



## Biomarkers at Eurofins Medinet

Over the next decade the use of biomarkers will play an increasingly prominent role in clinical trials. The use of biomarkers is expected to further streamline the drug development process with potential cost savings. In order to allow our customers to make most out of their clinical trials Eurofins Medinet routinely implements the analysis of laboratory biomarkers into each phase of clinical trials to enable our customers to prove the efficacy of the drug and thereby supporting to reduce attrition rates.

Eurofins Medinet has created a special dedicated committee on this subject. The Biomarker Working Group

focuses on safety and toxicology biomarkers and efficacy biomarkers. A Study Director is assigned to every single study to determine the level of required validation with you, to select the appropriate methods. For biomarker assays, we propose the adoption of a continuous and evolving fit-for-purpose strategy. We can offer a spectrum of assay validation from CLIA to more extensive GLP validation. Of course we will advise on sample handling and storage conditions. Our focus on biomarkers even extends across Eurofins Medinet borders in a close collaboration with our sister company Eurofins AvTech Laboratories (USA).

## Enrichment of the Bioanalytical portfolio through USA expansion

Eurofins Medinet has entered a business agreement with Prof. U. Christians from the University of Colorado Health Science Center to establish a new bioanalytical laboratory in Denver, Colorado. This laboratory will embody a highly qualified and recognized biomarker-profiling and development group and will be specialized in mass spectrometry-based quantification of endogenous compounds.

This collaboration complies with the business strategy of Eurofins Medinet to partner with an academic center to transfer technology and partner in method development. It will signify a perfect synergy of academic strength with the existing infrastructure and experience of Eurofins Medinet in order to collaborate efficiently with the pharmaceutical

industry. This initiative will expand Eurofins Medinet's portfolio even further and will greatly benefit our customers.



Bioscience Park Center, Colorado

Global Laboratory Services. Discover. Experience. safety biomarkers bioanalysis microbiology genomics



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In order to launch our new company name and corporate brand to a wide audience, Eurofins Medinet will advertise on the cover page of SCRIP magazine throughout 2007.



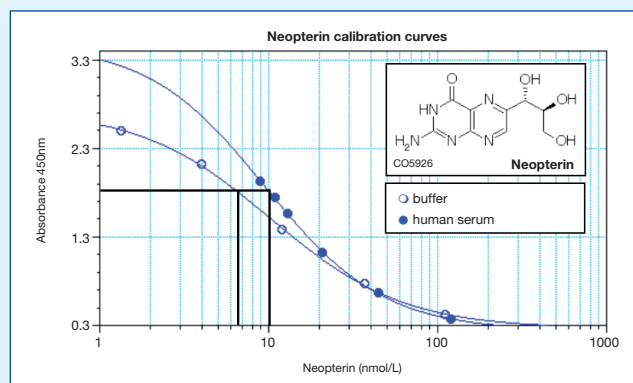
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## GLP Validation of Neopterin determination in human serum

Neopterin is produced in large amounts by Interferon- $\gamma$  activated monocytes/macrophages. Since an increase in serum Neopterin levels precede clinical manifestation of infection and seroconversion, it has become one of the most important markers for viral infection. Determination of Neopterin in body fluids usually is performed by competitive ELISA. However, as for many immuno-assays, these assay kits are designed for research only and are not suitable for pharmacodynamic profiling or efficacy examination. We have shown that there is a considerable matrix effect caused by serum components. As shown in the figure, determination of a serum 10 nmol/L Neopterin sample using a calibration curve in buffer would only return about 7 nmol/L. Therefore, we have prepared new calibration and quality control (QC) samples in human serum. In order to correct for the presence of endogenous Neopterin in human serum, this endogenous level of Neopterin has been determined by means of standard addition. Using this modified method and reagents from a commercially available Neopterin ELISA kit, we have performed a full GLP compliant validation based on the

FDA Guidance for Industry for Bioanalytical Methods Validation (May 2001). The method was shown to be precise with an overall precision of less than 6.7 % over the whole calibration range and an accuracy ranging between 90.1 and 108 %. Furthermore, storage stability of Neopterin in human serum has been shown at ambient temperature for 3 hours and at -70°C for up to 3 months. Also, Neopterin was shown to be stable after 3 freeze/thaw cycles. In conclusion, we have upgraded the commercially available Neopterin ELISA kit to a fully GLP compliant method.



## Mark your meeting calender and visit us at the following conferences

### Bioanalysis in Clinical Research

21-22 February 2007  
Olympia Conference Center,  
London, UK

### DIA 19<sup>th</sup> Annual Euro Meeting

26-28 March 2007  
Austria Center Vienna, Austria  
Booth # 603

### 17<sup>th</sup> European Congress of Clinical Microbiology and Infectious disease

31 March - 3 April 2007  
International Congress Center  
Munich, Germany  
Booth # 357 (+part of 353)

### 16<sup>th</sup> Annual Partnerships with CROs & Other Outsourcing Providers

10-12 April 2007, Orlando,  
Florida  
Booth # 413-414

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