

RedDrop



RedDrop ONE

Instructions For Use

Warnings

- Do not use after the expiration date.
- Limited to use within professional healthcare settings.
- This device is only for use with compatible collection tubes that are cleared for use with this device.
- This device is not intended for use as a blood collection kit.
- This device does not collect or transport blood samples.
- This device is not intended for at-home collection or collection by lay-users.

Incision Size

1.75 mm x 0.050 mm x 6 (Max Depth: 2 mm)

RedDrop Dx, Inc.
2401 Research Blvd, #206
Fort Collins, CO 80526
info@reddropdx.com

Preparation

1. Lay out all items needed for collection: RedDrop ONE, Heat Pack, Tube, Alcohol swab, Gauze, Bandage, Timer
2. Wash hands with warm soapy water

4. Place the heat pack vertically on the arm, below the shoulder as shown. Heat the arm for 4 minutes. If the temperature becomes uncomfortable, the heat pack may be removed for a few seconds, then placed back on the arm.



Note: Failure to use the heat pack may cause poor results.

6. Remove the RedDrop ONE device from its packaging by peeling from the top corner



7. Remove the cap of the tube using a twist. Set cap aside. Press the tube into the device until the tube is flush with the end of the device.



Note: Ensure tube is fully inserted before continuing



Intended Use

RedDrop is a single-use, blood lancing device intended for the production of microliter capillary whole blood samples. It does not collect or transport such samples.

Device Description

RedDrop is a sterile, single use, disposable lancet. When producing a sample, the device is held onto the skin by a mild adhesive. Triggering the device releases sterile needles that puncture the skin. Simultaneously, a slight vacuum is created that helps capillary blood flow under gravity into a tube. After a predefined period of time, or when the tube is full, the device is peeled off the skin. The tube is then removed and capped. The needles automatically retract into a safe position that prevents additional use.

Precautions

- For use only on a single patient. Discard entire device after use.
- Do not use on locations presenting edema, abnormal skin integrity, or atypical skin health.
- Do not use if allergic to stainless steel.
- Use on an upper arm location with minimal hair.
- Follow your institution's guidelines regarding personal protective equipment.



This device is not intended for more than one use. Do not use on more than one patient. Improper use or handling of blood lancing devices can increase the risk of inadvertent transmission or exposure to bloodborne pathogens, particularly in settings where multiple patients are tested.

Symbols



Do not use if package is damaged

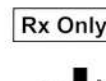


Single use only

STERILE R Sterilized by irradiation



This device contains sharps



Prescription use only



Consult IFU



Lot number



Manufacturer



Use by date



Catalog number



Do not resterilize



Store at 18°C to 28°C (64.4°F to 82.4°F)

Collect

8. Remove the liner from the back of the device by pulling on the tab to reveal the adhesive underneath. Discard.



9. Place the device on the arm in the center of the heated region with the tube pointing towards the ground. Press firmly on the device to ensure a good seal.



Note: Placing the device in the heated region is critical

10. Remove the safety clip from the device by peeling away from the skin. Discard. The sticker may remain.



11. Slide the level down until a click is heard. Relax your arm by your side.



Check for the green indicator to ensure successful activation.

12. Allow blood to collect into the tube until blood level is within the collection lines, or until 3 minutes is reached. Filling past the upper collection line, or past 3 minutes can affect sample quality.



13. Once blood has reached the upper line, or 3 minutes is reached, peel the device away from your body.



14. Remove the tube using a gentle pull and twist.



15. Cap the tube by pressing it on. A slight twist may be needed.



16. Gently invert the tube 10 times to mix the contents. A slight shake or flick may be required to get things moving. Any gel in tube will not mix.



Post-Collection

17. Clean any blood remaining on the arm with the gauze pad.



18. Place bandage over the wound to stop the bleeding.



19. RedDrop ONE collection is complete. All collection materials may be discarded.

If samples are being tested, consult with the laboratory on shipping and transportation instructions.

20. Wash hands with warm soapy water.

