

# Revised Technical Product Report

*For Research Use Only; Not for use in Diagnostic Procedures*

Product Description: Seraseq® Blood TMB Mix Score 20  
 Material Number: 0710-2089 Batch Number: 10573308  
 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. 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: 19 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 and 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 were 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 20 (0% tumor)	14.1	190	7.5 ± 1.4	N/A
Seraseq Blood TMB Mix Score 20 (0.5% tumor)	14.0	185	26.0 ± 2.3	18.5 ± 2.7
Seraseq Blood TMB Mix Score 20 (2% tumor)	12.8	170	35.6 ± 1.0	28.1 ± 1.7

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

Note: TMB variant lists and VCFs available upon request.

**Approval:**



19 SEP 2024

Prepared By

Date