# Seraseq®
## gDNA TMB Reference Panel Mix

Package Insert

**PLEASE NOTE:**
THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

### NAME AND INTENDED USE

The Seraseq® gDNA TMB Reference Panel Mix product is a reference material formulated for use with Next Generation Sequencing (NGS) assays that detect somatic mutations in human cancer patient samples. These products are intended for use as reference materials in the determination of the number of somatic mutations per genome in a cancer patient sample analyzed by NGS assays under a given set of bioinformatics pipeline parameters. Product is *For Research Use Only. Not for use in diagnostic procedures.*

### REAGENTS

| Material Number | Product Name |
|---|---|
| 0710-2463 | Seraseq gDNA TMB Reference Panel Mix |

Product kit consists of five (5) gDNA vials with WES-derived TMB Scores of 5, 10, 30, 50 and a matched normal reference sample; 5x25 ng/µl concentration; 5x20 µl fill volumes; and 5x500 ng total mass.

### WARNINGS AND PRECAUTIONS

***For Research Use Only. Not for use in diagnostic procedures.***
CAUTION: Handle Seraseq gDNA TMB Reference Panel Mix product as though it is capable of transmitting infectious agents. This product consists of purified DNA from a mutagenized cell line and its matched normal.

#### Safety Precautions

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens[1]. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

#### Handling Precautions

Do not use Seraseq gDNA TMB Reference Panel Mix product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

### STORAGE INSTRUCTIONS

Store Seraseq gDNA TMB Reference Panel Mix frozen at -20°C. After opening, record the date opened and the expiration date on each vial in the kit. Aliquoting of the vials into low DNA binding tubes may be advisable to limit the number of freeze-thaw cycles.

### INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq gDNA TMB Reference Panel Mix should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

### PROCEDURE

#### Materials Provided

Each Seraseq gDNA TMB Reference Panel Mix consists of 5 vials of purified DNA from a tumor-like human cell line and matched-normal human cell line, with different WES-derived TMB scores. Each purified DNA is present in a 1 mM Tris, 0.1 mM EDTA, pH 8.0 aqueous buffer, and ready to use in NGS assays in steps that follow DNA isolation. No further purification or DNA isolation is needed.

#### Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

#### Instructions for Use

Thaw the product vials on ice. Mix by vortexing to ensure a homogenous solution and spin briefly. Each vial of the Seraseq gDNA TMB Reference Panel Mix may be input directly into library preparation following procedures used for clinical specimens. Refer to your assay procedures to determine the amount of material to use.

### EXPECTED RESULTS & INTERPRETATION OF RESULTS

Table 1 provides the TMB scores for the Seraseq gDNA TMB Reference Panel Mix products as measured by whole exome sequencing and analyzed using a bioinformatics pipeline that uses sequencing parameters and filters prescribed by a TMB consortium (Friends of Cancer Research TMB Harmonization Project; https://www.focr.org/tmb). Detection of somatic mutations may differ across different NGS panels, and concomitantly the TMB scores determined by targeted NGS panels for the Seraseq gDNA TMB Reference Panel Mix products may differ. Each laboratory must establish an expected TMB score for each of the Seraseq gDNA TMB Reference Panel Mix product. When results for the product are outside of the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error include deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, or changes in bioinformatics pipeline parameters. Additional support documents (VCFs of filtered mutations from analysis pipeline) are available by contacting us at CDx-CustomerService@LGCGroup.com.

### LIMITATIONS OF THE PROCEDURE

Seraseq gDNA TMB Reference Panel Mix MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS. *TEST PROCEDURES* provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. This product is offered for Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly. Seraseq gDNA TMB Reference Panel Mix is not a calibrator and should not be used for assay calibration. These materials are not whole-process controls and do not evaluate the methods used for specimen extraction. Adverse shipping and/or storage conditions or use of outdated product may produce erroneous results.

### REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

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Table 1: Whole Exome Sequencing (WES) generated TMB scores for the Seraseq® gDNA TMB Reference Panel Mix products.

| gDNA TMB Reference Panel Mix | TMB Score |
|---|---|
| Seraseq® gDNA TMB Ref. Mix, Normal | Baseline |
| Seraseq® gDNA TMB Ref. Mix, Score 5 | 3.30 |
| Seraseq® gDNA TMB Ref. Mix, Score 10 | 9.94 |
| Seraseq® gDNA TMB Ref. Mix, Score 30 | 28.91 |
| Seraseq® gDNA TMB Ref. Mix, Score 50 | 51.87 |

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