



Oncology

KRAS Mutation Testing

Identify metastatic colorectal patients who are non-responsive to EGFR therapy.



Molecular Pathology Laboratory Network, Inc. (MPLN) offers KRAS mutation testing to assist with the identification of colorectal cancer (CRC) patients who are most likely to show limited clinical response to anti-epidermal growth factor receptor (anti-EGFR) therapies such as cetuximab (Erbix®) and panitumumab (Vectibix®).

In January 2009, the American Society of Clinical Oncology released its first Provisional Clinical Opinion recommending that all patients with CRC have tumors tested for KRAS gene mutations prior to the initiation of therapy.¹⁻⁵

Study Forecasts Savings Using KRAS Test

Based on annual incidence of new metastatic CRC cases, a savings of more than \$604 million for cetuximab alone would result through treatment drug stratification based upon KRAS status.⁶

Test Codes

KRAS

Specimen Requirement

10% neutral buffered formalin fixed paraffin embedded tissue. Notify MPLN when other fixatives are used.

NOTE: Please include a surgical pathology report with the sample.

Storage and Handling

Ship ambient

Specimen Stability

Stable at 18-25°C, indefinitely

CPT Codes

- 83890 x2
- 83892 x2
- 83898
- 83900
- 83901 x11
- 83907
- 83909 x2
- 83914 x2
- 83912-26
- 88305-TC

KRAS Mutations Tested

The incidence of KRAS gene mutations in CRC is approximately 35-45%. Identifying patients who will benefit from treatment is vital to ensuring better clinical outcomes as well as determining the best treatment strategies for each patient.

The KRAS mutation test performed at MPLN detects 12 somatic mutations in codons 12 and 13 of the KRAS oncogene.

KRAS Mutations Detected

Codon 12	Codon 13
Gly12Ser (GGT>AGT)	Gly13Ser (GGC>AGC)
Gly12Arg (GGT>CGT)	Gly13Arg (GGC>CGC)
Gly12Cys (GGT>TGT)	Gly13Cys (GGC>TGC)
Gly12Asp (GGT>GAT)	Gly13Asp (GGC>GAC)
Gly12Ala (GGT>GCT)	Gly13Ala (GGC>GCC)
Gly12Val (GGT>GTT)	Gly13Val (GGC>GTC)

Turnaround Time

7-10 business days

For more information about KRAS mutation testing, contact a client service specialist at **800.932.2943**.



Related Tests for Colon Cancer

Pharmacogenetics
UGT1A1 for risk of irinotecan-induced toxicity
Disease monitoring
CEA serum levels for disease recurrence CellSearch® circulating tumor cell test
Differential Diagnosis
Microsatellite Instability profile (MSI) by IHC Immunohistochemistry markers: · Cytokeratins (7; 20; 17) · CD117(c-kit) · CDX2

StrataFLEX™

The KRAS mutation test is a component of StrataFLEX™, an innovative health management strategy for colon cancer. StrataFLEX provides patient-specific reflex testing options to meet diagnostic challenges in a timely, cost effective manner.

About MPLN

For 20 years, MPLN has been making a difference in patient care by delivering the best technologies and services in laboratory medicine.

Headquartered in Maryville, Tennessee, MPLN is a fully-licensed laboratory certified by the CLIA, accredited by the CAP, and licensed in the states of Tennessee, New York, Florida and Maryland.

Reference

1. Lievre A et al. (2007). KRAS Mutation Status Is Predictive of Response to Cetuximab Therapy in Colorectal Cancer. *Cancer Res* 66:3992-3995.
2. Di Fiore F et al. (2007). Clinical relevance of KRAS mutation detection in metastatic colorectal cancer treated by Cetuximab plus chemotherapy. *Br J Cancer* 96:1166-1169.
3. De Roock W et al. (2008). KRAS wild-type state predicts survival and is associated to early radiological response in metastatic colorectal cancer treated with cetuximab. *Ann Oncol* 19:508-515.
4. Lievre A et al. (2008). KRAS Mutations As an Independent Prognostic Factor in Patients With Advanced Colorectal Cancer Treated With Cetuximab. *J Clin Oncol* 26:374-379.
5. NCCN Practice Guidelines v.3.2008. www.nccn.org.
6. V. Shankaran et al. (2009). Economic implications of KRAS testing in metastatic colorectal cancer (mCRC). *Gastrointestinal Cancers Symposium*. Abstract No. 298.

Trademarks

StrataFLEX is a trademark of Molecular Pathology Laboratory Network, Inc.

Cetuximab (Erbix®) is a trademark of Imclone systems, Inc NJ.

Panitumumab (Vectibix®) is a trademark of Amgen.

CellSearch is a trademark of Veridex, LLC.