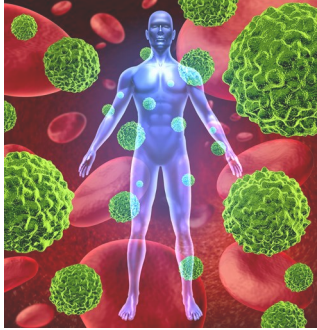




Blood-based PD-L1 Expression Assay

Assay in development to help identify patients who may benefit from cancer immunotherapies



Why PD-L1?

Programmed cell death ligand 1 (PD-L1) has been detected in up to 50% of all human cancers and has become a major focus of therapeutic and biomarker research.¹ Patients with cancers expressing the PD-L1 protein are more likely to respond to certain immunology therapeutics, and several PD-L1-related immunology therapies have received FDA approval. The expression of PD-L1 has been implicated in the tumor's evasion of immune response. Clinical benefit from treatment with anti-PD-1/PD-L1 varies widely, making it difficult to predict whether immunotherapy will be effective for a given patient.²⁻⁵

PD-L1 Expression Assay

Blood-based measurement of both PD-L1 expression and tumor load (as reflected by CK19) through multiplexed droplet digital PCR (ddPCR) detection of circulating mRNA.⁶

- Lack of tissue and the drawbacks of available IHC tests have created the need for a blood-based PD-L1 test.²
- Biodesix is developing a non-invasive solution for the detection and monitoring of PD-L1 mRNA in blood.
- The test uses the same proprietary and proven RNA isolation methodology and droplet digital PCR (ddPCR) platform as the GeneStrat[®] liquid biopsy tests for ALK, ROS1, and RET. With 72-hour turnaround time, GeneStrat[®] testing expedites time to treatment for newly diagnosed NSCLC patients.⁷
- Biodesix has detected varying levels of PD-L1 and CK19 mRNA in cell lines, immune cells, and prospectively collected samples from both healthy and NSCLC donors.
 - Levels of circulating PD-L1 mRNA are correlated with tumor marker mRNA in blood (CD45, CD3, CK18, CK19).⁶
 - Blood samples from patients with KRAS-positive NSCLC were shown to be more likely to exhibit elevated levels of PD-L1 mRNA than comparable samples from patients whose tumors were mutation-negative or harbored EGFR mutations. This is consistent with the observation that KRAS-mutant tumors are more likely to be PD-L1 positive than KRAS-wild type tumors.⁸

Biodesix is exploring opportunities to validate this test

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About Biodesix

Biodesix is a lung cancer diagnostic solutions company addressing the continuum of patient care from early diagnosis of lung nodules through late stage cancer. The company develops diagnostic tests addressing important clinical questions by combining simple blood draws and multi-omics with the power of artificial intelligence. Biodesix is the first company to offer three best-in class tests for patients with lung cancer, and multiple pipeline tests including one with the potential to identify patients who may benefit from immunotherapies. The Biodesix Lung Reflex[®] strategy integrates the GeneStrat[®] and VeriStrat[®] tests to support treatment decisions with results in 72 hours. The Nodify XL2[™] and EarlyCDT Lung[®] nodule tests, evaluate the risk of malignancy, enabling physicians to triage patients to the most appropriate course of action. Biodesix also partners with the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges. For more information about Biodesix, please visit www.biodesix.com.

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