

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: 10560031

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: 03 JUN 2021 Expiration Date: 26 MAY 2023

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)	Blood TMB Score	Adjusted ¹ Blood TMB Score
Seraseq Blood TMB Mix Score 7 (0% tumor)	12.8	7.5 ± 1.7	N/A
Seraseq Blood TMB Mix Score 7 (0.5% tumor)	12.7	13.1 ± 2.6	5.6 ± 2.1
Seraseq Blood TMB Mix Score 7 (2% tumor)	13.7	17.9 ± 1.3	10.4 ± 1.7

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

Note: TMB variant lists and VCFs available upon request

Approval:



16 JUN 2021

Prepared By

Date