

Tumor Mutational Burden (TMB) Assay for Response to Immunotherapy

Tumor Mutational Burden (TMB) is a putative biomarker of response to checkpoint inhibitor therapy. IQVIA Laboratories 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.

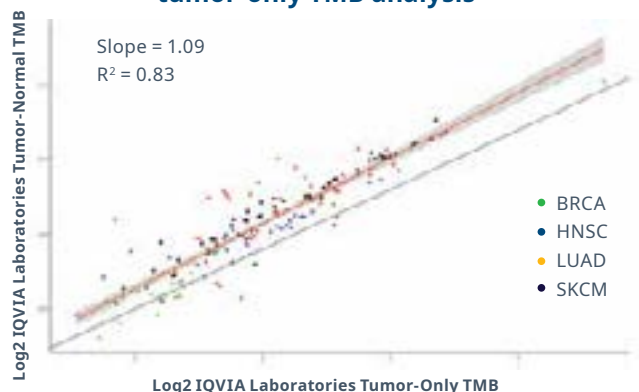
HIGHLIGHTS

- 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 ($CV\% \leq 20\%$) for TMB >2 , suitable for TMB analysis across a wide range of cancer indications including those with traditionally low TMB

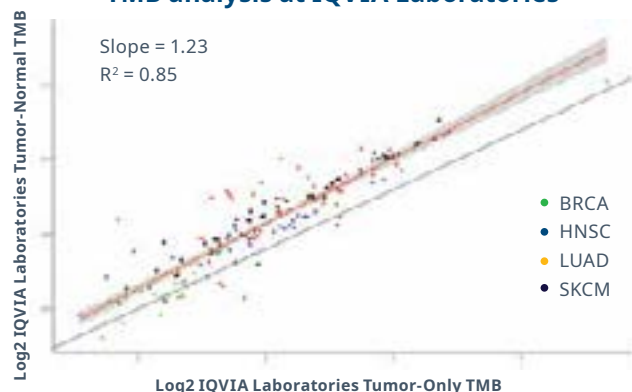
IQVIA Laboratories TMB levels trend with published TMB levels across different cancer types

	LGG	CHOL	KIRC	COAD	BLCA	LUSC	SKCM
IQVIA Laboratories 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)

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



Correlation between published TCGA TMB data³ and TMB analysis at IQVIA Laboratories



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
Assay performance	>99.9% accuracy of variant calling for variants above 10% allelic frequency Quantitative precision ≤20% CV% across TMB range of 2-32
Deliverables	TMB score, FASTQ, BAM, annotated VCF files
Turnaround time	6 weeks for defined testing, faster TAT options upon request

IQVIA Laboratories global testing footprint



GENOMICS	FLOW CYTOMETRY / IMMUNOASSAYS	ANATOMICAL PATHOLOGY
<ul style="list-style-type: none">TCR immune sequencingImmune gene signature/epigenetic signaturesDigital spatial profiling (AP-gene and protein expression)Minimal residual disease (MRD)Tumor mutation burden (TMB)DNA-mismatch repair (MMR) deficiency/microsatellite instability (MSI)HLA and KIR typingWhole exome sequencingNeoantigen discoveryMicrobiome 16S rRNA	<ul style="list-style-type: none">Immuno-phenotypingCAR-T trackingReceptor occupancy (mono/bispecific mAbs)Tumor infiltrating lymphocytes (TILs)Intracellular cytokine surveyMinimal residual disease (MRD)Circulating soluble proteinsPBMC processingELISpotPembrolizumab PK and anti-pembrolizumab antibody	<ul style="list-style-type: none">IHC (single and multiplex)Tumor infiltrating lymphocytes (TILs)Digital pathologyFISH



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