

Mutations in the BRAF oncogene are common in a variety of cancers. BRAF mutations are found in 25-80% of melanomas, 30-80% of papillary thyroid cancer, 12-18% of colorectal cancers, and 8% of solid tumors overall. The BRAF Test offers critical information that guides oncologists in decisions regarding specific therapeutic options for patients.

SUMMARY

Suggested for use in colorectal cancer patients who have tested negative for KRAS mutations

The BRAF Test is a highly sensitive and specific mutation analysis that guides oncologists as they seek to determine whether a patient will respond to drugs that target the Epidermal Growth Factor Receptor (EGFR). Recent studies suggest that patients who have BRAF mutations do not benefit from anti-EGFR monoclonal antibody therapy.

BIOETHERANOSTICS BRAF TEST

- Identifies the V600E (1799T>A) mutation
- Accounts for more than 90% of all known and clinically relevant mutations
- In combination with KRAS mutation testing, can detect up to 50% of patients who will be non-responsive to the anti-EGFR therapies, cetuximab and panitumumab

BACKGROUND

KRAS, BRAF and ANTI-EGFR THERAPY

KRAS mutations are detected in approximately 30-40% of all patients with colorectal cancer (CRC). Clinical guidelines now recommend that all patients diagnosed with metastatic colorectal cancer have their tumor tested for KRAS before starting anti-EGFR therapy. Mutations in the gene for BRAF, which codes for a protein downstream of KRAS, are detected in approximately 10% of patients with CRC and are also associated with non-responsiveness to anti-EGFR therapy. NCCN guidelines suggest that colorectal patients with wild-type KRAS be screened for the BRAF V600E mutation.

bioTheragnostics BRAF test, in combination with KRAS mutation testing, can detect up to about 50% of patients who may be non-responsive to cetuximab or panitumumab.

ADDITIONAL CLINICAL INDICATIONS

BRAF mutations are commonly detected in melanoma and papillary thyroid cancers. BRAF mutational analysis may become increasingly important as studies discover links between therapeutic response and BRAF status.

- **Colorectal carcinoma** – Associated with DNA mismatch repair deficiency (MMR)
- **Melanoma** – Selective BRAF inhibitors are in development for the treatment of melanoma in patients with the BRAF V600E mutation

SPECIFIC MUTATIONS

SUPERIOR SENSITIVITY OVER OTHER DETECTION METHODS

bioTheragnostics allele specific q-PCR assay

- Specifically detects the mutation, V600E, clinically shown to predict a lack of responsiveness to anti-EGFR therapy
- Detection level as low as 3% mutant BRAF

CAP-accredited, CLIA-certified CLIA # 05-D1065725
BRAF Gene Mutation Testing is not intended to be used to screen for cancer.

TECHNOLOGY

Quantitative real-time polymerase chain reaction (q-PCR)

SPECIMEN TYPE

- Formalin fixed, paraffin-embedded (FFPE) tissue
- Testing can be performed on primary tumor or a site of metastasis

Options:

1) FFPE tissue block containing 40-50% tumor

OR

2) Four precut charged glass slides from paraffin block in 10 micron sections AND one hematoxylin-and-eosin (H&E) reference slide

SPECIMEN STORAGE

Room temperature

SPECIMEN TRANSPORT

Cold pack for transport. Be sure cold pack is not in direct contact with specimen.

TURNAROUND TIME

5 business days after receipt of the specimen

REJECTION

Causes for Specimen Rejection

- Tumor block containing insufficient tumor tissue
- Broken or stained slides

SPECIAL INSTRUCTIONS

Please provide a copy of the pathology report.

HOW TO ORDER

1. Call the Client Services Line: (877) 886-6739
2. Complete a Test Requisition and order a free Shipping Kit online by visiting www.biotheranostics.com and clicking on "Ordering a Test"

BILLING

bioTheranostics will handle third party billing.

For information on BRAF Gene Mutation testing or other bioTheranostics tests (CancerTYPE ID® or KRAS testing), please contact us.



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Business hours:

Monday through Friday from 7:00 AM to 5:00 PM (Pacific Time)

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