

Talk Abstract

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EU Project SPIDIA - Standardisation and Improvement of Generic Pre-analytical Tools and Procedures for *In vitro* Diagnostics

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Background: Molecular *in vitro* diagnostics have allowed great progress in medicine. Further progress is expected by new technologies analysing cellular biomolecule profiles such as nucleic acids, proteins, and metabolites. Studies have demonstrated that profiles of these molecules can change drastically during sample transport and storage thus making a reliable diagnostic or research unreliable or even impossible(1). The lack of international guidelines in sample collection, stabilisation, transport and storage as well as missing technologies enabling the improvement of pre-analytical workflows are meanwhile recognised as a significant limitation to further progress in molecular diagnostics. The European Commission has therefore launched the four-year large-scale integrating research project SPIDIA within the European Union FP7 programme in October 2008 (grant agreement no. 222916).

SPIDIA Programme: The SPIDIA research consortium is built by seven public research organisations, eight companies and an official European standards organisation. The project is organised into three activities. The first activity will lead to pan-European guidelines for pre-analytical workflows of *in vitro* diagnostics. Such documents will be based on evidence gathered during ring trials in order to elucidate problematic steps in pre-analytical procedures. These procedures will have a specific focus on DNA, RNA, proteins, and metabolites isolated from tissue, tumour, whole blood, serum and plasma samples. In addition, quality assurance biomarkers will be discovered to serve as indicators for artificial, post-collection changes of clinical and biological samples. The second activity is dedicated to the discovery and integration of breakthrough technologies that strengthen weak steps in pre-analytical workflows. This work includes the discovery of novel stabilisation technologies for tissues, blood, and non-invasive samples. The third activity focuses on the spreading of excellence to the clinical, research and biobanking communities.

A project introduction and an overview on its progress will be presented.

1. Rainen L, Oelmueller U, Jurgensen S, Wyrich R, Ballas C, Schram J, Herdman C, Bankaitis-Davis D, Nicholls N, Trollinger D, Tyron V. Clin Chem 2002; 48(11): 1883-90.