INSTRUCTIONS FOR USE

Rhinostics GrooveSwab®

INTENDED USE

Rhinostics GrooveSwab® is a device intended for collection of nasopharyngeal, oropharangeal or other patient samples in the clinical office setting by a medical professional. The test must be ordered by a health care professional. The Rhinostics GrooveSwab® provides a method for clinical collection, stabilization, and dry transport of a nasopharyngeal or other sample and provided to a designated laboratory for testing.

Clinical Collection:

The collection swab may be used for collection by a healthcare provider in a healthcare facility. Specimens collected using the Rhinostics GrooveSwab® 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. Testing is limited to molecular diagnostic tests that are authorized for use with the Rhinostics GrooveSwab® or validated by the laboratory under their CLIA designation for its high complexity assays.

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.

The Rhinostics GrooveSwab® can be used to collect any appropriate patient sample including nasopharyngeal or oropharyngeal samples from patients being tested for SARS-CoV-2. The Rhinostics GrooveSwab® has a breakpoint to allow for transport in a standard collection tube. 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. Reconstituted samples can be tested on SARS- CoV-2 molecular assays validated for use with the collection swab.

MATERIALS PROVIDED

The GW-UF100001 Rhinostics GrooveSwab®: 1 sterile polypropylene 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.
- 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.
- 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.

NASOPHARYGEAL SPECIMEN COLLECTION

For nasopharygeal specimen collection, the swab portion for sample collection should be removed from the peel pouch without touching the collection end of the swab.

The swab portion of the collection device should be used to collect the sample as follows:

a. Tilt patient's head back slightly to straighten nasal passage.

b. Insert swab straight back horizontally to the nasopharynx until resistance is met.

c. Rotate swab up to 5 times and hold in place 5-10 seconds to collect sample.

The swab can be placed into a dry transport tube for transportation to the laboratory. In this case, make sure cap is completely closed to ensure that the swab does not come out during transport.

SAMPLE PREPARATION

Nasal and other patient specimens collected using the Rhinostics GrooveSwab® can be 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.

The dry swab should be reconstituted by using a pipette to place 300-500 ul of 0.9% physiological saline or other buffer 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 original 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.

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 GrooveSwab® 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 GrooveSwab® in conjunction with rapid diagnostic kits and instruments must be validated prior to use by the user.

QUALITY CONTROL

Each lot of the Rhinostics GrooveSwab® is sterilized with Ethylene Oxide. 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® GrooveSwab®

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

SYMBOLS

Table of Label Symbols					
	Manufacturer		Temperature Limit 2-25 ℃		Do Not Reuse
	Catalogue Number		Sterilization By Ethylene Oxide		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		

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