Therascreen EGFR RGQ PCR kit approved as CDx

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Oct. 1, 2018—Qiagen announced that the FDA has approved a PMA supplement expanding the labeling claim of the Therascreen EGFR RGQ PCR Kit to allow its use as a companion diagnostic with Pfizer's Vizimpro (dacomitinib) for first-line treatment of patients with non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or an exon 21 L858R mutation.

"The FDA's expanded approval of the Therascreen EGFR kit, which was used in the pivotal clinical trial for Vizimpro, will enable physicians to identify patients who may benefit from this medicine," Mace Rothenberg, MD, chief development officer, oncology, Pfizer global product development, said in a press release.

The Therascreen EGFR RGQ PCR kit is approved as a companion diagnostic to guide the use of three FDA-approved therapies, including Gilotrif (afatinib) from Boehringer Ingelheim and Iressa (gefitinib) from AstraZeneca.