



Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® Blood TMB Mix Score 7

Material Number: 0710-2087 Batch Number: 10659789

Material Description: Reference standard made from a human lung cancer cell line and its matched "normal" cell line generated from peripheral blood of the same patient. Extracted genomic DNA was blended at 3 tumor fractions (0%, 0.5% and 2%) and fragmented and sized to mimic ctDNA.

Date of Manufacture: 27 APR 2023 Expiration Date: 05 APR 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 in the TSO500 ctDNA enrichment kit and sequenced on a Novaseq 6000 NGS System (2 X 151 bp sequencing) on an S2 flow cell (3 samples per run). The minimum depth for a variant call was 1000X coverage to be included in TMB score. 96% of exons were covered at 1000X. Each sample was represented by a minimum of 600M paired end reads. The data were analyzed using DRAGEN TruSight Oncology 500 ctDNA Analysis Software v2.1.1.9.

Kit Component	Measured Concentration (ng/µL)	Average Fragment Size (bp)	Blood TMB Score	Adjusted ¹ Blood TMB Score
Seraseq Blood TMB Mix Score 7 (0% tumor)	16.7	201	6.5	N/A
Seraseq Blood TMB Mix Score 7 (0.5% tumor)	14.2	195	13.8	7.3
Seraseq Blood TMB Mix Score 7 (2% tumor)	14.3	194	16.2	9.7

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

Note: TMB variant lists and VCFs available upon request



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Approval:

21-JAN-2025

Prepared By

Date