Intended use

hemaPEN® is intended for the collection of fixed micro-volume blood and storage in a dried format (dried blood spot (DBS)).

Product

The hemaPEN is a robust handheld device supplied as a non-sterile, single-use unit, designed to collect from a single source, four accurate and precise fixed micro-volume of blood, and transfer to four 3.5 mm paper discs (substrate). Samples are contained within the hemaPEN's tamper-resistant housing, the integrated desiccant enables a consistent sample drying profile, and the dried sample format enables simplified storage and logistics. The entire collected sample goes directly into analytical workflow effectively eliminating the volumetric aspect of hematocrit bias inherent with conventional DBS cards.

Precautions

- Follow instructions for use.
- For use by research personnel and healthcare professionals.
- Single use only – do not reuse.
- Contains glass capillaries. Do not use if the capillaries are broken.
- Use the hemaPEN device within 30 minutes once removed from the packaging.
- hemaPEN performance may be impaired when collecting blood with hematocrit >55%.

Storage instructions

- Store the devices in original packaging at room temperature, in a dry area.
- Avoid direct sunlight exposure.
- After use, store the hemaPEN device sealed in original packaging. Store or transport product at room temperature.

Quality Management System

hemaPEN is assembled in Trajan Scientific Australia Pty Ltd's ISO 9001 certified Australian site.

Technical data

<table>
<thead>
<tr>
<th>Product features</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample type</td>
<td>Whole blood</td>
</tr>
<tr>
<td>Storage format</td>
<td>Dried</td>
</tr>
<tr>
<td>Sample volumetric accuracy</td>
<td>2.74 ±5% µL</td>
</tr>
<tr>
<td>Volumetric precision</td>
<td>CV &lt;2.5% (interdevice)</td>
</tr>
<tr>
<td>Number of samples collected</td>
<td>4</td>
</tr>
<tr>
<td>Capillary specification</td>
<td>K2 EDTA-coated borosilicate Type 1 USP</td>
</tr>
<tr>
<td>Substrate dimensions</td>
<td>3.5 mm diameter</td>
</tr>
<tr>
<td>Substrate</td>
<td>226™ supplied by PerkinElmer Pty Ltd, or 903® supplied by Eastern Business Forms, Inc.</td>
</tr>
<tr>
<td>Shelf life</td>
<td>One year</td>
</tr>
<tr>
<td>Material and colors</td>
<td></td>
</tr>
<tr>
<td>Product color</td>
<td>White main body, a clear plastic tip and base and a green indicator stripe</td>
</tr>
<tr>
<td>Packaging</td>
<td></td>
</tr>
<tr>
<td>Units/pack</td>
<td>Provided as a single unit per pack</td>
</tr>
<tr>
<td>Pack dimensions</td>
<td>160 mm x 230 mm x 50 mm</td>
</tr>
</tbody>
</table>

Part number

<table>
<thead>
<tr>
<th>Part number</th>
<th>Model number</th>
<th>Substrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>498100001</td>
<td>D3003</td>
<td>226™ supplied by PerkinElmer Pty Ltd*</td>
</tr>
<tr>
<td>498100011</td>
<td>W3005</td>
<td>903® 100% cotton fiber supplied by Eastern Business Forms, Inc.†</td>
</tr>
</tbody>
</table>

*226™ is a trademark of PerkinElmer, Inc or its affiliated entities. *903® is a registered trademark of Eastern Business Forms, Inc.

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

For more information about this product visit www.hemapen.com or contact techsupport@trajanscimed.com
Microsampling | hemaPEN continued

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