



**Targeted
Molecular
Diagnostics**

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PRESS RELEASE

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TARGETED MOLECULAR DIAGNOSTICS INTRODUCES *K-ras* MUTATION ASSAY TO IDENTIFY *K-ras* MUTATIONS IN METASTATIC COLON CANCER PATIENTS

Targeted Molecular Diagnostics (TMD) announced today the commercial availability of a new laboratory test to help identify colorectal cancer (CRC) patients who are resistant to EGFR targeted monoclonal antibody therapies. *K-ras* mutations have also been associated with resistance to EGFR tyrosine kinase inhibitors especially in non-small cell lung cancer (NSCLC). Mutated *K-ras* genes have been detected in about 40% of metastatic colorectal cancer and 15% of NSCLC patients. TMD's *K-ras* Mutation Assay may help identify patients who harbor specific *K-ras* mutations and therefore may not respond to EGFR inhibitors.

The TMD *K-ras* Mutation Assay utilizes SNP-based Real-Time PCR technology to identify 7 of the most common *K-ras* mutations in DNA from frozen or formalin fixed paraffin embedded (FFPE) tumor specimens. In one study, TMD identified mutations in 43% of CRC patients using this technology. The results of the assay are available within 4 – 5 days from receipt of the specimen at TMD. The TMD *K-ras* Mutation Assay is designed for use in clinical development of EGFR-based targeted therapies and to guide treatment options for patients with these mutations. TMD can provide specimen collection kits to collect patient blocks or slides that are compatible with this assay.

In addition to the new *K-ras* Mutation Assay, TMD offers two other tests relevant to EGFR-guided therapies:

- EGFR by IHC (immunohistochemistry) is available through a program known as the Targeted Diagnostic Advocacy Program (tdap™), where TMD performs EGFR screening of patient specimens with a 24 – 48 hour turn around time.
- EGFR by FISH (fluorescent in situ hybridization) which reports amplification of the EGFR gene.
- *B-Raf*^{V600E} mutation by SNP-based RT PCR is found in a large number of CRC patients. The ability to detect this mutation may be valuable in the clinical development of inhibitors of *B-Raf*^{V600E}.

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TMD is dedicated to improving the survival and quality of lives of cancer patients by using biomarker technologies to support the development of targeted therapies. Located in Westmont, IL near Chicago, the company currently supports the development of numerous targeted therapies in oncology such as EGFR, HER2, SRC, MEK, PI3K, HDAC and VEGF inhibitors.

With a wide variety of technologies, expert clinical and research staff, full certification with CAP, CLIA and GLP, GCP compliance, TMD is well-positioned to support the emerging needs of targeted therapy development. The laboratory employs a comprehensive set of technologies, such as IHC, FISH, quantitative Real-Time PCR, gene expression microarrays, image analysis and tissue microarrays (TMA), that are necessary for the pre-clinical and clinical development of targeted therapies. TMD's infrastructure also enables it to develop assays that can be used for screening of patients in clinical trials.

TMD currently supports clinical trials for pharmaceutical and biotech companies in over 40 countries and offers over 100 biomarker assays.