



Tumor Mutational Burden (TMB) Assay for Response to Immunotherapy

Tumor Mutational Burden (TMB) is a putative biomarker of response to checkpoint inhibitor therapy. Q² Solutions offers a TMB assay that utilizes a whole exome sequencing (WES) of tumor specimens for reliable quantification of TMB across various tumor indications. The TMB assay is a component of our comprehensive immuno-oncology assay portfolio and is available for RUO or GCP applications.

Highlights

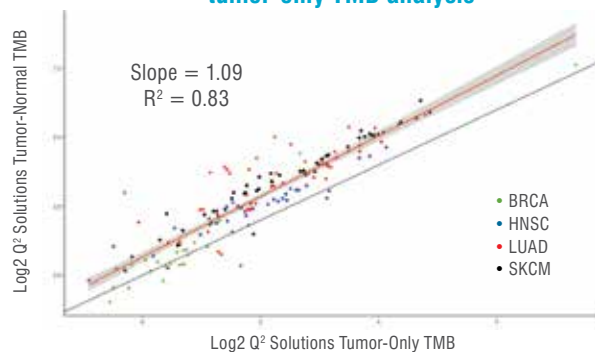
- TMB assay available in two formats: tumor-only specimens or matched tumor and germline control blood specimens.
- Based on validated WES assay targeting ~60Mb of coding region of the human genome.
- TMB tumor-only WES method modeled across multiple tumor indications.
- High quantitative precision (CV% ≤20%) for TMB >2, suitable for TMB analysis across a wide range of cancer indications including those with traditionally low TMB.

Q² Solutions TMB levels trend with published TMB levels across different cancer types

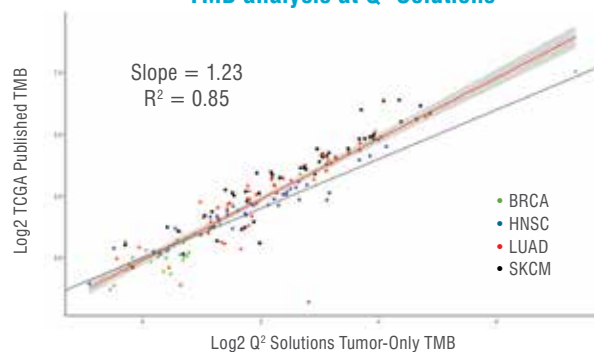
	LGG	CHOL	KIRC	COAD	BLCA	LUSC	SKCM
Q² Solutions TMB (WES)¹	1.5 (N=123)	2.4 (N=38)	2.4 (N=100)	4.6 (N=64)	8.7 (N=39)	10.1 (N=258)	13.2 (N=113)
Published TMB²	1.8 (N=220)	2.5 (N=1456)	2.7 (N=543)	4.5 (N=7758)	7.2 (N=80)	9 (N=2102)	14.4 (N=879)

¹Median TMB scores generated from TCGA whole exome sequencing reads through our pipeline. ²Median TMB scores per Chalmers et al., Genome Medicine 2017.

Correlation between paired tumor-normal and tumor-only TMB analysis



Correlation between published TCGA TMB data³ and TMB analysis at Q² Solutions



³<https://gdc.cancer.gov/about-data/publications/mc3-2017>

LGG=Lower Grade Glioma, CHOL=Cholangiocarcinoma, KIRC=Renal Clear Cell Carcinoma, COAD=Colon Adenocarcinoma, BLCA=Urothelial Carcinoma, LUSC=Lung Squamous Cell Carcinoma, SKCM=Cutaneous Melanoma, BRCA=Breast Invasive Carcinoma, HNSC=Head-Neck Squamous Cell Carcinoma, LUAD=Lung Adenocarcinoma, SKCM=Cutaneous Melanoma; STAD=Stomach Adenocarcinoma

TMB assay specifications

Sample types	Tumor tissue (FFPE, fresh frozen or DNA specimens) Normal tissue, optional (PBMC, whole blood or DNA)
DNA requirements	250 ng DNA
Assay method	Whole exome sequencing
System compatibility	NovaSeq 6000, HiSeq 2500
Assay performance	>99.9% accuracy of variant calling for variants above 10% allelic frequency Quantitative precision \leq 20% CV% across TMB range of 2-32
Deliverables	TMB score, FASTQ, BAM, annotated VCF files
Turnaround time	3 weeks for defined batch testing, faster TAT options upon request

Q² Solutions has a global testing footprint



Genomics	Flow cytometry / immunoassays	Anatomical pathology
<ul style="list-style-type: none"> TCR immune sequencing Immune gene signature/epigenetic signatures Digital spatial profiling (AP-gene & protein expression) Minimal residual disease (MRD) Tumor mutation burden (TMB) DNA-mismatch repair (MMR) deficiency/ microsatellite instability (MSI) HLA and KIR typing Whole exome sequencing Neoantigen discovery Microbiome 16S rRNA 	<ul style="list-style-type: none"> Immuno-phenotyping CAR-T tracking Receptor occupancy (mono/bispecific mAbs) Tumor infiltrating lymphocytes (TILs) Intracellular cytokine survey Minimal residual disease (MRD) Circulating soluble proteins PBMC processing ELISpot Pembrolizumab PK and anti-pembrolizumab antibody 	<ul style="list-style-type: none"> IHC (single & multiplex) Tumor infiltrating lymphocytes (TILs) Digital pathology FISH

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