

FOR IMMEDIATE RELEASE**US FDA listing of Trajan's hemaPEN® blood microsampling device****Melbourne, Victoria, Australia – 2 July 2020**

Trajan Scientific and Medical (Trajan) has listed its hemaPEN® blood microsampling device with the U.S. Food and Drug Administration (US FDA) as Class I for therapeutic and in vitro diagnostic (IVD) use.

This follows the hemaPEN's recent registration in May for supply in the EU and UK as a General IVD; as well as inclusion in the TGA's ARTG (Australian Register of Therapeutic Goods) in February as a Class I IVD.

This enables hemaPEN to be used to collect blood microsamples for clinical trials, diagnostics and applications to monitor health.

hemaPEN provides a convenient sampling procedure for collection and storage of four dried blood spot (DBS) samples. Unlike conventional DBS sampling tools, hemaPEN enables collection of an accurate and precise fixed micro-volume and is designed to maintain sample integrity for quantitative analysis. An easy-to-use sophisticated microsampling tool in the hands of non-analysts.

Remote microsampling facilitates more flexible blood sampling compared to traditional phlebotomy (blood draw) for scientific and clinical communities, for rapid R&D and implementation of new healthcare solutions for the public.

Trajan believes in science that benefits people – creating portable and affordable measurement solutions, enabling accurate results to inform preventative healthcare.

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.

Related news

[The third leg in at-home healthcare – microsampling](#)

[CE mark for Trajan's hemaPEN blood microsampling device, now available for diagnostic use across EU and UK](#)

[Trajan's hemaPEN included on TGA's ARTG as first blood microsampling device for use in Australia
Pens and prospering as a manufacturer](#)

Featured publication

[*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) 7703 828 309

media@trajanscimed.com



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

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

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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 μ L 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 ($\leq 7\%$ 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 $\geq 25\%$ 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>