

Roche CE-marked Cobas PIK3CA Mutation Test

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January 2021—Roche launched the Cobas PIK3CA Mutation Test CE-IVD for patients with advanced or metastatic breast cancer in countries accepting the CE mark. The test was previously available for research use only.

The Cobas PIK3CA Mutation Test is a real-time PCR test for the qualitative detection and identification of 17 mutations in exons 2, 5, 8, 10, and 21 in the gene encoding the catalytic subunit of PIK3CA in DNA isolated from formalin-fixed, paraffin-embedded tissue. The test is intended to identify patients with metastatic breast cancer whose tumors harbor these mutations. It processes up to 30 samples per run on the Cobas z 480 analyzer and provides results in less than eight hours. Specimens are processed using the Cobas DNA Sample Preparation Kit to isolate genomic DNA from FFPE human specimens.

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