

Seraseq[®] Blood TMB Mix Score 7, 13, 20, 26

0710-2087 | 0710-2088 | 0710-2089 | 0710-2090

This Product Datasheet provides more details around the Blood TMB assessments for Score 7, 13, 20 and 26, as determined using the TruSight Oncology 500 ctDNA panel.

Blood TMB Materials:

- Human diseased cell-lines and their SNP-matched normal cell lines
- Fragmented to ctDNA sizes of ~165 bp
- Blended at 3 tumor fractions - 0%, 0.5% and 2%
- Blood TMB Scores generated by a targeted NGS panel

Blood TMB Measurements:

TMB measurements of the Seraseq Blood TMB Mix Score 7, 13, 20 and 26 were performed using the TruSight Oncology 500 ctDNA assay. Each tumor fraction sample was analyzed in triplicate. All samples passed sequencing library QC metrics (see, e.g., Figure 1).

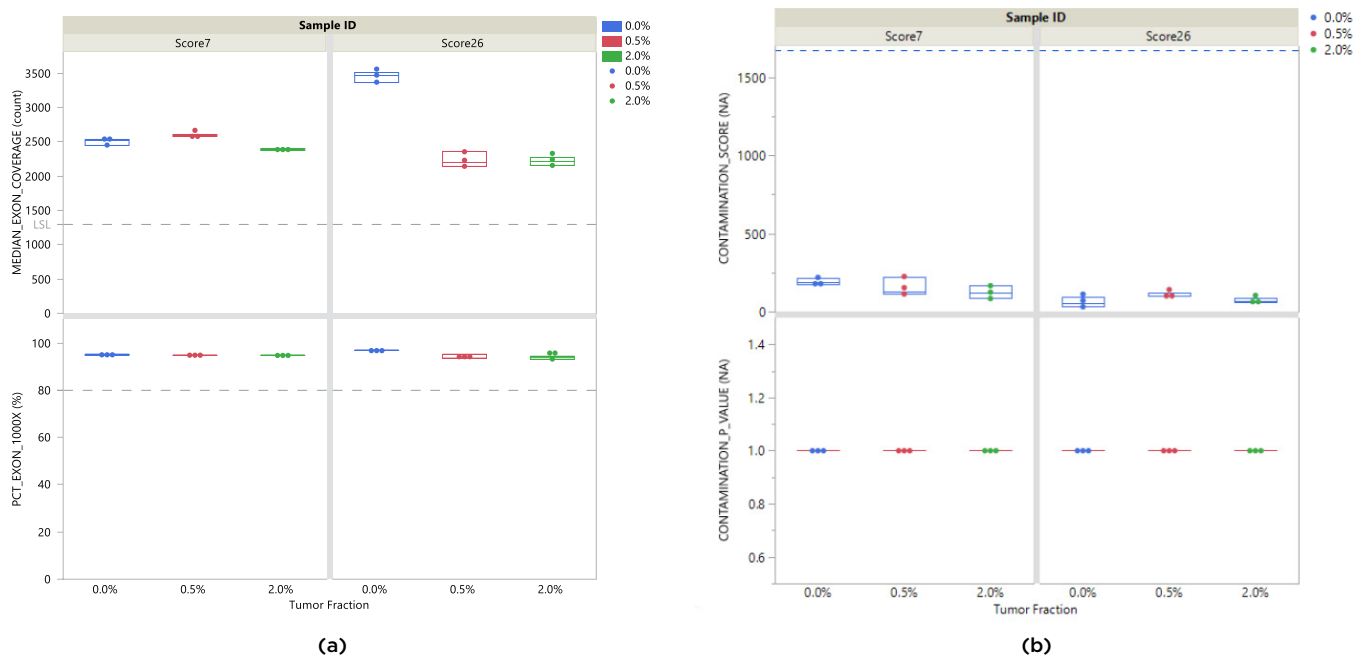


Figure 1: Sequencing library QC metrics check for (a) Minimum Exon Coverage (MEC; >1000X) and (b) Contamination analysis for all samples and replicates of the Seraseq Blood TMB products. All passed QC.

Blood TMB Score Analysis

- Assay = TruSight Oncology 500 ctDNA
- System = NovaSeq 6000 / S2 Flowcell
- Variant Call Min Depth = 1000X
- VAF > 0.2%
- Coverage Uniformity = 80% of exons covered at 1000X
- TMB Analysis = DRAGEN TruSight Oncology 500 ctDNA Analysis Software v1.1

Sample	%Tumor Fraction	Conc (ng/ul)*	Input (ng)	Reps	Ave Blood TMB Score**	Adjusted Blood TMB Scores***
Seraseq Blood TMB Mix Score 7	0%	41	30	3	7.5 ± 1.7	0
	0.5%	57.6	30	3	13.1 ± 2.6	5.6 ± 2.1
	2%	41.2	30	3	17.9 ± 1.3	10.4 ± 1.7
Seraseq Blood TMB Mix Score 13	0%	21.7	30	3	4.6 ± 0.5	0
	0.5%	31.9	30	3	18.7 ± 2.1	14.1 ± 2.2
	2%	33.7	30	3	24.6 ± 0.8	20.0 ± 0.9
Seraseq Blood TMB Mix Score 20	0%	17	30	3	7.5 ± 1.4	0
	0.5%	21.7	30	3	26.0 ± 2.3	18.5 ± 2.7
	2%	24.5	30	3	35.6 ± 1.0	28.1 ± 1.7
Seraseq Blood TMB Mix Score 26	0%	64.8	30	3	6.0 ± 0.5	0
	0.5%	11	30	3	20.7 ± 5.5	14.7 ± 2.4
	2%	11.9	30	3	30.4 ± 1.8	24.4 ± 1.5

Table 1: Seraseq Blood TMB Score Analysis by TSO500 ctDNA Assay.

