

instructions for use

Collection Convenience Kit Containing a Mitra® Clamshell

Follow these steps to correctly collect and transport blood microsamples.

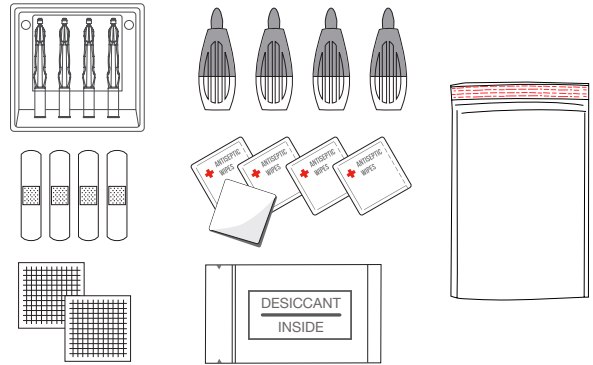
Step 1

Remove components from kit and lay them out.

- Mitra 4-sampler Clamshell (x1)
- lancet (x4)
- adhesive bandage (x4)
- alcohol prep pad (x4)
- gauze sponge pack (x2)
- aluminum bag with desiccant (x1)
- prepaid padded shipping envelope (x1)

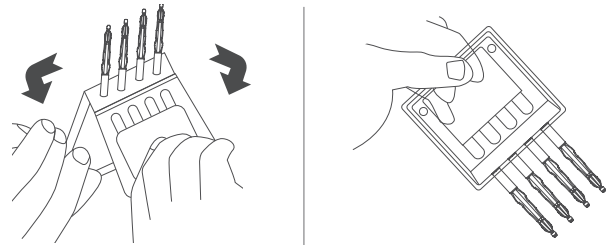
Items needed, not included in kit:

- Warm, soapy water (step 3)
- Warm, moist towel (step 5)



Step 2

Open clamshell by pulling apart the sides and pressing them together to form a handle.



IMPORTANT!

- Do NOT remove microsamplers from clamshell

Step 3

Identify the desired puncture site (shaded area).

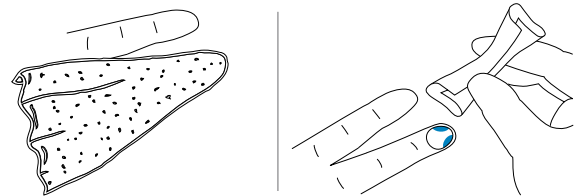
Wash your hands thoroughly with warm, soapy water. Rinse and dry.



Step 4

Use a warm, moist towel for three minutes to warm puncture site.

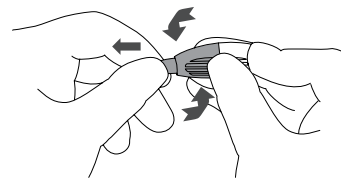
Then clean fingertip with alcohol prep pad provided and allow to completely dry.



Step 5

Twist off tab to break the seal and discard.

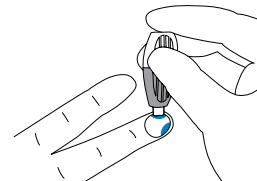
reference: BD Microtainer® Contact-Activated Lancet Quick Reference Card
(<https://www.bd.com/vacutainer/pdfs/VS7536.pdf>). See included insert.



Step 6

Position safety lancet firmly against puncture site as illustrated. Hold safety lancet between fingers.

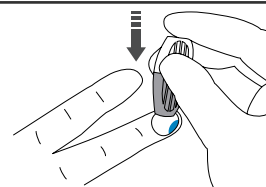
reference: BD Microtainer® Contact-Activated Lancet Quick Reference Card
(<https://www.bd.com/vacutainer/pdfs/VS7536.pdf>). See included insert.



Step 7

To activate, press safety lancet firmly against the puncture site. Do not remove the device from the site until an audible click is heard. Discard used safety lancet into an approved sharps container.

