

Device Description

The device included in Biobox is a sterile, disposable blood lancing device. When collecting a sample, the device is held onto the skin by a mild adhesive. A sterile lancet punctures the skin with a press of the button, simultaneously this creates a slight vacuum that helps capillary blood flow under gravity into a compatible tube. After a predefined time period, or when the tube is full, the device is peeled off the skin. The tube is removed and capped for transport. The lancet is single use and automatically retracts into the device in a safe position after use.

Materials Provided

- Blood lancing device (FDA 510(k) - cleared)
- Microtainer
- Instructions for use
- Biohazard bag
- Heat pack or other arm warming method
- Bandage
- Alcohol swab

Intended Purpose

The device included in Biobox is a single-use blood lancing device intended for obtaining microliter capillary whole blood samples.

Symbols

REF

Catalogue number

LOT

Lot number

Use by date

Single use only

18°C-28°C

Store at 18-28°C

25%-85%

Transport at 25-85% RH

Consult instructions for use

This device contains sharps

Do not use if package is damaged

STERILE R

Sterilized by irradiation

Do not resterilize

Rx ONLY

Prescription use only

Disposal

Follow local guidelines for discarding used sharps as a biohazard material.

Model

Length

Depth

Tasso+

3.8 mm

0.8 mm

Warnings

Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of blood-borne pathogens, particularly in settings where multiple patients are tested.

Precautions

- For use only on a single patient. Discard the entire device after use.
- Do not use after expiration date.
- Single use only.
- Keep out of reach of children.
- Not for use on infant heels.
- Prescription use only.
- Do not resterilize.
- For external use only.
- Do not use if device packaging has been opened or damaged.
- Use while seated as fainting may occur with any blood sampling procedure.
- Refer to manufacturer's instructions for individual components.
- Use personal protective equipment when handling biohazardous materials.
- Users must validate use of product for their specific assay.
- Minor bruising, residual marks, or scarring may occur at the sample collection site.
Note: The occurrence and severity of these events depend on patient physiological characteristics and chosen anatomic site.
- Multiple collections from the same anatomic location may increase the risk of residual marks or scarring and may impact the healing process.
- Do not perform collections on an area that shows evidence of skin issues such as infection, inflammation, extensive scarring, or broken skin.
- Patients taking blood thinners may experience prolonged bleeding.

bio**box**™

Collecting **Blood** Just Got **Easier**.

Instructions for Use
Ages 18 and older

Please read the instructions thoroughly before using this device.

Dos and Don'ts

- **DO** activate device **ONLY** at time of collection (one-time use).
- **DO** fill blood only to the fill line.
- **DO** invert your tube immediately after capping.
- **DON'T** activate device until time of collection.
- **DON'T** remove device until blood reaches the fill line. The device is painless.
- **DON'T** collect if you are unable to drop sample off or schedule sample pickup for the same day (**Monday-Thursday only**).

Additional Supplies



Razor (not included)
Shaving excess arm hair will improve the chances of a successful collection.

First time using Biobox?



Watch our instructional video:
www.accessmedlab.com/biobox-video



or scan the QR code to access the video.

Contact us for help:
866-720-8386



1 Prepare

Step 1



Wash hands before use. Healthcare workers must wear gloves during collection.

Step 2



Device will be placed on upper arm - for best results remove any excess hair.

Step 3



Remove all items from the box and then remove the device from its tray. Device is single-use- **DO NOT PUSH** red button yet.

Step 4



Before you begin collection, scan the QR code provided on the activation card in the box to activate your kit and follow the guide to complete your collection.

Step 5



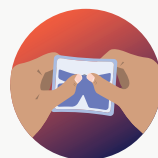
Twist and remove cap from tube.

Step 6



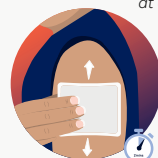
With fill lines facing out (same side as red button) press tube into device until snug.

Step 7



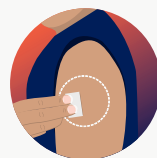
Bend the metal disc in the heat pack back and forth until it activates the heat pack.

Step 8



Set your timer for 4 minutes. Rub the upper arm with the heat pack for 4 minutes to warm the site and increase blood flow.

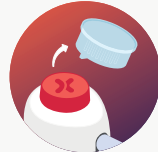
Step 9



Clean area with alcohol pad and allow to dry.

2 Collect

Step 10



Remove clear cover from red button. Take care not to push the button yet.

Step 11



Peel tab away from device and stick device to warmed area with tube pointing down. Hang arm straight at user's side.

Step 12



You may not feel the device; leave on for 5 minutes, or less if full.

Set your timer for 5 minutes then press the button down fully flush **ONCE** and release. Blood may not appear for the first 1-2 minutes. Watch tube fill using mirror as needed.

Step 13



Remove device after the 5-minute timer, or remove sooner if blood approaches upper fill line before 5 minutes is up.

Step 14



Remove device by peeling from one side. Apply bandage vertically starting below the incision and pulling up. Apply light pressure for 30 seconds.

Step 15



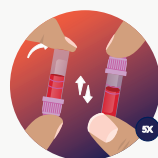
Remove tube from device by gently twisting and pulling it down. Be careful not to use excessive force to avoid spilled sample.

Step 16



Snap cap onto tube securely.

Step 17



Tap or flick tube then gently invert tube 5 times. The gel at the bottom of the tube will **NOT** mix with blood.

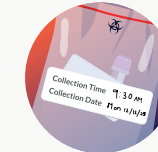
Step 18



Place tube in clear return bag and press to seal. Do not remove pad.

3 Disposal & Transport

Step 19



Record time and date on return bag label.

Step 20



Peel the adhesive tape off the top flap of the box, and then close the lid and seal the box for shipping.

Step 21



Scan the QR code provided on the shipping card in the box to schedule a pickup OR drop off at your nearest FedEx store (**Monday through Thursday ONLY**).

Step 22



Follow local guidelines for discarding used materials.

Step 23



Wash hands after use.