*Qubit dsDNA.

**Total bTMB score (syn + non-syn).

***Score subtracts bTMB variants of 0% tumor (WT) blend.

The observed Blood TMB scores for the 2% and 0.5% mix represent total TMB for synonymous and non-synonymous variants derived from the cancer cell line + the variants harbored in the 0% cell line used as the background. Hence, the Blood TMB scores in the 2% and 0.5% mixes are elevated by ~5-7 Mut/Mb observed in the 0% mix.

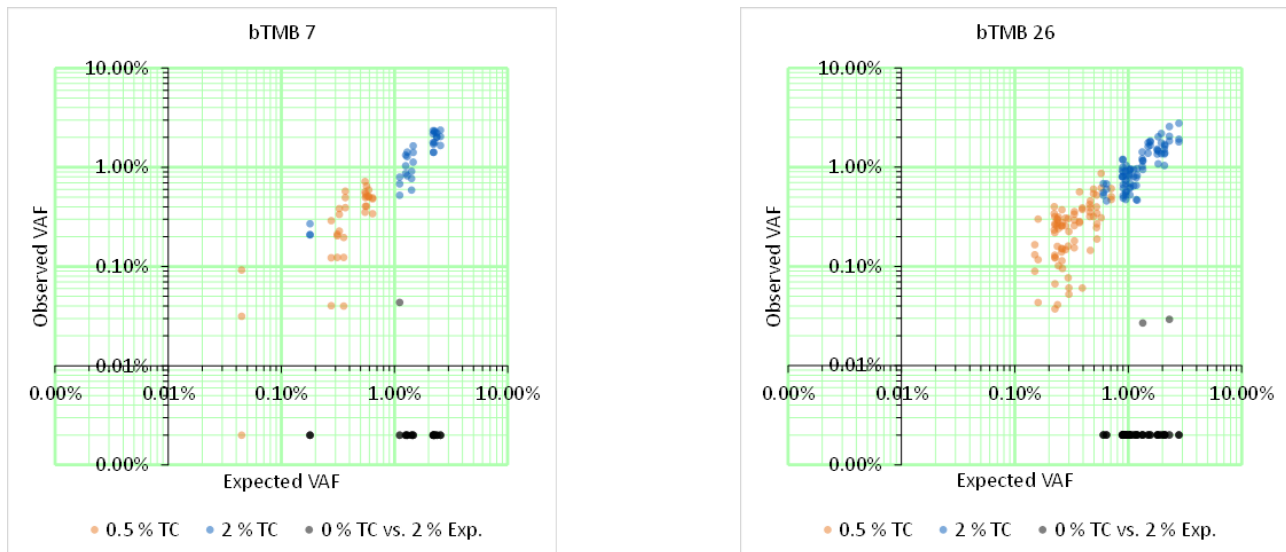


Figure 2: Analysis of observed versus expected VAFs for the bTMB variants for all replicates. Black dots (•) compare the 0% samples to what would be expected for 2%. Blue dots (•) compare observed 2% to expected 2%. Orange dots (•) compare observed 0.5% to expected 0.5%. Noise (when present) seems to be around 0.03% for the bTMB variants.

TMB Score comparisons: Tissue-derived vs Blood TMB

We have compared the TMB scores derived for tissue - (gDNA/FFPE) and blood-based (ctDNA) sample formats and these are shown in Table-2 below.

TMB Reference Material	Cell Line	gDNA TMB Scores*	FFPE TMB Scores*	Blood TMB Scores**
Seraseq TMB Score 7	Small cell lung cancer; carcinoma	7.2 ± 0.2	7.2 ± 0.4	5.6 ± 2.1 (0.5% TF) 10.4 ± 1.7 (2% TF)
Seraseq TMB Score 9	Lung adenocarcinoma	9.5 ± 0.4	7.5 ± 1.3	N/A
Seraseq TMB Score 13	B-Lymphocyte	12.6 ± 0.02	12.1 ± 0.3	14.1 ± 2.2 (0.5% TF) 20.0 ± 0.9 (2% TF)
Seraseq TMB Score 20	Non-small cell lung cancer; carcinoma	20.1 ± 0.2	18.6 ± 0.5	18.5 ± 2.7 (0.5% TF) 28.1 ± 1.7 (2% TF)
Seraseq TMB Score 26	Lung adenocarcinoma	25.8 ± 0.5	22.8 ± 3.6	14.7 ± 2.4 (0.5% TF) 24.4 ± 1.5 (2% TF)

Table 2: Tumor Mutational Burden (TMB) scores for various Seraseq TMB reference standards.

*WES-based measurement.

**Targeted Panel (TSO500 plasma) measurement.

TMB variant lists are available by contacting us at CDx-info@LGCgroup.com.

CONTACT US

For additional information on these TMB reference standards, please visit our dedicated product page at <https://www.seracare.com/Controls---Reference-Materials-NGS-Somatic-Cancer-Immuno-oncology/>, or call us at **+1-800-676-1881**.



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The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com or by phone at 508.244.6400.