



# Revised 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:** 10573307

**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:** 27 AUG 2021      **Expiration Date:** 18 AUG 2025

**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 in the TSO500 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 call 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 <sup>1</sup> Blood TMB Score
Seraseq Blood TMB Mix Score 13 (0% tumor)	14.3	185	4.6 ± 0.5	N/A
Seraseq Blood TMB Mix Score 13 (0.5% tumor)	12.2	195	18.7 ± 2.1	14.1 ± 2.2
Seraseq Blood TMB Mix Score 13 (2% tumor)	14.4	185	24.6 ± 0.8	20.0 ± 0.9

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

Note: TMB variant lists and VCFs available upon request.



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**Approval:**

09 SEP 2024

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Prepared By

Date