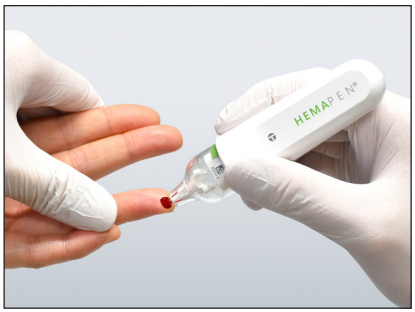
Description

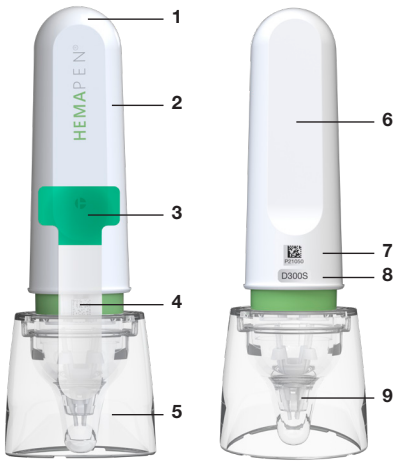
Trajan Scientific and Medical has developed the hemaPEN® as a microsampling device specifically for the collection and storage of blood in four discrete dried blood spots (DBS). The device is supplied as non-sterile and is single-use only. The device is intended to be used by health care professionals.

Delivering better patient outcomes.

Derived from standard capillary blood collection, hemaPEN provides additional benefits for better patient outcomes:

- Accurate, fixed micro-volume of blood – for quantitative testing, leading to better understanding of conditions.
- Minimally invasive sampling – enabling more frequent testing for better care decisions.
- Elimination of cold-chain – for simplified logistics and to promote out-patient sampling.
- Contained, dry sample – for minimizing contamination risk and improved sample integrity.





Components:

1. Top
2. Main body
3. Green tab
4. Data matrix label, front
5. Base
6. Custom laboratory label
7. Data matrix label, back
8. Model number
9. Capillaries

⚠ **Important**

The hemaPEN is a single-use device supplied for research only. This device is not for therapeutic or diagnostic use.

Please read these instructions for use before operating the hemaPEN.

Instructions

These instructions for use may be used in conjunction with the device instructional video:

ifuvideo.hemapen.com

The instructions are intended to guide user on how to collect blood from a participant. It is always recommended that you first wash your hands with soap and warm water, rinse and dry completely before using the hemaPEN. You may choose to wear gloves when taking or handling blood from the participant. Follow your institutions' biohazard policy and wear the appropriate personal protective equipment.

Before unpacking and using the device ensure you have:

- A clean and dry flat work surface.
- Sufficient time to complete the procedure uninterrupted.
- A permanent marker to write on a label.
- A laboratory label if required.

⚠ **Precaution**
If not using immediately store the unopened hemaPEN package in a dry environment at room temperature and not exposed to direct sunlight.

Opening the package

Place the hemaPEN kit on the work surface. Please allow 5 minutes to complete the procedure. Inspect the silver polyfoil bag and check that the heat seal is intact and that the bag is not damaged.

⚠ **Precaution**
Use the hemaPEN within 30 minutes once removed from the silver polyfoil bag.

- Tear open the silver polyfoil bag using the notch as a guide to remove the heat sealed section.
- Do not tear or damage the bag below the notch section.
- Remove the hemaPEN located in its protective plastic tray from inside the bag and place on the work surface. Do not 'tip' it out of the bag.
- Do not discard the bag. Reseal and set aside for later use for storage or transport.

Verify the kit contents:

1 x silver opaque polyfoil heat sealed bag which contains the hemaPEN device.
1 x hemaPEN device in blister tray with 1 quick guide attached.

⚠ **Warning**

The hemaPEN contains glass components. Care is required when opening the package in the rare event that capillaries are broken during transport.

Preparation of hemaPEN for use

Describes the procedure to remove the hemaPEN from its packaging and prepare the device for sample collection.

