Trajan Scientific and Medical

media@trajanscimed.com
www.trajanscimed.com

FOR IMMEDIATE RELEASE

Trajan's hemaPEN included on TGA's ARTG as first blood microsampling device for use in Australia

Melbourne, Victoria, Australia – 7 February 2020

Trajan Scientific and Medical's hemaPEN® device has been included on the Australian Register of Therapeutic Goods (ARTG). The device enables the volumetrically accurate collection and storage of four dried blood spot (DBS) samples remote to the clinical setting, to drive information-rich healthcare decision making.

Trajan's Group CEO and Chairman, Mr Stephen Tomisich says, "We believe the future of healthcare is preventative, personal, and will be increasingly based on analytical data. The hemaPEN design is all about delivering robust and reproducible blood sample collection in remote settings. Having confidence in results then allows for informed decision making, especially if we can identify trends over time or across populations. When there is variation in the underlying data it makes identification of the trends far more difficult."

This first version of the hemaPEN platform is just one of an evolving class of microsampling devices being developed by Trajan.

Microsampling technology is expected over time to deliver real benefits to society, enabling:

- Less invasive and pain-free blood collection compared with phlebotomy.
- More frequent and/or smaller blood volumes to be collected.
- Remote patient testing for many patient demographics.
- Samples to be collected by anyone in any place, and eliminates the need for cold chain transportation.
- Significant time and cost savings for healthcare providers, by reducing collection center costs, transportation fees, storage costs of samples, without compromising patient results.

Mr Tomisich said, "We are witnessing the transition towards more sensitive and selective analytical techniques into clinical pathology."

hemaPEN has had in-depth evaluations by independent laboratories, and features in a growing number of scientific publications demonstrating its analytical performance, including addressing the limitations of traditional DBS technology.

A recent publication in *Analytical Chemistry* by toxicology scientists at the University of Ghent in Belgium, concluded that bioanalytical methods can be successfully developed and validated in accordance with the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) using samples collected by the hemaPEN.*

Dr Anne Collins, Trajan's Business Unit General Manager, Microsampling, commented, "For inclusion on the ARTG, Trajan has declared compliance with the TGA regulatory requirements for safety and performance of hemaPEN, which alongside the independent validation of the analytical performance creates a unique opportunity in Australia and New Zealand, to enable the collection of blood samples that either couldn't or wouldn't normally be taken."

Since hemaPEN was first introduced for research use worldwide, Trajan has worked closely with its partners in healthcare, pathology, pharmaceutical, food and environmental testing laboratories; with the aim to develop patient-centric technology to improve the blood sampling experience for:

- Those who require frequent testing (e.g. therapeutic drug monitoring to better manage health prognosis).
- Individuals with limited access to healthcare facilities or clinics.
- Patients who are vulnerable to the complications of frequent or large volume blood sampling, such as young children and the elderly.
- Participants in drug development clinical trials, longitudinal studies, or biomonitoring.

“We are working on registering hemaPEN in each major global market.” said Dr Collins.

Trajan works one on one with partners and customers to ensure successful adoption by clinicians and smooth integration into existing laboratory workflows, while introducing all the benefits of hemaPEN technology.

“As a platform technology, there is enormous potential for customization and large-scale deployment of hemaPEN.” said Dr Collins.

Visit www.hemapen.com to purchase or learn more about hemaPEN, and to sign up for updates.

To learn more about Trajan’s microsampling technologies and capabilities visit www.trajanscimed.com/microsampling.

**Deprez, S. et al. “Evaluation of the Performance and Hematocrit Independence of the hemaPEN as a Volumetric Dried Blood Spot Collection Device.” (Analytical Chemistry 2019 91 (22), 14467-14475)*

More information
www.hemapen.com
www.trajanscimed.com

Media contact information
Trajan Scientific and Medical
Tel: +44 (0) 1908 568 844
media@trajanscimed.com

PR-0058-G

This information is relevant for hemaPEN supplied in Australia and New Zealand only.
For other areas please visit www.hemapen.com.
ARTG number: 280007

NOTES FOR EDITORS

1. Trajan Scientific and Medical

Science that benefits people

Trajan is focused on breakthrough solutions to improve human wellbeing through biological, environmental or food related measurements. Our focus is on developing and commercializing technologies that enable analytical systems to be more selective, sensitive and specific - especially those that can lead to portability, miniaturization and affordability.

