Cobas EGFR Mutation Test v2 gets expanded approval

Oct. 30, 2020—Roche announced FDA approval of expanded claims for the Cobas EGFR Mutation Test v2 as a companion diagnostic for a broad group of therapies in the treatment of non-small cell lung cancer. The expanded approval allows the test to be used as a companion diagnostic for all five currently FDA-approved EGFR tyrosine kinase inhibitor therapies targeting EGFR mutations L858R and exon 19 deletions in accordance with the approved therapeutic product labeling. The group claim will also enable the test to be used as a CDx for any future approved EGFR TKI therapies targeting the same mutations, without the need to conduct individual clinical studies with the test for each new therapy.

“Clinicians can now have greater confidence in the robustness, reliability, and proven clinical utility of the Cobas EGFR Mutation Test v2 when evaluating lung cancer patients who may benefit from targeted EGFR TKI therapies,” Neil Gunn, head of Roche sequencing solutions, said in a press release. “By approving a single test for a broad group of therapies, this new and innovative approach by the FDA can pave the way for future EGFR TKI therapies to utilize the Cobas EGFR Mutation Test v2 to help identify patients for personalized medicine.”

The Cobas EGFR Mutation Test v2 is an RT-PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor gene in NSCLC patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed, paraffin-embedded tumor tissue or circulating tumor DNA from plasma derived from EDTA anticoagulated peripheral whole blood. Results are available in less than eight hours.