials according to biohazard disposal regulations.

SPECIMEN COLLECTION

Remove the swab portion for sample collection from the packaging without touching the collection end of the swab, and then remove transport tube from the package so that after collection it is ready for the sample to be placed into the transport tube. Hold the swab portion of the collection device by the cap to collect the sample as required by the specific sample type and collection protocol as validated under the laboratories' procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

SARS-CoV-2/COVID-19 Sample Collection

For collection of a SARS-CoV-2 nasal sample specifically, the swab portion for sample collection should be removed from the polybag without touching the collection end of the swab. The transport tube should be removed from the package so that after collection it is ready for the sample to be placed into the transport tube. The swab portion of the collection device should be held by the cap to collect the sample as follows:

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

a. The swab is rotated around the inside of the nostril three (3) times being sure you are making firm contact with the inside of the nose.

b. The swab should be gently slid up and down against the inside of the nose one time.

c. The swab should be held against the inside of the nostril for ten (10) seconds.

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

The cap should be removed from the tube and discarded. The cap should be replaced with the swab into the tube portion of the collection device.

The swab cap should be carefully screwed into the tube, so that it is completely closed. Completely screwing the swab is critical to ensuring that the swab does not come out during transport.

RHINOSTICS
Revolutionizing Laboratory Workflows

RHINOstic Family

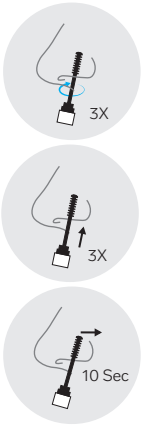
RH-S000001/RH-S000111/LV-2D1D002/LV-2D1D003 RHINOstic® Automated Swab

RHINOSTICS Instructions for Use

STEP 1
Removal

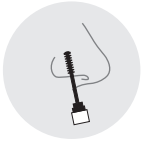
1. Carefully remove the swab portion for sample collection from the polybag without touching the collection end of the swab.
2. Remove the transport tube from the package so that after collection it is ready for the sample to be placed into the transport tube.

STEP 2
Collect Sample



3. Hold the swab portion of the collection device by the cap 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 (1 O) seconds.

STEP 3
Repeat



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

STEP 4
Seal

5. Remove the cap from the tube and **discard.** Replace the cap with the swab in the tube portion of the collection device.
6. Carefully screw the swab into the tube, so that it is completely closed. Make sure the tube is closed tightly. The original tube cap is no longer needed and should be thrown away.

SAMPLE PREPARATION

Patient specimens should be collected according to the laboratories collection instructions using the RHINOstic® Automated Swab. The polypropylene swab is used to collect the specified sample which is placed dry into the transport tube and shipped at ambient temperature to the laboratory for testing within 72 hours.

When the sample arrives in the laboratory, a properly collected swab specimen should have a single swab attached to the threaded cap inserted into the tube. Incoming specimen sample tubes with no swab or with two swabs have not been collected according to the instructions should not be tested.

The dry swab should be reconstituted according to the laboratories' protocols by pipetting the appropriate elution buffer into the transport tube after carefully opening and lifting the cap with the swab attached. The cap with the attached swab should be placed back into the tube containing the saline and should be mixed by flicking the sample by hand several times or gently and quickly vortex or through automated spin of the swab. The appropriate amount necessary for the assay protocol should be transferred into the reaction tube or well that will be used for the assay following the manufacturer's instructions.

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 RHINOstic® Automated Swab is designed for dry shipment. Shipment in viral transport media (VTM) or other media and buffers may dilute sample, cause variable results, and potentially leak during shipment.

Refer to the corresponding reference standard and procedures for optimum collection techniques.

Use of the RHINOstic® Automated Swab must be validated prior to use by the laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

QUALITY CONTROL

Each lot of the RHINOstic® Automated 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

RHINOstic® and Rhinostics®

Patent applications 63/051,263 and 63/019,620

SYMBOLS

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

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Revolutionizing Laboratory Workflows

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