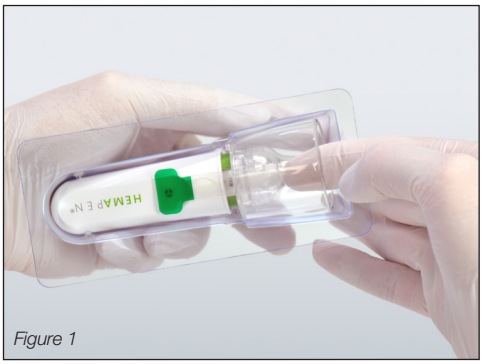


Figure 1

- Unclip the quick guide from the plastic tray. Unfold the guide and place it on your work surface, as a prompt of the key steps while the procedure is followed.
- You may scan the QR code on the quick guide to be directed to an animated instruction of how to follow the hemaPEN procedure.
- Pick up the plastic tray containing the hemaPEN, and cradle in your hand with the open side of the protective tray facing upwards as shown in Figure 1.
- Insert a finger into the bottom of the opening of the clear plastic base to remove the hemaPEN from the tray and gently lift the device from the protective plastic as shown in Figure 1 and step 1 in quick guide.
- A piece of adhesive tape with a green tab holds together the white main body of the device and the clear plastic base. Hold the white main body of the device and place the hemaPEN upright on the work surface, resting on the clear plastic base as shown in Figure 2.
- Discard the plastic tray.

⚠ **Precaution**
Do not apply pressure or push the white main body of the hemaPEN into the base. This may lock the device prematurely and render it unusable.

- Approach the hemaPEN side-on with your hand and hold the main body and the base together being careful not to apply downward pressure onto the base. Take hold of the green tab and peel off the tape by pulling downwards and discard the tape (Figure 2 and step 2 of quick guide).
- The hemaPEN is now ready for use and will be resting loosely on its base. Do not knock the hemaPEN as the device could fall and damage the capillaries.

Figure 2

⚠ **Precaution**
To prevent contamination or breakage do not touch the capillaries at the tip of the hemaPEN prior to blood collection.

As soon as the hemaPEN is ready for use, all steps of sample collection must be carried out in a timely manner to ensure optimum device performance. The collection procedure should take less than one (1) minute.

Prepare your blood sample then follow steps in one continuous motion.

Step 1 - Blood sample collection

Describes how the hemaPEN is used to ensure the optimal collection of blood sample from a variety of sources for example tubes and fingers.

Figure 3

Blood collection from a finger

Finger capillary blood may be collected using a skin puncture procedure where appropriate approval or consent is available. The hemaPEN is not supplied with a lancet and institutional protocols must be followed if this will be the source of blood. Where a lancet is available and the hemaPEN has been approved for clinical use in approved studies, institutional protocols for the use of a lancet and collection of capillary blood must be followed.

We recommend following the WHO guidelines [3] or CDC guidelines [4] for capillary blood sampling. The individual whose blood will be collected should wash their hands with soap and warm water, rinse and dry them.

Blood flow should be encouraged by massaging the hand of the individual in a downward motion towards the finger tips.

- Hold the middle or ring finger firmly and puncture the side of the finger using a sterile lancet.
- Encourage blood flow and wipe away the first droplet of blood with a piece of sterile gauze or tissue.
- Allow the blood to bead into a large droplet as shown in Figure 3.
- Remove the hemaPEN from the base using your dominant hand as if using a pen to write with.
- Touch the hemaPEN tip onto the surface of a large blood drop ensuring all four (4) capillaries are in contact with the blood. The capillaries should be held steady in the blood for approximately 10 seconds as shown in Figure 3 and step 3 in quick guide. The hemaPEN may be rotated if necessary to maintain capillary contact. Blood can be observed entering and moving up inside the capillaries.

⚠ **Precaution**
Do not submerge the capillaries into the blood droplet such that they contact the surface underneath. If contact occurs this may block the capillary tip and prevent or slow blood collection.

- Return the hemaPEN to its base. Immediately proceed to Step 2 - hemaPEN locking.


Figure 4

Blood collection from a tube

In cases where the blood source contains anticoagulant, a blood droplet (25 µL) may be deposited onto a clean surface such that the blood beads. The hydrophobic cap of a microcentrifuge tube is an ideal surface.

⚠ **Precaution**
Do not introduce air bubbles into the blood droplet as air trapped in the capillary will prevent accurate collection.

The blood can be collected using the hemaPEN as shown in Figure 4.

- Touch the hemaPEN tip onto the surface of a large blood drop. The capillaries should be held steady in the blood for approximately 10 seconds. Ensure all four (4) capillaries are in contact with the blood droplet by rotating the hemaPEN if necessary.
- Immediately proceed to Step 2 - hemaPEN locking.

Step 2 - hemaPEN locking

Describes the procedure to initiate blood storage onto the DBS papers and locking the device to prevent reuse. Performing the correct locking procedure initiates the sample transfer to the DBS paper and maintains the sample integrity. This should be performed within 5 seconds after blood collection in Step 1.

Figure 5

- Firmly hold the hemaPEN main body with your hand as shown in Figure 5.
- Swiftly push hemaPEN down into the base resting on your work surface. You may hear a CLICK. The device is now locked.
- Proceed immediately to Step 3 - Blood storage.

