

KRAS Mutation Detection Analysis by Real-Time PCR

Test Code 220

Patient Name: XXXXXXXX, XXXXXXXX Date of Birth: XX/XX/XXXX Oncotech ID No: XXXXXXXXXXXXXXXXXXXX Institution: XXXXXXXXXXXXXXXXXXXX Oncologist: XXXXXXXXXXXXXXXXXXXX Surgeon: XXXXXXXXXXXXXXXXXXXX Pathologist: XXXXXXXXXXXXXXXXXXXX Ordering Physician: XXXXXXXXXXXXXXXXXXXX Medical Record: XXXXXXXXXXXXXXXXXXXX Pathology Ref. No.: XXXXXXXXXXXXXXXXXXXX	Diagnosis: Prior Chemotherapy: Unknown Specimen Site: Specimen Size: Block Collection Date: XX/XX/XXXX Date Received: XX/XX/XXXX Date of Service: XX/XX/XXXX Date Reported: XX/XX/XXXX Date Printed: XX/XX/XXXX Report Page No: 1	<h1>Sample Report</h1>
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TEST	RESULT	MUTATIONS IDENTIFIED	INTERPRETATION
Mutation analysis in KRAS oncogene by real-time PCR	POSITIVE	Mutation Gly12Asp (GGT>GAT)	Presence of KRAS mutations is associated with lack of response to anti-EGFR therapy*

TEST DESCRIPTION: Detection of KRAS mutations in a background of wild-type genomic DNA in a real time PCR assay based on amplification refractory mutation system (ARMS) and real-time polymerase chain reaction, using DxS Scorpions Technology. The test can detect the presence or absence of 7 common mutations (Gly12Ala, Gly12Asp, Gly12Arg, Gly12Cys, Gly12Ser, Gly12Val, Gly13Asp) found in codons 12 and 13 of the KRAS oncogene against a background of wild-type DNA. The tumor tissue must be greater than or equal to 50% tumor cells for accurate test results.

METHODOLOGY: Formalin-fixed, paraffin-embedded tumor tissue sections are deparaffinized and DNA is isolated using proteinase K and a QIAmp mini spin column (Qiagen, Valencia, CA). Wild type and Mutated KRAS oncogenes were detected using a validated KRAS mutation kit (DxS Ltd, Manchester, United Kingdom) that identifies seven somatic mutations located in codons 12 and 13 using allele-specific real-time polymerase chain reaction (Light Cycler 480, Roche Diagnostics Ltd, Switzerland), with a detection sensitivity of 1% mutant in a background of wild-type genomic DNA.

***CLINICAL SIGNIFICANCE:** The confirmed KRAS mutation status is critical when evaluating a candidate patient for EGFR-targeted therapy. Mutations in the KRAS gene are associated with poor prognosis and non-response to anti-EGFR therapies (see references listed below). KRAS mutation testing is recommended by the National Comprehensive Cancer Network (NCCN) before starting EGFR-targeted therapy in both metastatic colorectal cancer and advanced non-small cell lung cancer.

NOTE: KRAS mutation test results should be interpreted in conjunction with all other available clinical and laboratory information when evaluating treatment options for cancer patients.

Laboratory testing performed by Oncotech, Inc. (dba Exiqon Diagnostics), a wholly owned subsidiary of Exiqon A/S.

This test was performed with Class I analyte specific reagents (ASR's). This test was developed and its performance characteristics were determined by Oncotech. As with all Class I ASR's, they have not been cleared or approved by the U.S. Food and Drug Administration, The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or research. Oncotech is certified under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high complexity clinical laboratory testing. This test was performed pursuant to a license agreement with Roche Molecular Systems, Inc.

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