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Introduction

Dear valued customer,

Welcome to the first issue of the print version of *MDXpress*, the new molecular diagnostics communication platform from QIAGEN. A complete electronic version is also available if you subscribe by e-mail.

Since 2003, the diagnostic segment of QIAGEN has grown dramatically. Experience gained from customer cooperations, acquisitions, and development of new workflow solutions have supported this development. Today we are able to provide high-quality, CE-IVD-marked solutions in our three diagnostic core segments — prevention, personalized healthcare, and profiling.

For prevention, the focus is on HPV testing for prevention of cervical cancer. As the market leader, we provide complete workflow solutions for clinically relevant results. We deliver complete solutions in personalized healthcare for detection of mutations in genes involved in the development of cancers. For profiling, we specialize in infectious disease testing by real-time PCR, with the QIAasymphony® RGQ providing an automated workflow solution from sample to results.

We would like to strengthen our communication with you and encourage you to use the *MDXpress* with us as a communications platform for news, opinions, interviews, and publications from your region. Contact us anytime at MDXpress@qiagen.com.

We look forward to developing a close diagnostic communications network in Europe, with you as customers playing the most important role.

Yours sincerely,



Dr. Tobias Ruckes

Senior Director, Head of MDx Marketing EMEA

Spotlight

Complete workflow solution from sample to results!

Olivier Pasquier,
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The QIAasymphony RGQ system provides automated sample purification, assay setup, and PCR with a CE-IVD compliant workflow. The flexible system was developed to run ready-to-use *artus*® diagnostic kits as well as your laboratory-developed tests.

Molecular diagnostic laboratories today face a variety of complex challenges. Labs are expected to provide reliable test results quickly and to expand the menu of tests available. The availability of new technologies, consideration of health economics, and the emerging field of personalized healthcare are only a few of the factors driving laboratories to adapt technologies and workflows to current needs.



The QIAasymphony RGQ — a complete workflow that really makes a difference.

The automated QIAasymphony RGQ system was designed to address these needs. The flexible system allows use of ready-to-use *artus* diagnostic kits in a CE-IVD-compliant workflow or your laboratory-developed tests.

The workflow starts with sample purification on the QIAAsymphony SP using an improved magnetic-bead technology. A wide range of sample types can be processed, including plasma, serum, whole blood, respiratory samples, urine, and stool. Cartridges for additional sample sources, such as for food testing, are under development. In a recent survey, 100% of QIAAsymphony users were satisfied with extraction performance.

Assay setup on the QIAAsymphony AS module, which is physically connected to the QIAAsymphony SP, is followed by PCR on the Rotor-Gene® Q real-time PCR cyclers. Use of the complete QIAAsymphony RGQ system with *artus* PCR kits has been proven effective in several evaluation trials. Analytical sensitivity is lower than 35 copies/ml for detection of HIV and only 10.22 IU/ml for HBV. This high sensitivity enables viral load monitoring comparable to existing standards. Currently there are 8 CE-IVD-marked *artus* QS-RGQ Kits for use with the QIAAsymphony RGQ system. Assays for 5 additional pathogens are available for use on the Rotor-Gene Q with different sample preparation, and further assays for the complete system are under development.



Reliable pathogen detection using *artus* QS-RGQ Kits.

Continuous loading, random access, and the ability to do runs in parallel mean that labs are not constrained to a 96-sample system. Samples can be processed as soon as they arrive, followed by automated assay setup and quantitative real-time PCR analysis. Assays can be run in parallel, and in some cases multiple assays for the same sample can be performed in a single run.

The QIAAsymphony RGQ system offers a new approach to laboratory workflows to bring molecular testing to the next level. QIAGEN will continue to expand the QIAAsymphony series, and you can expect many

more developments with respect to sample input and processing, instrument performance, additional features, and continuous menu expansion. Visit www.qiagen.com/complete-workflow-01 for more information about the QIAAsymphony RGQ.



Diagnostic market news

Cost efficiency convinces NHS — HPV DNA testing added to cervical cancer screening in UK

From April 2011, the UK will start using HPV DNA testing to triage borderline/abnormal smears. The follow-up strategy proved effective in initial HPV triage pilots in 2004 and the HPV Sentinel Sites project. QIAGEN's *digene*® HC2 High-Risk HPV DNA Test was the test used to generate data that led to this decision. Read more online at www.qiagen.com/HPV-01.

Wolfsburg pilot project — a successful model for primary HPV screening in Germany

In February 2011, the successful Wolfsburg Cervical Cancer Prevention Project, which started in 2006, was extended for another 5 years. The project provides a risk-adapted HPV testing strategy with defined patient pathways and extended screening intervals for women of 30 years and older. Read more online at www.qiagen.com/HPV-screening-01.





Diagnostic market news

Personalized healthcare plays a key role in the present and future of pathology

Personalized healthcare uses information about a person's genes, proteins, and environment for the prevention and treatment of disease. This emerging field gives physicians the opportunity to customize treatment for the individual patient. That is the promise of personalized healthcare. Read more online at www.qiagen.com/personalized-healthcare-01.

NTCC study shows efficacy of HPV DNA testing for cervical cancer prevention

The final results of the New Technologies for Cervical Cancer (NTCC) study, led by Guglielmo Ronco, are published in *Lancet Oncology*. The study, started in 2002, assessed the benefits and risks of shifting from standard cytology (Pap testing) to HPV DNA testing in cervical cancer screening programs. Read more online at www.qiagen.com/NTCC-study-01.

About QIAGEN

QIAGEN partners with pharmaceutical companies to provide better patient care through personalized healthcare

QIAGEN is a world leader in companion diagnostics, forming partnerships with pharmaceutical companies to co-develop a diagnostic along with a drug. This companion diagnostic is co-marketed with the therapy, and the drug labeling reflects that a patient's mutation status must be tested before the drug can be administered. Read more online at www.qiagen.com/about-qiagen-01.



Literature review

Automated processing of complex clinical samples and shortened protocols for the QIAAsymphony SP

Two publications from the Laboratory for Infectious Diseases, Groningen, The Netherlands, show how the QIAAsymphony SP can be used for automated processing of complex clinical samples and how protocols can be modified to suit the needs of individual laboratories. The articles appeared in the February 2011 issue of the *Journal of Microbiological Methods*. Read more online at www.qiagen.com/microbiological-methods-01.

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