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Roche has announced that the US Food and Drug Administration (US FDA) has approved the cobas KRAS mutation Test for diagnostic use. The real-time PCR test is designed to identify KRAS mutations in tumor samples from metastatic colorectal cancer (mCRC) patients and aid clinicians in determining a therapeutic path for them.

"As more targeted treatment options for cancer patients become available, the importance of identifying the right molecular information to define their disease becomes critical," said Mr Paul Brown, head, Roche Molecular Diagnostics. He added, "The cobas KRAS Mutation Test gives clinicians actionable insights that enable them to make informed decisions about treatment for their patient. With this approval, Roche now offers the most comprehensive companion diagnostic FDA approved portfolio for oncology in the US, including tests for BRAF (melanoma), EGFR (lung cancer) and KRAS (mCRC) mutations."

According to the Centers for Disease Control and Prevention, colorectal cancer is the second leading cause of cancer-related deaths in the United States and the third most common cancer in men and women. The cobas KRAS Mutation Test is intended to be used as an aid in the identification of mCRC patients for whom treatment with Erbitux (cetuximab) or Vectibix (panitumumab) may be effective if no KRAS mutation is present.