With over 450 staff worldwide across Australia, Europe, USA and Asia, Trajan serves customers in over 100 countries with highly specialized consumables and components used in scientific analysis and clinical applications.

Trajan is building a suite of technologies and solutions around hemaPEN® as a platform technology that can be applied to any microsampling workflow challenge:

- Synthetic substrates that can be functionalized to improve sample stability, reduce ubiquitous impurities of standard cellulose-based DBS papers, or streamline sample extraction.
- Customizable cartridge design.
- Custom analytical workflow integration or automation solutions

www.trajanscimed.com/microsampling

2. hemaPEN®

Advanced precision microsampling

Confident and accurate results begin with hemaPEN.

hemaPEN is a microsampling tool that enables the collection of four volumetrically fixed, accurate and precise, samples from a single source.

Where there is no option to compromise, the hemaPEN is designed to maintain sample integrity for quantitative analysis and enable information-rich decision making.

hemaPEN is an easy to use advanced precision microsampling tool that can be used by anyone in any place.

www.hemapen.com

hemaPEN included on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG)
ARTG number: 280007

The Australian Register of Therapeutic Goods is a register of therapeutic goods that can be lawfully supplied in Australia. Trajan has declared hemaPEN as a Class 1 IVD specimen collection and storage device, in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002. Trajan Scientific Australia Pty Ltd is the sponsor and manufacturer.

www.tga.gov.au

TRAJAN

3. Evaluation of the Performance and Hematocrit Independence of the hemaPEN as a Volumetric Dried Blood Spot Collection Device

Sigrid Deprez†, Lucía Paniagua-González‡, Sofie Velghe†, and Christophe P. Stove†
†Laboratory of Toxicology, Department of Bioanalysis, Faculty of Pharmaceutical Sciences, Ghent University, Ottergemsesteenweg 460, 9000 Ghent, Belgium
‡Toxicology Service, Institute of Forensic Sciences, Faculty of Medicine, University of Santiago de Compostela, Rúa San Francisco s/n, 15782 Santiago de Compostela, Spain
Analytical Chemistry 2019 91 (22), 14467-14475
DOI: 10.1021/acs.analchem.9b03179

Abstract
Dried blood spots (DBS) are often used as a less invasive alternative to venous blood sampling. Despite its numerous advantages, the use of conventional DBS suffers from the hematocrit (hct) effect when analyzing a subpunch. This effect could be avoided by using hct-independent sampling devices, of which the hemaPEN is a recent example. This device collects the blood via four integrated 2.74 μL microcapillaries, each depositing the blood on a prepunched paper disc. In this study, we evaluated the technical performance of the hemaPEN devices, using an extensive bioanalytical validation and application on authentic patient samples. An LC-MS/MS method quantifying caffeine and its metabolite paraxanthine in dried whole blood (using the hemaPEN device) was fully validated, meeting all preset acceptance criteria. A comparative analysis of 91 authentic patient samples (hct range: 0.17–0.53) of hemaPEN, 3 mm DBS subpunches, and whole blood revealed a limited hct dependence (≤7% concentration difference over a 0.20–0.50 hct range) for the hemaPEN devices, which we could not attribute to the analytical procedure. Using conventional partial-punch DBS (3 mm punches), concentration differences of ≥25% over this hct range were found. The hemaPEN showed to be robust to the effects of blood sample volume, device lot, analytical operator, and storage stability. The technical performance of the hemaPEN when dealing with patients having a high hct and in cases where a large blood drop is present should be further investigated. Based on the successful validation and application on patient samples, we conclude that the hemaPEN device shows good potential for the volumetric collection of DBS.

https://pubs.acs.org/doi/abs/10.1021/acs.analchem.9b03179