

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%).

Nominal Concentration: 10 ng/μL

Concentration Test Method: Qubit dsDNA BR Assay

Fill Volume: 20 μL

Date of Manufacture: 27 AUG 2021 Expiration Date: 18 AUG 2024

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)	Measured Blood TMB Score	Adjusted ¹ Blood TMB Score
Seraseq Blood TMB Mix Score 13 (0% tumor)	14.3	4.6 ± 0.5	N/A
Seraseq Blood TMB Mix Score 13 (0.5% tumor)	12.2	18.7 ± 2.1	14.1 ± 2.2
Seraseq Blood TMB Mix Score 13 (2% tumor)	14.4	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.

Approval:



28 JUN 2023

Prepared By

Date