



Colorectal Cancer Testing

StrataFLEX™ and Colorectal Cancer Management

Management of colorectal cancer (CRC) requires a rational approach to reduce treatment costs and provide effective chemotherapy.

Molecular Pathology Laboratory Network, Inc. (MPLN) offers StrataFLEX™, a strategic approach to laboratory medicine. StrataFLEX provides evidence-based, patient-specific testing and consultative support to assist clinicians with diagnostic and prognostic challenges in a timely, cost-effective manner.

MPLN Laboratory Testing/ Consultation

At Diagnosis

- Carcinoembryonic tumor antigen (CEA) levels
- Pathology review /Genetic consultation
- Microsatellite instability (MLH1, MSH2, MSH6, PMS2)
- KRAS gene mutation (codon 12 and 13) to evaluate anti-EGFR therapy
- BRAF V600 mutation to evaluate anti-EGFR therapy if KRAS normal^{5,6,7}
- UGT1A1 genotype for irinotecan toxicity risk⁸
- CellSearch™ Circulating Tumor Cell (CTC) detection⁹ (baseline)

Assessment of patient risk for hereditary CRC should be performed using Amsterdam or Bethesda guidelines.

Surveillance/ Therapeutic Monitoring¹

- CEA levels
- CellSearch™ Circulating Tumor Cell (CTC) detection⁹

Genetic heterogeneity and the high incidence of local or distant recurrence highlights the need for adjunctive molecular testing of patients to delineate sporadic vs. hereditary types of CRC as well as to assist with the stratification and selection of targeted therapies.

Microsatellite Instability (I MSI) Testing

Microsatellite instability (MSI) is commonly detected in ~90% of patients with hereditary non-polyposis colorectal cancer (HNPCC) and ~15% of sporadic CRC.

MSI testing can be performed utilizing either immunohistochemistry for the expression of MLH1, MSH2, MSH6 and PMS2 or by PCR for the NCI panel of microsatellite markers (BAT-25, BAT-26, D2S123, D5S346, D17S250).

KRAS Mutation Test (KRAS)

KRAS mutation testing (codon 12 and 13) is used to identify CRC patients most likely to show limited clinical response to anti-epidermal growth factor receptor (anti-EGFR) therapies.

The incidence of KRAS gene mutation in colorectal cancer is approximately 35-45%. The presence of a KRAS mutation is highly predictive of a patient's non-responsiveness to EGFR inhibitors cetuximab (Erbix®) and panitumumab (Vectibix®).^{4,10,14}

BRAF V600 Mutation (BRAF)

BRAF V600 mutation testing identifies the subset of colorectal cancer patients who have normal KRAS gene and do not respond to anti-EGFR therapy. BRAF mutation testing is utilized as an independent predictor of (CRC) patient responsiveness to EGFR inhibitor therapy and to assist with the differentiation of microsatellite instability high (MSI-H) hereditary non-polyposis colon cancer (HNPCC) from sporadic MSI-H CRC.^{5, 6, 7, 15.}

UGT1A1 Genotyping (UGT1A1)

This test is indicated for CRC patients who are candidates for first-line chemotherapy with CAMPTOSAR® (irinotecan) to assist with the identification of those patients who may be at risk for therapy related toxicity.⁸

CellSearch™ Circulating Tumor Cell Test (CTC)

The CellSearch™ System identifies and counts circulating tumor cells (CTCs) in a single blood sample. Results and serial testing for CTCs, in conjunction with other clinical methods for disease monitoring, assists physicians in predicting progression-free survival and overall survival in patients with metastatic CRC.⁹



MPLN

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and visit our website at **www.MPLNET.com**.

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