Seraseq® gDNA, ctDNA and FFPE TMB Products

HUMAN CELL LINE DERIVED REFERENCE SAMPLES, TUMOR-NORMAL MATCHED SET, WITH RANGE OF TMB SCORES FOR VALIDATION AND USE OF TARGETED NGS PANEL IN TMB MEASUREMENTS.

HIGHLIGHTS

DERIVED FROM DISEASED HUMAN CELL LINES AND MATCHED NORMAL CELL LINES; IN PURIFIED DNA AND FFPE FORMATS.

REFERENCE STANDARDS DEVELOPED IN PARTNERSHIP WITH INDUSTRY EXPERTS.

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL; GUARANTEES CONSISTENT GROUND TRUTH

INTRODUCTION

In immuno-oncology (I-O), the goal is to enable a patient's immune system to locate and eliminate cancerous cells. Checkpoint inhibitors (CPI), which have recently improved the prognosis for a significant number of cancer patients, work by blocking inhibitory molecules such as PD-L1 and CTLA-4 that may be allowing cancers to evade the adaptive immune system. The US FDA has approved several CPIs such as ipilimumab (Yervoy®, 2011; BMS), pembrolizumab (Keytruda®, 2014; Merck), and nivolumab (Opdivo®, 2014; BMS) primarily for melanoma treatment, but extended to cover treatment of patients with Non-Small Cell Lung Cancer (NSCLC) and other renal cancers. However, by taking the brakes off the immune system, the use of CPI is associated with a significant risk of developing autoimmune disease.

In order to maximize the safety and efficacy of checkpoint inhibitors, it is beneficial to identify patients who are likely to respond to their use. Since the adaptive immune system can detect changes to proteins, it is thought that the number of somatic mutations that lead to such changes may be correlated with efficacy. The metric of non-silent somatic mutations per megabase of coding DNA has been termed tumor mutational burden (TMB), which has shown some correlation to the efficacy of checkpoint inhibitors. Assessments of TMB are being added to many NGS assays to enable their use for patient selection in I-O clinical trials, and perhaps as companion diagnostics to these therapies. However, it is also known that TMB scores can differ significantly between assays and especially around levels that may be clinical decision points.

SERASEQ TMB REFERENCE MATERIALS – gDNA, ctDNA AND FFPE

Purified gDNA TMB reference materials were made from human diseased cell lines and their matched peripheral blood (normal) lymphoblastoid cells derived from the same patients. FFPE TMB reference materials were made from human diseased cell lines, blended to 30% tumor content, formalin treated and paraffin embedded into FFPE blocks, then cut into 10 µm sections. Blood TMB (ctDNA) reference materials were made from human diseased cell lines and their SNP-matched normal cell lines, bulk mix is fragmented and sized to typical cfDNA fragment sizes, purified and blended at 0%, 0.5% and 2% tumor fractions. Tissue TMB/Blood TMB scores were determined using whole exome sequencing (WES – tissue TMB) and a targeted NGS panel (Blood TMB), and analyzed by TMB analysis pipelines in a tumor-normal setting (WES) or tumor-only setting filtered with germline variants (targeted panel).

TMB Reference Material	Cell Line	gDNA TMB Scores	FFPE TMB Scores	Blood TMB Scores
Seraseq® TMB Score 7	Small cell lung cancer; carcinoma (stage E)	7.2 ± 0.2	7.2 ± 0.4	5.6 ± 2.1 (0.5% TF) 10.4 ± 1.7 (2% TF)
Seraseq® TMB Score 9	Lung adenocarcinoma (stage 1)	9.5 ± 0.4	7.5 ± 1.3	N/A
Seraseq® TMB Score 20	Non-small cell lung cancer; carcinoma	20.1 ± 0.2	18.6 ± 0.5	TBD
Seraseq® TMB Score 26	Lung adenocarcinoma (stage 4)	25.8 ± 0.5	22.8 ± 3.6	14.7 ± 2.4 (0.5% TF) 24.4 ± 1.5 (2% TF)
Seraseq® TMB Score 13	B-Lymphocyte	12.6 ± 0.02	12.1 ± 0.3	TBD

ABOUT LGC SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM

FEATURES AND BENEFITS

- gDNA TMB:
  - 100% tumor-normal matched reference materials
  - Purified DNA in buffer
  - Ready as input into WES or targeted NGS library preparation
- FFPE TMB:
  - 30% tumor FFPE reference standards
  - FFPE sectioned to 10 µm per vial
  - Compatible with a range of FFPE extraction kits
- Blood TMB:
  - 0%, 0.5%, 2% tumor fractions to mimic tumor levels in cell free DNA
  - Purified ctDNA in buffer
  - Ready as input into targeted NGS library preparation
- TMB scores range of 7 to 26
- Manufactured in GMP-compliant and ISO 13485 certified facilities

ORDERING INFORMATION

Each part code is available for individual purchase.

Product	Format	Material No.	Concentration	Fill Volume	Total Mass
Seraseq® gDNA TMB Mix Score 7	100% tumor-normal matched set - provided in separate vials. No extraction required. Purified DNA in buffer.	0710-1326	50 ng/µL/vial (x2)	10 µl/vial (x2)	500 ng (x2)
Seraseq® gDNA TMB Mix Score 9		0710-1325	50 ng/µL/vial (x2)	10 µl/vial (x2)	500 ng (x2)
Seraseq® gDNA TMB Mix Score 13		0710-1586	50 ng/µL/vial (x2)	10 µl/vial (x2)	500 ng (x2)
Seraseq® gDNA TMB Mix Score 20		0710-1324	50 ng/µL/vial (x2)	10 µl/vial (x2)	500 ng (x2)
Seraseq® gDNA TMB Mix Score 26		0710-1323	50 ng/µL/vial (x2)	10 µl/vial (x2)	500 ng (x2)
Seraseq® Blood TMB Mix Score 7	Tumor-normal blends at 0%, 0.5% & 2% - provided in separate vials. No extraction required. Purified DNA in buffer.	0710-2087	50 ng/µL/vial (x3)	20 ul/vial (x3)	200 ng (x3)
Seraseq® Blood TMB Mix Score 26		0710-2090	50 ng/µL/vial (x3)	20 ul/vial (x3)	200 ng (x3)
Seraseq® FFPE TMB RM Score 7	30% tumor content. Full Process. Extraction Required - FFPE	0710-1310	1 FFPE curl/vial (x2)	10 µm (x2)	>100 ng/curl* (x2)
Seraseq® FFPE TMB RM Score 9		0710-1308	1 FFPE curl/vial (x2)	10 µm (x2)	>100 ng/curl* (x2)
Seraseq® FFPE TMB RM Score 13		0710-1618	1 FFPE curl/vial (x2)	10 µm (x2)	>100 ng/curl* (x2)
Seraseq® FFPE TMB RM Score 20		0710-1309	1 FFPE curl/vial (x2)	10 µm (x2)	>100 ng/curl* (x2)
Seraseq® FFPE TMB RM Score 26		0710-1307	1 FFPE curl/vial (x2)	10 µm (x2)	>100 ng/curl* (x2)

**Based on Qiagen QIAamp DNA FFPE Tissue Kit and the Qubit dsDNA HS Assay*

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