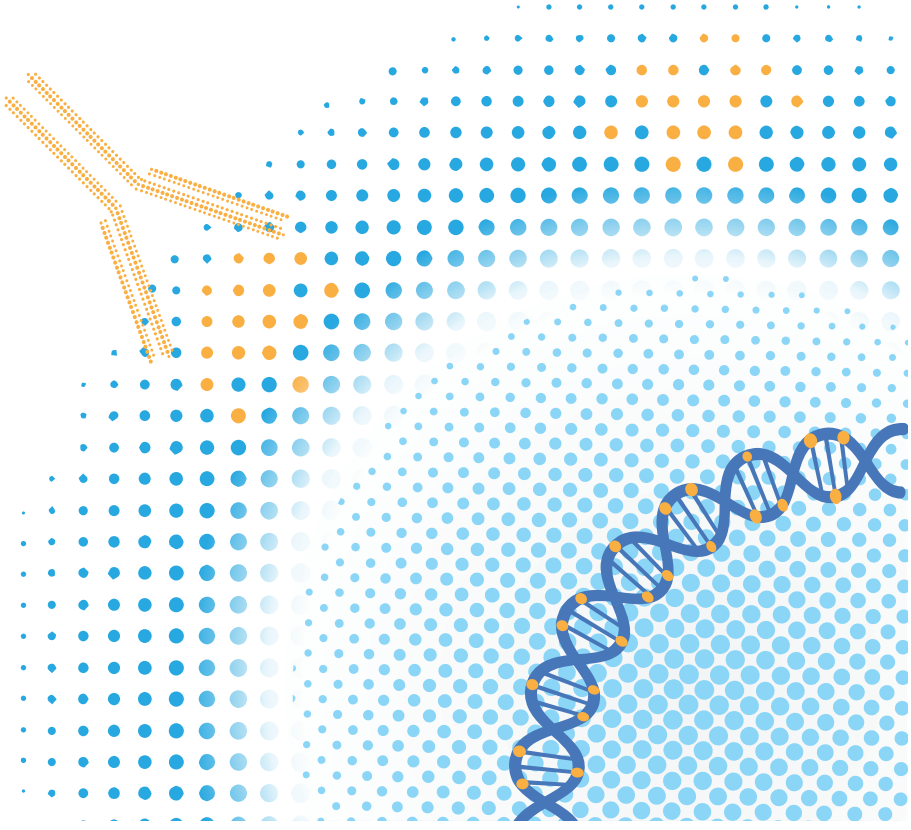
Prima
Cancer Genetics

MEDGENOME

Tumor Mutation Burden:

A biomarker for cancer immunotherapy



Tumor Mutation Burden and its significance

Tumor mutational burden (TMB) is a genomic biomarker that quantifies the frequency of somatic mutations in a patient's tumor. TMB-high correlates with higher neoantigen expression, which helps the immune system recognize tumors. It has been detected across numerous tumor types and has been associated with improved response rate and prolonged progression-free survival for patients on immunotherapy. TMB expands the population of patients who can be considered candidates for immunotherapy beyond standard PD-L1 testing.

Nivolumab, Ipilimumab, Pembrolizumab, and Atezolizumab have shown good ORR (Overall Response Rate), PFS (Progression Free Survival) and OS (Overall Survival) in NSCLC and other cancers in various clinical trials.[1]

MedGenome's Tumor Mutation Burden Test

Gene Coverage	A single test that analyzes all guideline-recommended genes in solid tumors, in addition to some of the rarely mutated genes in tumors. It identifies genomic alteration biomarkers across therapeutically / prognostically relevant (with FDA approved therapies) >400 genes with a median depth of coverage of 300X (LOD of 5%)
Result	Results include TMB to help inform immunotherapy decisions, along with actionable driver mutations in solid tumors based on standard guidelines
Value additions	The assay covers 1.65 Mb genomic region, across >400 genes relevant across major cancer types for the TMB estimation.
Dual Application	Single assay that provides the Somatic mutation profiling to derive targeted therapy as well as immunotherapy based on the TMB score
Input DNA and Sample Type	Low input requirement (as little as 100 ng of DNA/RNA) and Sample type is FFPE
Sample-to-report	Sample-to-report solution with tumor mutation burden and relevant variant insights, with a TAT of 21 working days

Validation Summary for TMB:

