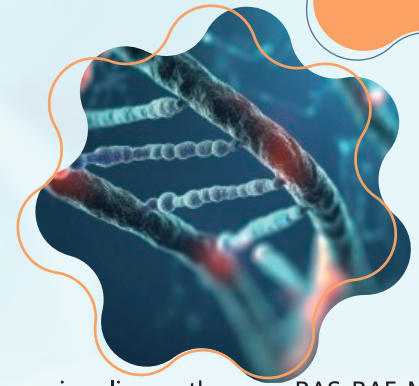


Human KRAS/NRAS/PIK3CA/BRAF Genes Mutation Detection (Real-Time PCR assay)



BACKGROUND

KRAS, NRAS, PIK3CA and BRAF genes are four important genes in the EGFR downstream signaling pathways - RAS-RAF-MEK pathway and PI3K-AKT pathway. Mutations in the above genes will lead to continued activation of downstream signaling pathways, thereby causing abnormal cell proliferation and differentiation, ultimately leading to the occurrence and development of tumors.

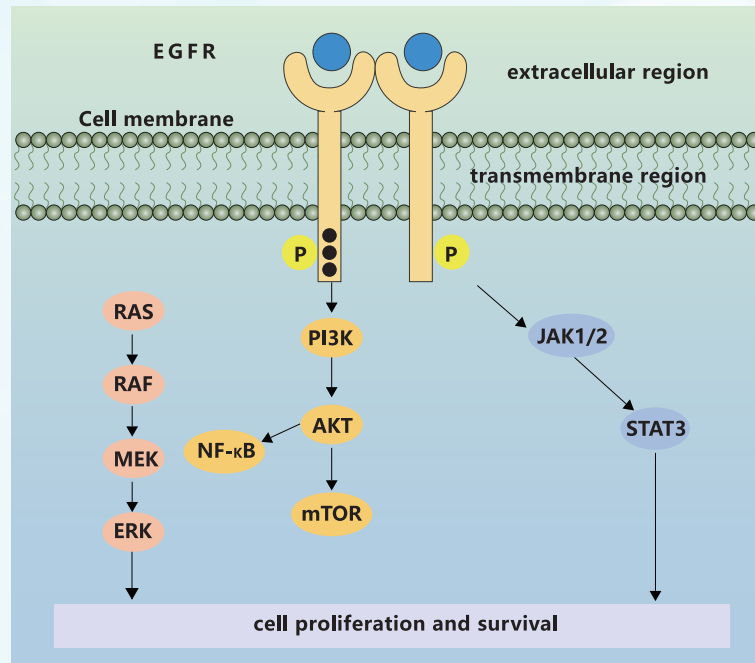



Figure 1. EGFR downstream RAS-RAF-MEK pathway and PI3K-AKT pathway

Mutations in KRAS, NRAS, PIK3CA and BRAF genes occur in a variety of malignant tumors, but are of greater concern in colorectal cancer.

KRAS, NRAS and BRAF gene mutations generally lead to poor prognosis, and colorectal cancer patients are resistant to anti-EGFR antibody drugs. NCCN guidelines and colorectal cancer testing regulations stipulate that RAS gene status must be clarified before colorectal cancer treatment, and when recurrent or metastatic colorectal cancer is determined, KRAS, NRAS, and BRAF gene testing is recommended. According to some existing research results, PIK3CA mutations may be predictive markers for response to Aspirin.



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NCCN Guidelines Version 2.2023 Colon Cancer

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PRINCIPLES OF PATHOLOGIC AND MOLECULAR REVIEW

Methods of Testing

- The testing can be performed on formalin-fixed paraffin-embedded tissue (preferred) or blood-based assay.
- **KRAS, NRAS, and BRAF Mutation Testing**
- All patients with metastatic colorectal cancer should have tumor genotyped for RAS (KRAS and NRAS) and BRAF mutations individually or as part of an NGS panel. Patients with any known KRAS mutation (exons 2, 3, and 4) or NRAS mutation (exons 2, 3, and 4) should not be treated with either cetuximab or panitumumab.⁵³⁻⁵⁵ BRAF V600E mutation makes response to panitumumab or cetuximab highly unlikely unless given with a BRAF inhibitor.⁵⁶⁻⁵⁸
- BRAF V600E mutation testing via IHC is also an option.
- Testing for KRAS, NRAS, and BRAF mutations should be performed only in laboratories that are certified under the clinical laboratory improvement amendments of 1988 (CLIA-88) as qualified to perform high-complexity clinical laboratory (molecular pathology) testing. No specific methodology is recommended (eg, sequencing, hybridization).
- The testing can be performed on the primary colorectal cancers and/or the metastasis, as literature has shown that the KRAS, NRAS, and BRAF mutations are similar in both specimen types.⁵⁹

Figure 2. KRAS, NRAS and BRAF gene testing recommended in NCCN guidelines

DETECTED GENES

Gene	Cover exon position	Covered sites (23 in total)
KRAS	Exons 2, 3 and 4	G12D\G12A\G12V,etc.
NRAS	Exons 2 and 3	G12D\Q61R\Q61K
PIK3CA	Exon 20	H1047R
BRAF	Exon 15	V600E

PRODUCT INFORMATION

Product Name	Technology	Pack Size	Instruments Validated	Sample Type
Human KRAS/NRAS/PIK3CA/ BRAF Genes Mutation Detection	Real-Time PCR assay	6 Tests/Kit 12 Tests/Kit	Stratagene Mx3000P™ ABI7500 etc	Tumor tissue

DETECTION SIGNIFICANCE

Assist clinicians in selecting colorectal patients who may benefit from tumor-targeted drugs.

FEATURES & ADVANTAGES

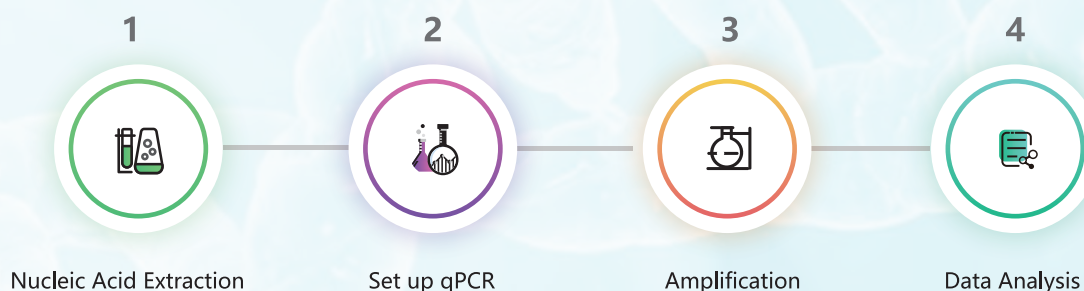
Stable and reliable: Pre-packaged closed-tube detection is used to effectively avoid cross-contamination.

High sensitivity: It can detect KRAS/NRAS/PIK3CA/BRAF gene mutations with content as low as 1% in 10 ng DNA samples.

Good reproducibility: It can be carried out in ordinary PCR laboratories, and reproducible results can be obtained without special training.

Fast testing: The testing process only takes 1 day.

DETECTION PROCESS



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