Biocept
Completing the Answer™

Clinical experience in ctDNA profiling of NSCLC 2000 cases using TargetSelector™ demonstrates high sensitivity.

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Background:

Targeted cancer therapy relies on identifying specific DNA mutations from a patient's tumor. Tyrosine kinase inhibitors (TKIs) tend to be effective for non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations, of which exon 19 deletions (Del19) and L858R are most common. Acquired resistance to TKI therapy is associated with a T790M mutation. Standard biomarker analyses may not reflect tumor heterogeneity; they entail tissue biopsies often with surgical complications. To address these limitations, Biocept developed a minimally invasive method to characterize cancer biomarkers in blood. Proprietary TargetSelector™ assays selectively amplify relevant mutations from circulating tumor DNA (ctDNA). Clinical validations demonstrated high concordances between molecular tests in blood vs tissue. As further validation, EGFR mutation detection frequencies were compared to US averages (mycancergenome.org). Here we analyze 2000 blood samples received at Biocept from 1Mar 2016 to 4Jan 2017 from late stage NSCLC patients.

Methods:

Blood was collected in Biocept OncoCEE BCT validated to preserve DNA ≤ 8 days. TargetSelector™ was used to detect ctDNA L858R, Del19 and T790M. EGFR allele copy numbers for wild type and each mutant were calculated. The prevalence of each mutation was compared to US averages.

Results:

Del19, L858R, and T790M mutations were detected in 12.9%, 8.5%, and 9.9% of the analyzed blood samples, respectively. This is concordant with US averages, which are 10% for each mutation. Median copy numbers/ml of blood were 30 for Del19 (range: 1 − 91974), 15 for L858R (range: 1 − 91200), and 10 for T790M (range: 1 − 137360). The median wild type EGFR copy number detected/ml blood was 2304 (range: 8 − 2498725). In ~80% of T790M cases, ≥ 1 concomitant activating mutation was detected.

Conclusions:

Biocept's TargetSelector™ detects EGFR mutations (Del19, L585R, and T790M) at a very high level of sensitivity down to 1 mutant copy/ml in advanced NSCLC patients at frequencies consistent with cited US rates. Moreover, the underlying activating mutation was detected in ~80% of T790M cases.