Trajan Scientific and Medical

media@trajanscimed.com
www.trajanscimed.com

FOR IMMEDIATE RELEASE

Advantages of hemaPEN blood microsampling validated for therapeutic drug monitoring in RSC's Analyst

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Trajan Scientific and Medical's (Trajan) hemaPEN® has been independently evaluated and the results of the study published in the Royal Society of Chemistry's journal *Analyst* - selected for the cover of issue 17. hemaPEN demonstrated significant advantages for blood sampling to support better healthcare decision making.

What sets hemaPEN apart from other blood microsampling methods, is its easy-to-use pen-like design and the ability to provide volumetrically accurate and precise samples for analysis.

The independent study, proving the hemaPEN methodology to be valid and reliable for application to therapeutic drug monitoring (TDM) of psychiatric patients treated with antidepressant drugs used to manage major depressive disorder, obsessive-compulsive disorder and eating disorders. The study was undertaken by the Research Group of Pharmaco-Toxicological Analysis (PTA Lab), headed by Professor Laura Mercolini at the Department of Pharmacy and Biotechnology (FaBiT) of the Alma Mater Studiorum - University of Bologna, Italy.

The study found that hemaPEN will only collect a volumetrically accurate and precise volume. Even when trying to over or underfill the device by holding it in the sample for longer or shorter periods of time, it was only possible to collect the defined volume.

Researcher Dr Michele Protti said "The original methodology developed in this work proved to be a promising tool for volumetric sampling of capillary whole blood from patients undergoing pharmacological treatment with central nervous system (CNS) drugs."

"hemaPEN also has high potential for future implementation in self- and home-sampling procedures, paving the way toward patient-centric precision medicine and therapy personalization within the framework of psychiatric pharmacological regimens and neuro-degenerative diseases." said Dr Protti.

The current challenge with at-home microsampling for TDM is the ability to collect quality samples for laboratory analysis. Inaccurate volume sampling can lead to unreliable results and poor healthcare decision making – particularly for monitoring patients over extended periods of time, or for drugs with a narrow therapeutic index.

"hemaPEN was developed to provide a foolproof sample collection procedure, so even if you make mistakes, any samples you did collect will still be volumetrically accurate and precise." said Dr Andrew Gooley, Chief Scientific Officer, Trajan Scientific and Medical.

"It is great to see a growing number of independent studies taking advantage of hemaPEN blood microsampling; and it is also available for therapeutic and diagnostic use in the EU and UK, and is listed as a Class I IVD by the US FDA and TGA ARTG." said Dr Gooley.

The published study method was validated according to European Medicines Agency (EMA) and the U.S. Food and Drug Administration (US FDA) guidelines and is available open-access from *Analyst*.

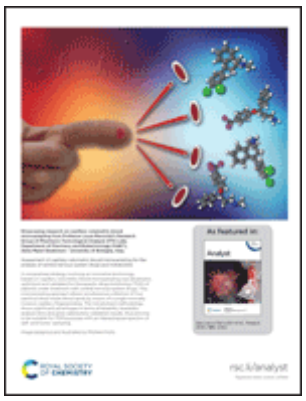
Trajan believes in science that benefits people – creating portable and affordable measurement solutions, enabling accurate results to inform preventative healthcare.

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.

Featured publication

Protti, M., Marasca, C., Cirrincione, M, Cavalli, A, Madrioli, R, and Mercolini, L. (2020), 'Assessment of capillary volumetric blood microsampling for the analysis of central nervous system drugs and metabolites', Analyst, 7 September 2020, Volume 145, Issue 17, page 5744 to 5753.



Related news

The third leg in at-home healthcare – microsampling
US FDA listing of Trajan's hemaPEN blood microsampling device
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
European patent for Trajan's hemaPEN

Related publications

Deprez, S. et al. (2019) "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
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Media contact information
Trajan Scientific and Medical
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

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2. hemaPEN®

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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.

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3. Assessment of capillary volumetric blood microsampling for the analysis of central nervous system drugs and metabolites

*Michele Protti[‡a], Camilla Marasca[‡ab], Marco Cirrincione[a], Andrea Cavalli[bc], Roberto Mandrioli[d] and Laura Mercolini[*a]*

a. *Research Group of Pharmaco-Toxicological Analysis (PTA Lab), Department of Pharmacy and Biotechnology (FaBiT), Alma Mater Studiorum – University of Bologna, Via Belmeloro 6, 40126 Bologna, Italy. E-mail: laura.mercolini@unibo.it*
b. *bItalian Institute of Technology (IIT), Via Morego 30, 16163 Genoa, Italy*
c. *Department of Pharmacy and Biotechnology (FaBiT), Alma Mater Studiorum – University of Bologna, Via Belmeloro 6, 40126 Bologna, Italy*
d. *Department for Life Quality Studies, Alma Mater Studiorum – University of Bologna, Corso d'Augusto 237, 47921 Rimini, Italy*

*‡These two authors contributed equally to the study. *Corresponding authors.*

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Abstract
Therapeutic drug monitoring (TDM) is an important tool for correlating the administered drug dose to drug and metabolite concentrations in the body and to therapeutic and adverse effects. In the case of treatment with drugs active on the central nervous system (CNS), frequent TDM becomes really useful, especially for patient compliance checking and for therapy optimisation. The selective serotonin reuptake inhibitors (SSRIs) fluoxetine and sertraline, chosen as target compounds for this study, are two antidepressants mainly used for major depression, but also for obsessive-compulsive disorder associated with neurodegenerative diseases and for eating disorders. Microsampling approaches can be used to make TDM patient-friendly, by means of minimally invasive fingerpricking instead of classic invasive venipuncture. In this study, an innovative volumetric microsampling approach based on the use of hemaPEN technology is proposed to simultaneously obtain four identical dried whole blood microsamples by means of a single capillary sampling. The developed strategy shows significant advantages in terms of blood collection and storage, fast and feasible extraction procedure and sensitive LC-MS/MS analysis, also providing satisfactory validation results (extraction yield >81%, RSD <12.0%, and <6.3% loss in analyte stability after 3 months). The proposed methodology has proven to be sound and reliable for application to the TDM of psychiatric patients treated with antidepressant drugs such as fluoxetine and sertraline. The original capillary volumetric microsampling procedure using hemaPEN has been demonstrated to be suitable for the accurate sampling of capillary whole blood, in order to be successfully exploited in self- and home-sampling procedures in future and to pave the way for precision medicine approaches for the treatment of CNS disorders.

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