

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: 10801982

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: 28 JAN 2026 Expiration Date: 28 JAN 2030

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)	13.4	184	4.6 ± 0.05	N/A
Seraseq Blood TMB Mix Score 13 (0.5% tumor)	12.2	198	18.7 ± 2.1	14.1 ± 2.2
Seraseq Blood TMB Mix Score 13 (2% tumor)	14.3	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:

05 MAR 2026

Prepared By

Date