

VERIstic Family

VS-S000001/ VS-S000011 Rhinostics VERIstic®

INSTRUCTIONS FOR USE**VERIstic® Collection Device****INTENDED USE**

The VERIstic® collection device is intended for the collection, transportation, and preservation of microsamples of arterial blood or other biological fluids in the home or in any healthcare setting by medical professionals or self-collected by patients for diagnostic testing or other analysis.

Samples that can be collected with the VERIstic® include blood and other types of biological samples. For arterial blood collection, a sample can be collected from a skin puncture site by placing the open end of the device against the blood drop and allowing the blood to wick into the capillary and fill the device. When the VERIstic® is full, the device can be screwed into its transportation tube for returning to the laboratory for testing. Samples collected using the VERIstic® collection device can be 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 VERIstic® collection device or validated by the laboratory under their CLIA designation for its high complexity assays.

SUMMARY AND EXPLANATION

The VERIstic® is a novel capillary device developed to bring improved materials and remove laboratory workflow bottlenecks for small volume blood and other biological samples when they reach the laboratory. By combining a capillary with a cap that is enabled for automated, robotic decapping, the VERIstic® lowers the time and cost significantly for diagnostic assays that need small volume blood samples. The VERIstic® can be used with a wide variety of biological sample types where the assays are validated by a 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 VERIstic® automated capillaries 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 VERIstic® collection device consists of a polypropylene capillary with a threaded cap attached for transport in a 1 ml transport tube. Once the sample is collected, the capillary is screwed securely into the transport tube, so the threaded cap aligns with the threading on the open portion of the transport tube. The threaded 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 collection device is delivered to an approved testing site, the technician reconstitutes the sample in accordance with the laboratory's validated protocols.

MATERIALS PROVIDED

The VS-S000001 Rhinostics VERIstic® includes:

1 polypropylene capillary

The VS-S000011 Rhinostics VERIstic® includes:

1 polypropylene capillary

1 capped and unlabeled transport tube

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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 package containing the capillary is damaged or not sealed completely. Do not use if the capillary 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 capillary should be placed into the collection tube and screwed on firmly 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.

FINGER PRICK BLOOD SPECIMEN COLLECTION

RHINOSTICS Instructions for Use

STEP 1 Removal



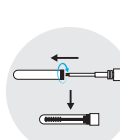
1. Before collection, the capillary portion for sample collection should be removed from the peel pouch without touching the capillary end of the device.
2. The collection tube should also be removed from packaging to prepare for the sample.

STEP 2 Collect Sample



3. For blood specimen collection from the finger, the capillary portion of the collection device should be used to collect the sample as follows:
 - a. Select the ring or pinkie fingertip and clean the desired puncture site using the alcohol prep pad. The best site for a finger puncture is just off the center of the finger pad.
 - b. Remove and discard the plastic safety end on the lancet by twisting and pulling it (lancet color may vary depending on the test).
 - c. Place the finger against a firm surface. Firmly place the tip of the lancet against the puncture site. Activate and puncture once. To activate the lancet, press down until an audible click is heard.
 - d. Squeeze the finger, moving from the base of the finger toward the fingertip to draw blood towards the puncture site.
 - e. Blot the first drop of blood on a gauze pad and discard pad.
 - f. Allow a second large blood drop (3-5mm) to form. Feel for the flat side of the VERIstic® and hold this side facing up while placing the tip of the VERIstic® to the drop of blood forming on the fingertip. Be careful to hold the capillary at a downward angle, allowing gravity to assist in blood collection.
 - g. Repeat this step and collect drops of blood into the collection device by gently massaging the finger. Avoid excessive pressure that may squeeze tissue fluid into the drop of blood.
 - h. Continue to collect blood until the capillary completely fills (the entire length and capacity of the capillary). Filling the capillary will likely require at least 3 blood drops but could require up to 8 or even 10 depending on the individual.

STEP 3 Seal



4. Remove the cap from the tube and **discard**. Replace the cap with the capillary in the tube portion of the collection device.
5. Hold the VERIstic® horizontally after collection and when screwing into the transport tube.
6. Carefully screw the VERIstic® 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.

Collection Tips:

- Patient should drink plenty of water prior to collecting your sample to ensure hydration.
- Ensure that patient's hands are warm. If self-collecting, patient can warm hands by thoroughly rinsing hands in warm water or showering. If patient has calluses on fingers, soak hands in warm water to soften the skin before collection.
- Patient can promote adequate blood flow to the arms by swinging by their side or by exercising beforehand.
- Once the finger is punctured, wipe away the first drop of blood.
- If a blood drop is not forming, it's helpful to promote blood flow by massaging from the patient's wrist down to your fingertip.
- The additional lancets can be used if needed but it's recommended to choose a different finger.
- It is recommended to hold the VERIstic® horizontally when inserting into the transport tube.

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HEEL PRICK COLLECTION FOR CHILDREN UNDER 6 MONTHS

Before collection by a medical professional, the capillary portion for sample collection should be removed from the peel pouch without touching the collection end of the device. The collection tube should also be removed from packaging to prepare for the sample.

For blood specimen collection from the heel of children under 6 months of age, the capillary portion of the collection device should be used to collect the sample as follows:

- a) The heel should be warmed with a warm compress or warm water.
- b) A heel puncture is performed on the lateral or medial plantar surface of the foot. The area of the arch should be avoided, as should the posterior curvature of the heel; a puncture in these areas could cause injury to the underlying bone.
- c) Prepare the heel by warming it using an instant chemical heel warmer, or a warm cloth for 3-5 minutes. Sanitize the heel with an alcohol prep pad. Wipe dry with sterile gauze.
- d) Grasp the foot, and using a sterile lancet, press firmly against the heel to make a puncture.
- e) The first drop contains excess tissue fluid and must be wiped away.
- f) Collect the drops of blood into the collection device by gently squeezing the foot. Avoid excessive pressure that may squeeze tissue fluid into the drop of blood or cause bruising.
- g) When full, the VERIstic® should 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 VERIstic® does not come out during transport.
- h) Hold a gauze pad over the puncture site for a couple of minutes to stop the bleeding, and then tie gauze around the foot.

SAMPLE TRANSPORT AND STORAGE

Samples should be transported at ambient temperatures. Specific storage conditions for testing will be dependent on the laboratory protocols based on the test being performed.

SAMPLE PREPARATION

Blood and other patient specimens collected using the Rhinostics VERIstic® can be placed dry into the transport tube and shipped at ambient temperature to the laboratory for testing. Specific storage conditions for testing will be dependent on the laboratory protocols based on the test being performed.

LIMITATIONS

The VERIstic® is intended to be used for a broad range of biological fluid collection. Refer to specific laboratory tests for storage, transport, and sample preparation conditions.

Capillary puncture may be used for obtaining specimens in children or in adults where venipuncture is difficult.

Patients over the age of 6 months should have capillary specimens collected by fingerstick.

Capillary punctures are not suitable for blood culture testing and most coagulation tests.

QUALITY CONTROL

Parts are manufactured under ISO 13485 compliant Quality Management Systems.

PATENTS AND TRADEMARKS













VERIstic®

Patent applications 63/051,263, 63/019,620, 29/737,922 and 63/418869.

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SYMBOLS

Table of Label Symbols					
	Manufacturer		Temperature Limit 2-25° C		Do Not Reuse
	Catalogue Number		European Union 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

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CONTACT INFORMATION



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



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 Inc.

quality@rhinostics.com
www.rhinostics.com