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FDA gives nod to extend the Use of QIAGEN's therascreen

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The approval extends the labeling claim to include detection of EGFR mutations L681Q, G719X and S768I to aid the identification of NSCLC patients for whom GILOTRIF® (afatinib) is indicated

QIAGEN N.V. is a provider of sample and assay technologies for molecular diagnostics, applied testing, academic and pharmaceutical research.

A biotechnology company announced that the U.S. Food and Drug Administration (FDA) has approved a PMA supplement extending the indications for use of QIAGEN's therascreen® EGFR RGQ PCR Kit as a companion diagnostic.

It helps to guide the use of Boehringer Ingelheim's targeted therapy GILOTRIF® (afatinib) for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with non-resistant epidermal growth factor receptor (EGFR) mutations.

The approval extends the labeling claim to include detection of EGFR mutations L681Q, G719X and S768I to aid the identification of NSCLC patients for whom GILOTRIF® (afatinib) is indicated.

The therascreen® EGFR RGQ PCR Kit now detects the most comprehensive panel of EGFR mutations in which the safety and efficacy of GILOTRIF® (afatinib) have been established.

The kit provides reagents optimized for rapid and sensitive detection of 21 somatic mutations using the QIAamp DSP DNA FFPE Tissue Kit and the Rotor-Gene Q MDx instrument.