FDA approves Qiagen CDx for NSCLC

Dec. 14, 2022—Qiagen announced FDA approval of its Therascreen KRAS RGQ PCR kit as a companion diagnostic test to aid in identifying non-small cell lung cancer patients who are eligible for treatment with adagrasib (Krazati, Mirati Therapeutics).

Qiagen said a press release that the tissue-based KRAS companion diagnostic assay was developed specifically to identify patients with NSCLC who have a KRAS G12C mutation. Krazati is indicated for the treatment of adult patients with KRAS G12C–mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy. Qiagen and Mirati Therapeutics announced their partnership to develop the companion diagnostic in May 2021.