

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq[®] Blood TMB Mix Score 26

Material Number: 0710-2090 Batch Number: 10560032

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: 19 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 26 (0% tumor)	13.0	6.0 ± 0.5	N/A
Seraseq Blood TMB Mix Score 26 (0.5% tumor)	11.0	20.7 ± 5.5	14.7 ± 2.4
Seraseq Blood TMB Mix Score 26 (2% tumor)	11.9	30.4 ± 1.8	24.4 ± 1.5

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