Instructions for Use

Rhinostics Standard Nasal Swab

INTENDED USE

Rhinostics Standard Nasal Swab Collection Device provides a method for clinical collection, stabilization, and transport of an anterior nasal sample collected in a clinical setting and provided to a designated laboratory for testing. Specimens collected using the Rhinostics Standard Nasal Swab Collection Device are transported at ambient temperature for testing at a qualified testing laboratory. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

SUMMARY AND EXPLANATION

SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however the SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets.1 The WHO declared that COVID-19 was a pandemic on March 11, 2020, and human infection has spread globally, with hundreds of thousands of confirmed infections and deaths. The pandemic has put unprecedented pressure on testing laboratories on a global basis, including supply chains and the ability to source collection devices as well as laboratory throughput. The Rhinostics collection devices 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 Rhinostics Standard Nasal Swab Collection Device is for the collection, stabilization and transport of an anterior nasal sample collected on a hydrophobic polymer nasal swab from patients. The Rhinostics Standard Nasal Swab Collection Device consists of a polypropylene anterior nasal swab with a snap-point designed for transport in a 1 ml (1000ul) capped collection tube. Once the sample is collected, the swab is placed into the storage tube, and the tube is capped. The tube is placed into a specimen bag for transport to the testing laboratory. The specimen bag should be placed into the pre-labeled shipping box/envelope and shipped 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 collection device is delivered to an approved testing site, the technician reconstitutes the sample in accordance with instructions provided.

MATERIALS PROVIDED

The PG100001 Rhinostics Nasal Swab Collection Swab includes:
1 sterile polypropylene nasal swab
1 capped collection tube

MATERIALS NEEDED BUT NOT PROVIDED

Specimen bag for collected sample
No reconstitution buffers or assay materials are included with the Rhinostics Nasal Swab Collection Swab

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.

Gently collect the nasal sample following the Rhinostics Standard Nasal Collection Device collection instructions without using excessive force in the nostril. Refer to the Centers for Disease Controls and Prevention's instructions on how to collect an anterior nares sample.

After collection, the collection end of the swab should be placed into the collection tube up to the snap point and then firmly bent to snap off the tip into the tube without touching the collection end.

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

Dispose of the used collection device materials according to biohazard disposal regulations.

COLLECTION DEVICE STORAGE

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

SAMPLE TRANSPORT AND STORAGE

Samples should be transported at ambient temperature and tested within 72 hours. If not tested within 72 hours, the samples can be frozen at -70 C until able to test.

SPECIMEN COLLECTION

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 prepared so that after collection it is ready for the collection head containing the sample to be placed into the transport tube.

The swab portion of the collection device should be used 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.

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. Replace the cap into the collection device.

Make sure cap is completely closed to ensure that the swab does not come out during transport.

The collection tube should be placed into the specimen bag and shipping envelope provided and sent to the laboratory for testing. The testing laboratory will provide you with instructions on how to receive the test result.

RHINOSTICS Instructions for Collection

STEP 1
Removal

1. Carefully remove the swab portion for sample collection from the Tyvek package without touching the collection end of the swab.

2. Prepare the capped transport tube so that after collection it is ready for the sample to be placed into the transport tube.

STEP 2
Take Sample

3. Hold the swab portion of the collection device on the shaft and 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 3
Repeat

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

STEP 4
Package & Seal

5. 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. Replace the cap into the collection device.

6. Make sure cap is completely closed to ensure that the swab does not come out during transport.

7. Place the collection tube into the specimen bag and seal. Then, place in the shipping envelope and send the device to the laboratory for testing.

8. The testing laboratory will provide you with instructions on how to receive your test result.

SAMPLE PREPARATION

Nasal specimens should be collected according to the Rhinostics Standard Nasal Swab collection instructions using the Rhinostics Standard Nasal Swab Collection Device. The polypropylene swab is used to collect an anterior nares sample which is placed dry into the transport tube and shipped at ambient temperature to the laboratory for testing within 72 hours. If samples cannot be tested within 72 hours of collection, they should be frozen in the laboratory at -70°C or colder.

When the sample arrives in the laboratory, a properly collected swab specimen should have a single swab with the shaft broken at the score-line. Incoming specimen sample tubes with no swab or with two swabs have not been collected according to the instructions in their respective collection kit Instructions for Use and should not be tested. Some samples may contain excessive mucus which may result in pipetting errors or result in errors when tested on diagnostic instruments. If the sample appears to have significant mucus, vortex the sample for 30 seconds.

The dry swab should be reconstituted by using a pipette to place 350 ul of 0.9% physiological saline into the collection tube. The tube containing the swab and saline should be mixed by flicking the sample by hand several times or gently and quickly vortex. From the 350 ul sample volume, 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. In the case where the manufacturer's protocol requires a larger sample volume than 350 ul, the sample can be transferred into a new tube and diluted to the appropriate volume to enable the protocol.

- Unscrew the primary sample tube cap.
- Lift the cap and insert pipette into the sample tube to the side of the swab collection head.
- Transfer the appropriate amount of the sample into the prepared secondary tube or well and dilute (if necessary) with physiological saline for the final volume required in the manufacturer's instructions for use.
- Ensure complete mixing after addition of sample to the secondary tube and test in accordance with manufacturer's instructions for use.
- Close the primary sample tube cap and store sample at -70 C.

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 Rhinostics Standard Nasal Swab Collection Device is designed for dry shipment. Shipment in viral transport media (VTM) 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 Rhinostics Standard Nasal Swab Collection Device in conjunction with rapid diagnostic kits and instruments must be validated prior to use by the user.

The use of tubes from any other source are not qualified for use with the Rhinostics Standard Nasal Swab Collection Device and could affect the performance of the product and laboratory test results.

QUALITY CONTROL

Each lot of the Rhinostics Standard Nasal Swab 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, 63/019,620 and 29/737,922

SYMBOLS

Table of Label Symbols					
	Manufacturer		Temperature Limit		Do not Reuse
	Catalogue Number		European Union Conformity		Do not use if packaging is damage
	Use by Date		*In vitro* Diagnostic Medical Device		Protect from direct sunlight
	Lot Number		Serial Number		Consult instructions for use

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