

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® Blood TMB Mix Score 13		
Material Number:	0710-2088	Batch Number:	10766354
Material Description:	Reference standard made from a mutagenized reference cell line (GM24385) and its matched “normal” cell line generated from peripheral blood of the same patient. Genomic DNA was extracted, fragmented, sized, purified, and blended at 3 tumor contents (0%, 0.5% and 2%).		
Date of Manufacture:	12 JUN 2025	Expiration Date:	18 AUG 2027
Fill Volume:	20 µL		
Concentration Test Method:	Qubit dsDNA BR Assay		
Nominal Concentration:	10 ng/µL		
Fragment Size Test Method:	Agilent Bioanalyzer High Sensitivity DNA Analysis		
Acceptance Criteria for Average Fragment Size:	150-220 bp		
NGS Assay Test Method:	30 ng of each product was used as input iSO500 ctDNA enrichment kit sequenced on a Novaseq 6000 NGS system (2 x 151 bp sequencing) on an S2 flow cell (6 samples per run). The minimum depth for a variant cell was 1000X coverage to be included in TMB score. 80% of exons were covered at 1000x. Each sample was represented by a minimum of 800M paired end reads. The data was analyzed using DRAGEN TruSight Oncology 500 ctDNA Analysis Software v1.1.		

Kit Component	Measured Concentration (ng/µL)	Average Fragment Size (bp)	Measured Blood TMB Score	Adjusted ¹ Blood TMB Score
SeraSeq Blood TMB Mix Score 13 (0% tumor)	14.9	184	4.6 ± 0.05	N/A
SeraSeq Blood TMB Mix Score 13 (0.5% tumor)	13.0	198	18.7 ± 2.1	14.1 ± 2.2
SeraSeq Blood TMB Mix Score 13 (2% tumor)	15.2	187	24.6 ± 0.8	20.0 ± 0.9

¹Score subtracts somatic contributions/Mb of 0% tumor (WT) blend.

Note: TMB variant lists and VCFs available upon request.



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Approval:

T.B.

Prepared By

20 JUN 2025

Date