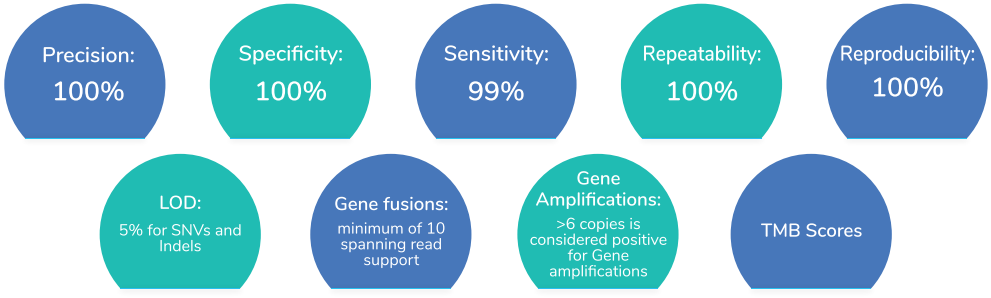
Extensive validation for TMB panel was performed in-house on 44 different tumor samples, that included 12 different cancer types such as Breast, Ovarian, NSCLC, Pancreatic, Prostate, Urinary Bladder, Colon, Rectal, Renal cell carcinoma, glioblastoma and other rare tumors. The validation also included reference standard cell lines with known TMB status, MSI and MMR status and Inter-laboratory comparison with CLIA certified laboratory.

In addition to TMB score, the actionable driver mutations were also screened as part of the panel and their concordance was assessed with alternate NGS panel developed and validated in-house.

All the metrics of validation were calculated based on the TMB score and its concordance across platforms and between laboratories (for Interlaboratory Comparison). Based on the results derived from this validation: this panel demonstrated 100% accuracy, specificity and sensitivity for the TMB score estimation.

The Precision (Repeatability and Reproducibility) for the measure of TMB was verified by choosing clinical samples in the low, intermediate and high range and processed them across different days and in multiple sequencing runs and the results were satisfactory. The standard deviation and %CV were within the allowed limits of experimental accuracy for the three different groups of TMB scores (Low, Intermediate and High).

Validations



Reference

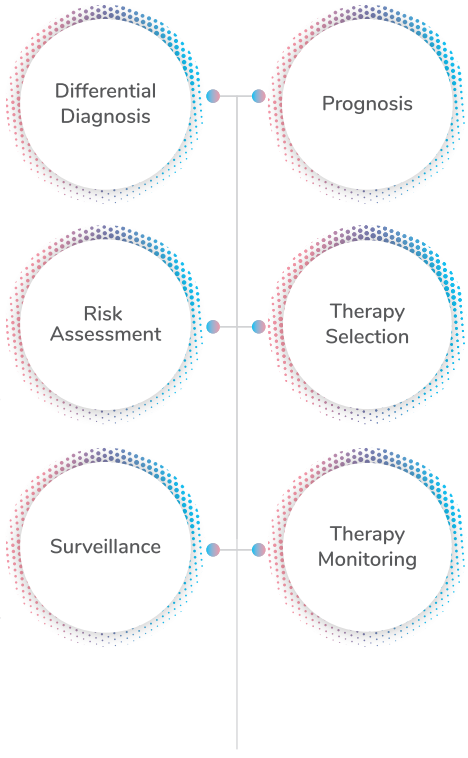
1- https://www.onclive.com/web-exclusives/fda-accepts-application-for-frontline-nivolumabipilimumab-in-tmbhigh-nsclc

Test Details

MedGenome offers	Test Code	Testing Technique	Test Sample requirements	TAT
Tumour Mutation Burden with actionable genes	MGM1558	NGS	FFPE Blocks	21 working days

MEDGENOME

Prima by MedGenome offers a wide range of Oncology and Haematology genetic tests, these include:



Molecular Testing for Hematological Malignancies, Comprehensive Leukemia Panel

IGHV Gene Mutation Testing for CLL, Comprehensive Leukemia Panel, BCR-ABL1 gene fusion analysis

Hereditary Cancer Panel, BRCA1 and BRCA2 gene test, Thalassemia Mutation Test

Comprehensive Tumor Gene Panel, Somatic Mutation Panel, Comprehensive Leukemia Panel, Molecular Testing for Lung Cancer

OncoTrack, OncoSelect, OncoFocus (Liquid Biopsy Test)

NGS based IRMA, BCR-ABL1 gene fusion analysis

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