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## **EU Launches Project to Improve In-Vitro Diagnostics**

***QIAGEN led-consortium to develop standards for patient sample processing in order to facilitate the discovery and prediction of diseases***

**Venlo, The Netherlands, January 12, 2009** – The European Union launched a new research project targeting to expand the potentials and utility of in-vitro diagnostics through the creation of new standards for the collection, handling and processing of blood, tissue, tumor and other sample materials. Under the 7<sup>th</sup> Framework Programme, the European Commission approved the initiative's funding and scope to develop corresponding standards, tools and quality assurance schemes. The SPIDIA project ("*Standardisation and improvement of generic Pre-analytical tools and procedures for In-vitro DIAgnostics*") is scheduled to run for four years and has a total budget of over 13 million Euros. The consortium, consisting of a total of 16 companies and research institutions from 11 countries, will be led by QIAGEN (Nasdaq: QGEN; Frankfurt, Prime Standard: QIA), Europe's largest biotechnology company and a global leader in molecular sample and assay technologies.

The project has been set up to standardize the pre-analytical handling of patient samples used for in-vitro (in glass) diagnosis of human diseases. Such diagnostic procedures are performed in laboratories, hospitals and doctors' practices. In in-vitro diagnostics, the collection, handling and processing of sample materials are regarded as particularly critical procedures, as the reliability of the subsequent analysis and therefore the meaningfulness of the diagnosis are vitally dependent upon the integrity of the sample. For example, the molecular profiles of target molecules may change or disappear without proper treatment or stabilisation during collection, transportation or storage of the sample – thus making improperly handled samples useless for subsequent analysis.

"Far too many differing sample processing methods, which then lead to different results, are still being used", said Arnd Hoeveler, Head of Unit "Health biotechnology" in the Directorate "Health" of the Commission's Directorate-General for Research. "This variance hampers the comparability and reproducibility of results and reduces the meaningfulness of the analyses. More standardized guidelines and quality assurance schemes will help to introduce new and better diagnostic methods, which will benefit all European patients."

It is believed that molecular diagnostics, in which DNA and RNA are the molecules of interest, will play a particularly vital role in future healthcare in Europe. These so-called molecular diagnostic methods allow earlier and more reliable information about the status of a disease than conventional methods. Molecular diagnostics can also facilitate predictions concerning the future courses of diseases and lead to individualised therapeutic measures. They are therefore viewed as fundamental to the emergence of the new era of personalised medicine.

"QIAGEN welcomes this initiative and considers it extremely important in paving the way for a significant expansion of the potential of in-vitro diagnostics", said Peer M. Schatz, CEO of QIAGEN. "The ongoing standardization of the collection, handling and processing of relevant samples will speed up the dissemination of new in-vitro diagnostic methods. With its support of this project, the Commission is providing strong leadership in emphasizing the importance of these processes in general and molecular diagnostics and their role as cornerstones of future healthcare in Europe in particular."

SPIDIA is designed as an integrative project and further along the road, the intention of the project is also to develop standards for the other in-vitro diagnostics steps, i.e. the actual analysis. At the end of the four years a proposal for quality controls and uniform guidelines for the execution of the entire in-vitro diagnostic process should be in place. The network anticipates to share first results after two years.

#### **About SPIDIA**

The SPIDIA project (*Standardisation and improvement of generic Pre-analytical tools and procedures for In-vitro DIagnostics*) is an amalgamation of 16 members from 11 countries, including companies such as TATAA BIOCENTER AB, PreAnalytiX GmbH (a QIAGEN/BD Company), DIAGENIC ASA, Aros Applied Biotechnology A/S, Dako Denmark A/S, ACIES, ImmunID Technologies, academic partners such as universities and research institutes in Munich, Florence, Graz, Prague and Rotterdam. The International Agency for Research and Cancer and the European Standardisation Committee are also members of the project, which is being led by QIAGEN GmbH in Hilden. This is also the location of the contact office. The project is being sponsored as part of the European Union's 7th framework programme. More information is available at [www.spidia.eu](http://www.spidia.eu).

#### **About QIAGEN:**

QIAGEN N.V., a Netherlands holding company, is the leading global provider of sample and assay technologies. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are used to make such isolated biomolecules visible. QIAGEN has developed and markets more than 500 consumable products as well as automated solutions for such consumables. The company provides its products to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers for purposes such as forensics, animal or food testing and pharmaceutical process control. QIAGEN's assay technologies include one of the broadest panels of molecular diagnostic tests available worldwide. This panel includes the only FDA-approved test for human papillomavirus (HPV), the primary cause of cervical cancer. QIAGEN employs more than 3,000 people in over 30 locations worldwide. Further information about QIAGEN can be found at [www.qiagen.com](http://www.qiagen.com).

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