Seraseq®

gDNA TMB Mix (Score 7, 9, 13, 20 & 26) Products 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 Mix products are reference materials 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	gDNA TMB Reference Standards
0710-1326	Seraseq® gDNA TMB Mix Score 7
0710-1325	Seraseq® gDNA TMB Mix Score 9
0710-1586	Seraseq® gDNA TMB Mix Score 13
0710-1324	Seraseq® gDNA TMB Mix Score 20
0710-1323	Seraseq® gDNA TMB Mix Score 26

For each item, 2 vials (1x tumor, 1x normal), 2x50 ng/µl concentration, 2x10 µl fill volumes, and 2x500 ng total mass.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq gDNA TMB Mix product as though it is capable of transmitting infectious agents. This product consists of purified genomic DNA from a diseased (lung or breast cancer, i.e., tumor) and a matching non-diseased (i.e., normal) human cell line

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 Mix product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq gDNA TMB Mix frozen at -20°C. Aliquoting of the product into low DNA binding tubes may be advisable to limit the number of freeze-thaw cycles. Shelf life when stored under these conditions is two years from date of manufacture.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq gDNA TMB Mix is formulated as a tumor-normal reference standard, derived from expanded/cultured human cell lines of diseased (tumor) and matching non-diseased (normal) patients, it 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

Seraseq gDNA TMB Mix consists of high molecular weight DNA purified from human cell lines (diseased and normal). The purified DNA is present in a 1 mM Tris, 0.1 mM EDTA, pH 8.0 aqueous buffer. Material is 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 vial on ice. Mix by vortexing to ensure a homogenous solution and spin briefly. Seraseq gDNA TMB Mix may be input directly into library preparation following procedures used for clinical specimens. Refer to your assay procedures in order to determine the amount of material to use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Table 1 provides the TMB scores for the Seraseq gDNA TMB 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 Mix products may differ. Each laboratory must establish an expected TMB score for each of the Seraseq gDNA TMB Mix products. 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 seracaremarketing@seracare.com.

LIMITATIONS OF THE PROCEDURE

Seraseq gDNA TMB 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 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 Mix products.

gDNA TMB Reference Standards	Material Number	TMB Score*
Seraseq® gDNA TMB Mix Score 7	0710-1326	7.2 ± 0.2
Seraseq® gDNA TMB Mix Score 9	0710-1325	9.5 ± 0.4
Seraseq® gDNA TMB Mix Score 13	0710-1586	12.6 ± 0.02
Seraseq® gDNA TMB Mix Score 20	0710-1324	20.1 ± 0.2
Seraseq® gDNA TMB Mix Score 26	0710-1323	25.8 ± 0.5

**TMB scores by WES averaged from two independent lab measurements or from 3 replicate runs.*

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