



## Tumor Mutational Burden (TMB) Emerges as a Promising Biomarker for Immunotherapy Cancer Treatment

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The number of mutations in the DNA of tumor cells – known as tumor mutational burden (TMB) – is a promising clinically validated biomarker that can help oncologists identify patients most likely to respond to immunotherapy for certain cancers. Immunotherapy, the ability to use a patient's own immune system to fight malignancy, is one of the most innovative, recent treatment advances impacting a range of cancers that were once considered largely untreatable. Research in precision medicine has focused on the identification of biomarkers, such as TMB, that can help match patients to the most effective treatment.

CSI Laboratories offers TMB testing for lung cancer in correlation with the biomarkers PD-1/PD-L1. It's also used for other cancers for which TMB has been clinically validated, such as melanoma and urothelial carcinomas. CSI Laboratories uses next-generation sequencing, performed through a partnership with Genomic Testing Cooperative (GTC), to provide in-depth consultation and guidance to assist clinicians in determining the suitability of TMB testing for these cancers. This innovative partnership combines quality cancer diagnostics with advanced genomics technology, providing oncologists and pathologists with comprehensive and detailed cancer data.

### **Guidepost for Immune Checkpoint Therapy**

TMB is a new clinical biomarker that can help predict responses to immunotherapy in a range of advanced cancers. Unlike protein-based biomarkers such as PD-1 and PD-L1, TMB provides a quantitative measurement of somatic mutations present in a tumor – a unique fingerprint of a tumor's natural and mutated proteins. Tumors with higher levels of TMB are believed to express more neoantigens, a cancer-specific antigen that may allow for a greater immune response with immunotherapy treatments such as immune checkpoint inhibitors (ICIs). These therapies stimulate a patient's immune system by blocking the receptors that cancer cells use to send inactivating signals to T-cells. When the inactivating signal is blocked, T-cells may be better able to differentiate a cancer cell from a healthy cell and launch an attack. As an example, treatment with immune checkpoint inhibitors such as anti-PD-1, anti-PD-L1, and anti-CTLA4 can result in robust immune responses in a subset of patients with cancer.

### **A Useful Tool for Oncologists**

A growing body of clinical research has demonstrated the potential benefits of TMB as a diagnostic marker based on its accuracy, sensitivity, and reproducibility. For oncologists, TMB provides a quantitative measure that can be used to better inform treatment decisions. Further research is needed to better understand the role of TMB and other biomarkers, and multiple biomarkers will likely be required to accurately predict responses to immunotherapy in a range of cancers. However, TMB has emerged as an essential tool in helping oncologists identify patients who may benefit from the latest innovation in cancer care.