Step 3 - Blood storage

Describes the confirmation that the sample transfer has either been initiated or completed by inverting the hemaPEN.

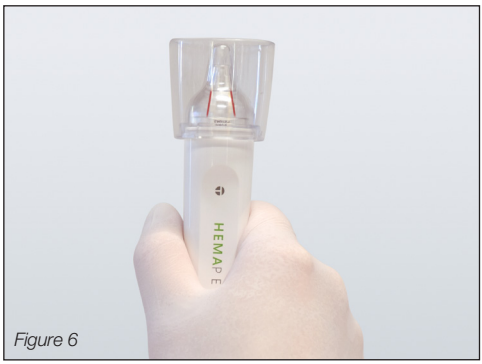


Figure 6

- Turn the hemaPEN upside down to ensure blood storage onto the DBS papers as shown in Figure 6. Hold the inverted hemaPEN for 2 seconds and prepare for repackaging.
- The blood is being stored inside four DBS pads within the body of the hemaPEN.

⚠ **Precaution**
Do not attempt to forcibly remove the locked hemaPEN from the clear plastic base. This will damage the device and compromise the integrity of the collected sample.

Step 4 - Repack and label

Describes the additional labeling requirements, placement of the used hemaPEN into the polyfoil bag for drying the samples as dried blood spots and storage under dry conditions to maintain sample integrity.

Figure 7

- The hemaPEN carries a unique 2D data matrix to allow traceability. Alternatively a clear space is available on the main body to attach any custom labeling.
- Return the hemaPEN to the bag and reseal as shown in Figure 7.
- It is recommended that the hemaPEN remain in the bag for at least two hours so the samples dry completely before attempting to perform any analysis on the DBS [2].
- The bag can be shipped in a standard postal bag or envelope with the delivery and return address clearly marked.
- Dried blood spots are not restricted by International Air Transport Association (IATA) but any shipping container should be clearly labeled with the contents and display a biohazard symbol.
- The hemaPEN is subject to aviation security and clearing procedures as identified in the aviation security and dangerous goods declaration [5].

⚠ **Precaution**
If the sample is known to contain infectious material consult a medical practitioner to ensure the sample is safe to transport via the mail service. Special precautions may be required. Always follow international, national and local regulations with respect to packaging and labeling.

- Dispose of any waste materials and biological samples in accordance with local waste management policies and procedures.

References

[1] GHTF/SG1/N70:2011 Label and Instructions for Use for Medical Devices.

[2] Australian Regulatory Guidelines for Medical Devices: Essential Principle 13.

[3] World Health Organization Guidelines on drawing blood: best practices in phlebotomy (2010) IBSN 978 924 159922 1 Chapter 7: Capillary Sampling

[4] https://www.cdc.gov/labstandards/pdf/vitaleqa/poster_capillaryblood.pdf

[5] http://www.cdc.gov/labstandards/pdf/nsqap/Bloodspot_Transportation_Guidelines.pdf

Information and support

The hemaPEN is a single-use device supplied for research only. This device is not for therapeutic or diagnostic use.

Visit www.hemapen.com or contact techsupport@trajanscimed.com

Specifications are subject to change without notice.

Trajan Scientific Australia Pty Ltd
7 Argent Place, Ringwood, VIC 3134, AU. Tel: +61 (0) 3 9874 8577

Australia and New Zealand

Trajan Scientific Australia Pty Ltd
7 Argent Place, Ringwood
Victoria 3134, Australia
Toll Free: 1800 257 213
Tel Melbourne: +61 (0) 3 9874 8577
anz@trajanscimed.com

Americas

Trajan Scientific Americas Inc
Wells Branch Tech Center - Austin TX
1421 W Wells Branch Pkwy # 108
Pflugerville, Texas 78660, USA
Toll Free: 800 945 6154
Tel: 512 837 7190
Fax: 512 836 9159
usa@trajanscimed.com

Europe, Middle East, Africa and India

Trajan Scientific Europe Ltd
Crownhill Business Centre
14 Vincent Avenue
Crownhill, Milton Keynes
MK8 0AB, United Kingdom
Tel: +44 (0) 1908 568 844
Fax: +44 (0) 1908 566 790
europe@trajanscimed.com

Asia

Trajan Scientific Japan Inc
RK CUBE 3F, 6-85 Otamachi
Naka-ku, Yokohama-shi
Kanagawa 231-0011, Japan
Tel: +81 (0) 45 222 2885
Fax: +81 (0) 45 222 2887
japan@trajanscimed.com

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