LUNG CANCER

Real-time PCR assays

EGFR Mutation Analysis Kit

Cell-free EGFR Mutation Detection Kit

PIK3CA Mutation Detection Kit

KRAS Mutation Analysis Kit

EML4-ALK Fusion Gene Detection Kit

Lung Cancer RNA Panel

EntroGen

Predictive • Preventive • Personalized

LUNG CANCER

SOMATIC MUTATIONS IN LUNG CANCER

Non-small cell lung cancer (NSCLC) accounts for up to 85% of lung cancer cases in the United States. Somatic mutations in EGFR, KRAS and PIK3CA, as well as chromosomal translocations involving ALK, RET, ROS1, and MET exon 14 skipping mutations have been identified in a subset of NSCLC. The use of targeted therapies based on defined genetic alterations in these oncogenes has become standard practice in treatment of NSCLC.

The most frequently occurring mutations in EGFR (L858R, exon 19 deletions) are associated with sensitivity to EGFR tyrosine kinase inhibitors (TKIs). Upon progression, T790M gatekeeper mutation accounts for more than half of the cases of resistance to first generation TKIs (gefitinib, erlotinib). However, the same mutation confers sensitivity to recently approved second generation EGFR TKI (osimertinib). Fusion genes involving ALK, ROS1 and RET have been identified as driver mutations in approximately 6-10% of NSCLC. The presence of the ALK and ROS1 fusion genes is used to identify responders to several recently approved TKIs (crizotinib, ceritinib and alectinib). Mutations in KRAS are negative predictors to EGFR TKIs and predict poor prognosis. PIK3CA mutations are found in approximately 5% of lung cancer cases. Although there are currently no approved therapies targeting PIK3CA, mutations in this gene have been found in EGFR-mutated lung tumors with acquired resistance to EGFR TKIs.

AVAILABLE KITS FOR LUNG CANCER

PRODUCT NAME	CAT NO.	INTENDED USE
EGFR Mutation Analysis Kit	EGFR-RT52	RUO, CE-IVD
Cell-free EGFR Mutation Detection Kit	CTEGFR-48	RUO, CE-IVD
PIK3CA Mutation Detection Kit (exons 9 and 20)	PI3K-RT48	RUO, CE-IVD
KRAS Mutation Analysis Kit (exons 2, 3, 4)	KRAS-RT50	RUO, CE-IVD
EML4-ALK Fusion Gene Detection Kit	ALKFG-RT46	RUO, CE-IVD
Lung Cancer RNA Panel (ALK, RET, ROS1, & MET exon 14 skipping mutations)	LUNG-RT48	RUO*

The assessment procedure involves three simple steps:

1) Isolation of DNA or RNA from tumor biopsies, paraffin-embedded sections (FFPE), fresh frozen tumors, or plasma (for cell-free kit).
2) Amplification using the provided reagents.
3) Data analysis and interpretation using the real-time PCR software or provided analysis worksheet†.

The EGFR, PIK3CA, and KRAS assays require genomic DNA. Mutation detection is based on allele-specific amplification and detection with hydrolysis probes. The EML4-ALK assay and the Lung Cancer RNA Panel require total RNA input and are based on a one-step cDNA synthesis and PCR method. The cell-free EGFR assay requires circulating tumor DNA extracted from plasma. Mutation detection is based on allele-specific amplification and detection with hydrolysis probes.

* Pending.
† Automated analysis worksheets available for certain kits and instruments; please contact support@entrogen.com for more information.

EQUIPMENT AND MATERIALS

All kits require a real-time PCR instrument capable of detecting FAM and VIC fluorescent probes. Additionally, the Cell-free EGFR Mutation Detection kit and Lung Cancer RNA Panel requires the capability to detect ROX and CY5 fluorescent probes.

All reagents required for PCR amplification/detection, as well as validated reaction controls, are included. Columns and reagents for DNA or RNA isolation are not included.