

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.

Nominal Concentration: 10 ng/μL

Concentration Test Method: Qubit dsDNA BR Assay

Fill Volume: 20 μL

Date of Manufacture: 27 APR 2023 Expiration Date: 05 APR 2025

NGS Assay Test Method: 30ng 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)	Blood TMB Score	Adjusted ¹ Blood TMB Score
Seraseq Blood TMB Mix Score 7 (0% tumor)	16.7	6.5	N/A
Seraseq Blood TMB Mix Score 7 (0.5% tumor)	14.2	13.8	7.3
Seraseq Blood TMB Mix Score 7 (2% tumor)	14.3	16.2	9.7

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

Note: TMB variant lists and VCFs available upon request

Approval:

BK

06/09/2023