Highlights: QIAGEN launches liquid biopsy workflow for GeneReader NGS System

QIAGEN N.V. today announced the launch of its liquid biopsy workflow for clinical cancer research using QIAGEN's GeneReader NGS System for next-generation sequencing (NGS). The Actionable Insights Tumor Panel, a member of the growing family of GeneRead QIAact Panels, is the industry's first complete Sample to Insight NGS solution for both non-invasive liquid biopsies and FFPE tissue samples. The panel is now optimized for NGS analysis of blood plasma using proven automated QIAGEN sample technologies for circulating cell-free DNA (cfDNA), enabling both tumor characterization and monitoring of cancer resistance markers as a complement to initial tissue biopsies.

“The QIAact Actionable Insights Tumor Panel is now also available as a reliable solution for liquid biopsies, tracking a broad range of biomarkers to add valuable insights on the progression of cancers – and making NGS more accessible for any clinical cancer research laboratory using our GeneReader NGS System,” said Kai te Kaat, Vice President of QIAGEN's Oncology Franchise. “This new application of the QIAact panel underscores QIAGEN’s leadership in liquid biopsies and our commitment to deliver on the promise of NGS. The liquid biopsy workflow, which detects hundreds of critical variants in 12 clinically actionable cancer genes, is the second QIAact panel application in our expanding menu of molecular content for the GeneReader NGS System.”

QIAGEN’s complete liquid biopsy workflow includes the Company's Actionable Insights Tumor Panel and industry-leading liquid biopsy sample technologies for plasma, plus specialized software and bioinformatics. The solution creates a fully integrated and cost-effective workflow for testing plasma samples when formalin-fixed, paraffin-embedded (FFPE) tissue is not available or preferred. The NGS panel has demonstrated highest sensitivity of 1% in analyzing cancer variants in liquid biopsy clinical samples and Horizon control material, the industry-standard reference control data set. Bioinformatics analysis and interpretation are seamlessly integrated into the GeneReader NGS System workflow, powered by QIAGEN Clinical Insight (QCI™), interacting with expertly-curated and proprietary knowledge databases to enable efficient interpretation of NGS variants for actionable insights.

Expanding menu for GeneReader NGS System and leadership in liquid biopsies

QIAGEN is developing additional QIAact panels to run on the GeneReader NGS System, including a lung cancer panel expected in the second half of 2016 for detection and analysis of genetic copy number variations (CNVs) from tissue and blood, and a breast cancer panel for tissue-based detection and analysis of single nucleotide variants (SNVs) and genomic insertions and deletions (INDELs). An “All-in-One” lung cancer panel is also in development, adding gene fusions to coverage of actionable variants.

The GeneReader NGS System, introduced in late 2015, is rapidly gaining worldwide adoption as a highly efficient solution to address fragmented NGS workflows and bottlenecks
that have hindered many labs from achieving actionable insights from next-generation sequencing. GeneReader NGS delivers the world's first truly complete NGS workflow from primary sample to a final report, providing a simpler, more cost-effective way for clinical research to take advantage of NGS technology and improve outcomes.

The new QIAact Liquid Biopsy workflow complements QIAGEN's industry-leading liquid biopsy portfolio, which spans sample technologies, assay technologies and bioinformatics. QIAGEN provides gold-standard solutions for the extraction of circulating cell-free nucleic acids (cfDNA), circulating tumor cells (CTCs), and exosomes. These encompass convenient manual (including the QIAamp Circulating Nucleic Acid Kit) and automated solutions (including the QIAasympmny circulating DNA kit). In partnership with pharmaceutical companies, QIAGEN is also developing and commercializing a broad portfolio of companion diagnostics based on liquid biopsies.

**Demonstrating Sample to Insight solutions at ASCO**

As part of its broad portfolio of Sample to Insight solutions for molecular diagnostic and research applications in oncology, QIAGEN will showcase the GeneReader NGS System — including the QIAact Actionable Insights Tumor Panel and QIAGEN Clinical Insights informatics solution for NGS — at Booth 18031 at the American Society of Clinical Oncology (ASCO) 2016 Annual Meeting on June 3-7, 2016, in Chicago.

Many abstracts published at the meeting applied QIAGEN liquid biopsy solutions. For instance, in a study conducted by the University of Nantes, QIAGEN's QIAamp Circulating Nucleic Acid Kit — in combination with QIAGEN’s therascreen BRAF assay — has demonstrated excellent performance in the detection of BRAF mutations in circulating tumor DNA of melanoma patients.

In another French study with liquid biopsies, researchers using the QIAamp Circulating Nucleic Acid Kit in tandem with the QIAGEN EGFR therascreen kit detected EGFR mutations in 27 lung-cancer patients who could not be evaluated by tissue. The study concluded that cfDNA is a relevant alternative for TKI prescription in naïve and relapsing patients when routine tissue biopsy is not available or evaluable.