
**BACKGROUND AND PURPOSE**

The availability of targeted immunotherapies has provided NSCLC patients with more effective treatment options. However, this has resulted in an increasing number of tests required for targeted treatment selection. Given 30-50% of advanced lung cancer patients have insufficient or unavailable tissue for comprehensive genomic profiling, there is a need for a non-invasive assay that can accurately detect all guideline-recommended markers for NSCLC treatment selection. To this end, we have developed a novel circulating tumor DNA (ctDNA) detection platform for targeted and immunotherapy selection for more information.

**METHODS AND STUDY DESIGN**

In this poster, we present the CellMax liquid biopsy, an accurate blood test that enables the detection of all 6 NCCN-recommended markers (SNV, indels, fusions, CNAs, PD-L1 IHC, and fluorescent background).

**RESULTS**

CellMax PD-L1 assay was validated in accordance with the latest ACMG/AMP guidelines to accurately identify a wide range of clinically relevant variants (SNVs) across multiple genes, from ctDNA of NSCLC patients. CellMax PD-L1 assay results were consistent with 35 IHC PD-L1 positive NSCLC patients in this study, 32/35 (91.4%) of which were found to be PD-L1 positive by CTC PD-L1 assay.

For details, see:

**PD-L1 Positive Rates in Patients**

- Positive rates available for 31 (93%) of these patients had detectable CTCs
- 22 (66.7%) patients were PD-L1+ per IHC
- 23 (68%) patients were PD-L1+ per CTC

**CONCLUSIONS**

These tissue and blood PD-L1 positive percentages are consistent with what has been reported in clinical trial (66%) for NSCLC patients.

**CTC and ctDNA Profiling to Detect 6 NCCN-Guideline Recommended Classes of Alterations For Immunotherapy and Targeted Therapy Selection Using Sample From a Single Blood Draw**

**PD-L1 High Expression in Patients**

- 9/15 (60%) IHC PD-L1 were high (≥30% PD-L1 cells), consistent with literature2

**PD-L1 Positive CTCCs Detected in IHC Negative Patients**

- 7 (out of 9) IHC PD-L1 High Expressers confirmed by CTCs
- Of the 7 (out of 9) IHC PD-L1 High Expressers confirmed by CTCs, 3 are early stages

**PD-L1 Clinical Trial (66%) on tissue3**

- 66% (29/44) of patients with detectable CTCs were found to have at least one PD-L1 expressing CTC (PD-L1 positive), consistent with PD-L1 clinical trial (66%) on tissue3

**SMSGQ™ Performance**

Detection of 5 NCCN-Guideline Recommended Alterations2

For details, see: "SMSGQ™ Performance in Clinical Trials" in AACR 2018 abstract 2675.