

hemaPEN® | D300S

Research use only

Intended use	Research use only. hemaPEN® is designed to collect and store accurate and precise micro volumes of blood or a bio-sample. Samples are transferred from a collection capillary on to a substrate and stored in a dried blood spot format suitable for shipping by standard postal service for analysis in a central laboratory. hemaPEN RUO D300S is a research only device and does not have regulatory approval for medical use.
Product	The hemaPEN is a hand held device for blood microsampling. As the device name implies, the hemaPEN has a pen-like design and is supplied as a non-sterile, single use device for the collection of small accurate volumes of blood via four (4) small glass capillaries that protrude slightly from the body of the hemaPEN. After blood collection, the device is engaged into its protective cap and the blood transfers from the capillaries onto four discrete 3.5 mm pre-punched substrate discs. The four replicate blood spots are contained within the body of the device and the blood dries within one hour. The dried samples within the device can then be transported under ambient conditions to the testing laboratory using standard postal services. The most common blood source is anticipated to be derived capillary blood from a finger stick draw however hemaPEN's use is not limited to the collection of capillary blood.
Precautions	<ul style="list-style-type: none"> • Follow instructions for use. • Recommended use by research personnel and healthcare professionals trained on the device. • Single use only. • Contains glass capillaries. Do not use if the capillaries are broken. • Use the hemaPEN device within 30 minutes once removed from the silver polyfoil bag.
Storage instructions	<ul style="list-style-type: none"> • 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.
Manufactured in accordance to Trajan's internal Quality Management System.	

Technical data	
Part number	498100001
Product features	
Sample type	Whole blood, serum, plasma or other biological fluids
Storage format	Dried
Sample volumetric accuracy*	2.74 ± 0.14 µL
Volumetric precision*	CV < 0.6% (interdevice)
Substrate†	226™ supplied by PerkinElmer Pty Ltd
Number of samples	4
Number of capillaries	4
Capillary specification	Borosilicate 0.36 mm internal bore diameter
Number of pre-punched discs	4
Disc dimensions	3.5 mm diameter
Shelf life	Six months

* Based on preliminary data generated by Trajan Scientific Australia Pty. Ltd.

† 226™ is a trademark of PerkinElmer, Inc or its affiliated entities.

The hemaPEN is under development and the prototype device is supplied for research or investigational purposes only. This device is not for therapeutic or diagnostic use.

hemaPEN D300S - continued

Technical data	
Material and colours	
Product colour	White main body, a clear plastic base and a green indicator stripe
Product material	Modified poly (acrylonitrile-butadiene-styrene) thermoplastic
Capillary material	Borosilicate glass HGB1 3.3 for laboratory glassware ISO3585
Desiccant	Multiform CSF® - Silica gel with high density polypropylene filler and hydroxypropyl methylcellulose with titanium oxide
Clear base	Poly (bisphenol-A-carbonate) thermoplastic
Tape	Polyester film with an acrylic adhesive polymer
Packaging material	Polyethylene terephthalate co polyester blister tray in a polyfoil bag
Packaging	
Units/pack	Provided as a single unit per pack
Pack dimensions	160 x 230 x 50 mm

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