



Intended Use & Indications for Use

The Blood Collection Kit is intended to provide a way to collect and transport venous blood samples to a biobanking facility.

Device Description

The Blood Collection Kit contains blood specimen collection devices and associated materials necessary to transport the samples to a biobanking facility. The kit may be used to collect blood samples for patients being treated with Epicel® (cultured epidermal autografts) prior to first grafting.

Precautions

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

How Supplied

The kit contains two vacutainer tubes and shipment notification form pre-labeled with patient-specific information.

Storage



Store at 4°C to 25°C.

Do not refrigerate or freeze the gel pack prior to use.

Limitations of Use



The Blood Collection Kit is single-use only.

Kit Contents

The Blood Collection Kit contains:

- 1 – Shipping box with Styrofoam insert and lid
- 2 – 10.0mL K2 EDTA (K2E) Plus Blood Collection Tubes (366643)¹

- 1 – VonSeal® 95kPA Biohazard Specimen Bag²
- 1 – Absorbent sheet
- 1 – Ambient temperature gel pack
- 1 – UN3373 Biological Substance, Category B transport label
- 2 – Pre-Printed FedEx return label
- 1 – Tape strip
- 1 – Client Notification of Shipment Form

Instructions for Use

Receipt and Inspection

1. Inspect Blood Collection Kit label to ensure kit is to be used within expiry.
2. Inspect patient labels applied to the shipping box, vacutainer tubes, and shipment notification form.

Specimen Collection

Collect 20mL blood sample (two 10mL K2 EDTA vacutainer tubes). For specimen collection instructions and related equipment not provided, refer to original manufacturer instructions for use.¹

Packaging Instructions following Sample Collection

1. Place vacutainer tubes and gel pack inside the 95kPA bag with absorbent sheet.
2. Remove adhesive backing and seal the 95kPA bag. Press firmly at the corner areas indicated by the arrows. Refer to original manufacturer sealing instructions.
3. Place the 95kPA bag inside the Styrofoam insert. Place Styrofoam lid on top of insert.
4. Place Client Notification of Shipment Form on top of the Styrofoam lid.
5. Close the shipping box.

Blood Collection Kit Instructions for Use (IFU)

6. Apply pre-printed FedEx return label to the top of the shipping box. (Retain other FedEx return label for reference to tracking number.)
7. Attach the UN3373 Biological Substance, Category B transport label to the front closure of the shipping box.
8. Tape the transport box closed.

Kit Pickup



Contact Vericel Customer Care at 1-800-232-7546 to arrange pickup.

Symbols Glossary

	Manufacturer
	Unique Device Identifier
	Refer to Instructions for Use
	Caution
	Prescription only
	Single-use only
	Keep away from sunlight
	Temperature limit



Vericel Corporation

64 Sidney Street
Cambridge, MA 02139

L65-632.2 September 2022

¹ Becton, Dickinson, and Company. Refer to www.bd.com/vacutainer/referencematerial.

² Vonco Products, LLC. Refer to <https://www.vonco.com/product/95kpa-bags/>.

CLOSING INSTRUCTIONS

FOR THESE VONSEAL® SPECIMEN SHIPPING BAGS



The specimen shipping bags in this carton are designed to perform at high internal pressure should an airliner lose it's cabin pressure.

In order for the bag to perform to it's design capabilities, it is imperative that the bag be closed properly after insertion of the specimen.

PLEASE FOLLOW THE PROCEDURES ILLUSTRATED BELOW

FIG. #1



Figure 1: shows the bag laying flat on a counter with the tape side up and the tape end towards the person closing the bag.

FIG. #2



Figure 2: shows the specimen at the bottom of the bag and the area above the specimen being flattened in preparation for the adhesive tape to fold over.

FIG. #3

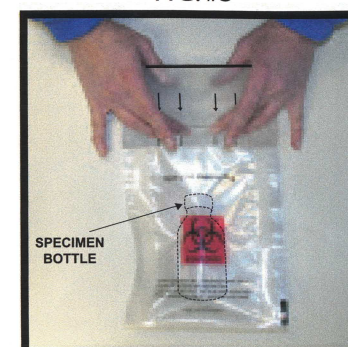


Figure 3: shows the bag after the paper adhesive cover has been removed and with the middle fingers touching the adhesive at the middle of the bag below the slit opening. It also shows the thumbs under the end of the bag ready to fold the top of the bag over.

FIG. #4



Figure 4: shows the bag after the top is folded at the slit opening and the thumbs pressing the folded end of the bag.

FIG #5



Figure 5: shows the middle finger of both hands being used to press the adhesive together. Start at the center of the fold and work outward. Please be sure to firmly press the entire adhesive area, especially the folded edge and corners. **PRESS FIRMLY AT THE CORNER AREAS INDICATED BY THE ARROWS.**

**This is a high performance bag.
Thank you for making the effort
to close it properly.**

VONCO PRODUCTS, LLC.
TREVOR, WISCONSIN 53179
1-800-323-9077
www.vonco.com