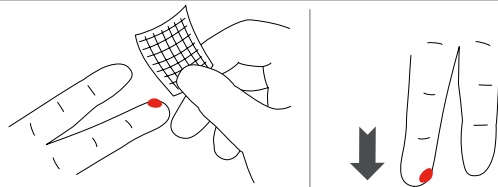
reference: BD Microtainer® Contact-Activated Lancet Quick Reference Card
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Step 8

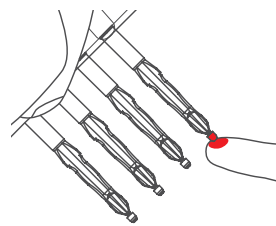
Wipe off first blood drop with gauze sponge provided.

Position hand downward towards floor allowing gravity to help increase blood supply to the punctured finger and allow second blood drop to form.



Step 9

One at a time, apply microsampler tip to the surface of the blood drop. Watch sampler tip turn FULLY red and then count 2 additional seconds. SLOWLY and SMOOTHLY remove microsampler tip from blood.

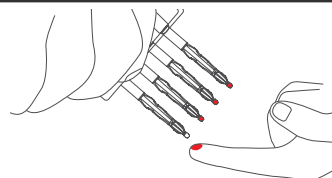


IMPORTANT!

- Tip should always point downward towards floor
- Do NOT drop blood onto the tip from above

Step 10

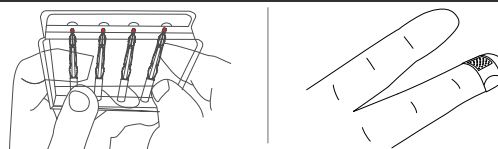
Repeat step 8 with remaining microsamplers in Clamshell. If more blood is required to fill the remaining microsamplers go back to step 3 and use a new lancet provided in the kit.



Step 11

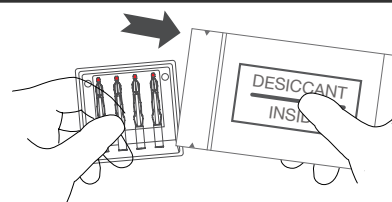
Unfold Clamshell to cover microsamplers and press firmly on both sides until a click is heard and place on surface.

Apply adhesive bandage to lancet puncture site.



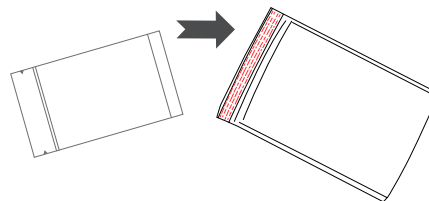
Step 12

Microsamplers secured in Clamshell should be immediately placed in provided aluminum bag containing desiccant and SEALED tightly using the zipper-top closure.



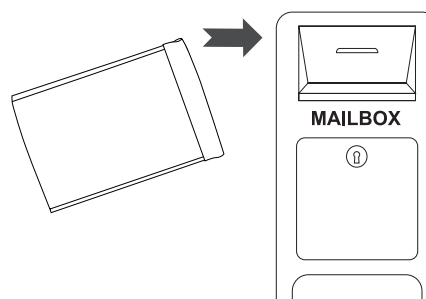
Step 13

Place the SEALED aluminum bag in the provided prepaid padded shipping envelope and seal it using the adhesive strip.



Step 14

Insert your SEALED prepaid padded shipping envelope into a mailbox.



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The Mitra Microsampler class I medical device is for direct specimen collection of blood and other biological fluids. It is not specific to any clinical test, and is not for use in diagnostic procedures. Use of the Mitra Microsampler in Laboratory Developed Tests (LDTs) requires further processing including the establishment of performance characteristics and successful validation by the laboratory in a manner consistent with CLIA requirements.

The Mitra Microsampling Device is a FDA listed Class 1 device (D254956). Neoteryx complies with FDA good manufacturing practices, CFR 820 regulations, and ISO 13485.