QIAGEN launches *therascreen*® EGFR Plus RGQ PCR Kit featuring C797S detection to help guide non-small cell lung cancer (NSCLC) treatment

- Sensitive detection of *EGFR* mutations including T790M and C797S, empowering oncologists with greater insights to tailor NSCLC patients’ treatment
- Enables less-invasive sampling through the option to test plasma from liquid biopsies
- Automated sample extraction options and automated results analysis, with a simple, ready-to-use system and next-day results to inform rapid treatment decision making

Germantown, Maryland, and Hilden, Germany, May 17, 2022 - QIAGEN today announced the launch of the *therascreen*® EGFR Plus RGQ PCR Kit, a new in-vitro diagnostic test for sensitive *EGFR* mutation analysis, detecting all currently known activating and resistance *EGFR* mutations. The real-time qPCR test builds on the established *therascreen* EGFR RGQ PCR Kit and provides improved limits of detection, quicker turnaround times, automated sample extraction options and automated results analysis.

In addition to the T790M mutation, the new kit now also detects C797S. This key biomarker indicates resistance to third-generation *EGFR* tyrosine kinase inhibitor [TKI], giving oncologists additional insights to adjust *EGFR* treatment for NSCLC patients. The kit also delivers next-day results and automated analysis, making it an ideal choice for labs that require a high-performing test solution for either tissue or plasma with a rapid turnaround.

“*The therascreen* EGFR Plus RGQ PCR Kit combines sensitivity in mutation detection with the flexibility to test both tissue and liquid samples, helping oncologists to make confident, informed treatment decisions for patients with advanced NSCLC”, said Kai te Kaat, Vice President, Head of Global R&D Molecular Diagnostics at QIAGEN. “With this launch, we continue to further advance our Precision Medicine portfolio by covering new clinically relevant mutations such as C797S that further improve patient outcomes.”

Genomic testing is instrumental for patient management in non-small cell lung cancer, and testing for driver mutations in *EGFR* aids oncologists to make informed treatment decisions for patients. The *therascreen* EGFR Plus RGQ PCR Kit is a more cost-effective and simpler alternative to NGS for routine follow-up testing once an *EGFR* mutation is known. The kit can test FFPE and plasma samples within the same run, allowing for matched testing of FFPE and plasma and removing the need for laboratories to batch samples of either type before a run. The decreased invasiveness of plasma sampling allows clinicians to schedule routine testing of patients on treatment to track treatment effectiveness and establish whether resistance is occurring.

Extraction can be performed manually or automated on the QIAsymphony® SP for walkaway sample processing. Sensitive real-time PCR is then performed on the Rotor-Gene® Q MDx 5plex HRM instrument with automated data analysis using Rotor-Gene AssayManager® software. The software displays qualitative results informing the operator if one or more of the 42 *EGFR* mutations are present. The Sample to Insight workflow can be completed in under 8 hours, providing next-day results and informing earlier treatment decisions.

QIAGEN is a pioneer in Precision Medicine, particularly through its *therascreen* assay portfolio that allow the detection of clinically relevant genetic alterations to provide insights that guide clinical decision-making in diseases such as cancer.

To learn more about *EGFR* mutation testing in NSCLC, visit [www.qiagen.com/EGFR-Plus](http://www.qiagen.com/EGFR-Plus).
Images are available upon request at PR@qiagen.com.

About QIAGEN
QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in molecular diagnostics (human healthcare), Applied Testing (primarily forensics), Pharma (pharma and biotech companies) and Academia (life sciences research). As of March 31, 2022, QIAGEN employed more than 6,000 people in over 35 locations worldwide. Further information can be found at https://www.qiagen.com/.

Forward-Looking Statement
Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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