INSTRUCTIONS FOR USE

HIPPOstic™

INTENDED USE

The HIPPOstic™ is intended for the collection, transportation, preservation of biological samples in the home or in any healthcare setting by medical professionals or self-collection by patients for diagnostic testing or other analysis. Samples that can be collected with the devices include but are not limited to buccal cells, pox, melanoma, dermatological, sores, wounds, growths, tumors, swab samples, anal and fecal samples, vaginal samples, and any other types of biological samples. Samples collected using the HIPPOstic™ 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 HIPPOstic™ or validated by the laboratory under their CLIA designation for its high complexity assays.

SUMMARY AND EXPLANATION

The HIPPOstic™ was developed to improve sample collection and to remove laboratory workflow bottlenecks for swab samples when they reach the laboratory. By combining a sample collection device with a cap that is enabled for automated, robotic decapping, the HIPPOstic™ 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 HIPPOstic™ brings 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 collection device consists of HIPPOstic™ hydrophobic polymer collection head attached to 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,

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 HS-S000001 HIPPOstic™ includes:
1 sterile polypropylene device

The HS-S000011 HIPPOstic™ collection device includes:
1 sterile polypropylene device
1 capped and unlabeled transport tube

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 device if the sterile package containing the swab is damaged or not sealed completely. Do not use if the device 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 device should be screwed tightly into the transport tube to ensure it stays in the tube during transport to the laboratory for testing.

COLLECTION DEVICE STORAGE

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

COLLECTION DEVICE DISPOSAL

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

SPECIMEN COLLECTION

Remove the flat swab collection portion of the device from the packaging without touching the collection end, 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 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.

Buccal cell collection

The flat swab portion of the collection device should be held by the cap to collect the sample as follows:

a. Insert the tip of the swab into the mouth and firmly place the swab flat against the inside of the cheek. Move the swab up and down 30 times along the inside of the cheek and upper gum. The swab should be gently slid up and down against the inside of the nose one time.

b. Make sure you are making firm contact with the flat side of the swab and the inside of the cheek.

c. Flip the swab over to the opposite side of the mouth and repeat, using the other side of the flat swab to move up and down 30 times along the inside of the cheek and upper gum.

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

The flat 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.

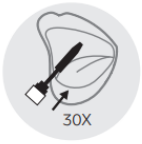
RHINOSTICS Instructions for Use

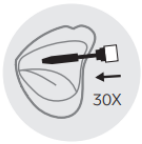
Important: Do not eat, drink, smoke, or chew gum for 30 minutes before collecting a buccal sample. Do not touch the flat swab tip. Only handle the flat swab by the cap.

STEP 1
Removal

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

STEP 2
Collect Sample





3. Hold the flat swab by the cap and collect the sample as follows:
   - **a.** Insert the tip of the swab into the mouth and firmly place the swab flat against the inside of the cheek. Move the swab up and down 30 times along the inside of the cheek and upper gum.
   - **b.** Make sure you are making firm contact with the flat side of the swab and the inside of the cheek.
   - **c.** Flip the swab over to the opposite side of the mouth and repeat, using the other side of the flat swab to move up and down 30 times along the inside of the cheek and upper gum.

STEP 3
Seal

4. Remove the cap from the tube and **discard**. Replace the cap with the flat swab in the tube portion of the collection device.
5. Carefully screw the flat swab into the tube, so that it is completely closed. Make sure the cap 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 HIPPOstic™. The polypropylene flat 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 flat 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.

The HIPPOstic™ is designed for dry shipment. Shipment in 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 HIPPOstic™ 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 HIPPOstic™ is sterilized with gamma irradiation. All testing procedures are established per the definitions in Clinical Laboratory Standards Institute M40-A2.

PATENTS AND TRADEMARKS

HIPPOstic™

Patent applications 63/051,263, 63/019,620, 63/326,465 and 63/418,869

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

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