Seraseq®

FFPE TMB RM (Score 7, 9, 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® FFPE TMB RM products are full-process 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 standards 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 No.	FFPE TMB Standards
0710-1310	Seraseq® FFPE TMB RM Score 7
0710-1308	Seraseq® FFPE TMB RM Score 9
0710-1309	Seraseq® FFPE TMB RM Score 20
0710-1307	Seraseq® FFPE TMB RM Score 26

For each item, 2 vials x10 µm FFPE curls.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq FFPE TMB RM product as though it is capable of transmitting infectious agents. This product is derived from diseased human cell lines blended to 30% tumor content, lightly fixed and then paraffin embedded (FFPE). The FFPE-treated curls are made by treating cells with HistoGel, then fixing with 10% Formalin, and washing prior to embedding and sectioning.

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 FFPE TMB RM product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq FFPE TMB RM at 2-8°C. Shelf life when stored under these conditions is two years from date of manufacture.

PROCEDURE

Materials Provided

Seraseq FFPE TMB RM consists of high molecular weight DNA from human cell lines which have been formalin treated and embedded in paraffin to create an FFPE block, which is then cut into 10 µm sections. One 10 µm FFPE curl is provided per vial, and each kit includes 2 vials.

Materials Required but not Provided

Seraseq FFPE TMB RM products require extraction. Refer to instructions supplied by manufacturers of the extraction kit to be used.

Instructions for Use

Allow the product vial to come to room temperature before use. Seraseq FFPE TMB RM must go through an extraction process. Refer to your assay procedures in order to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Seraseq FFPE TMB RM products are compatible with commercially available nucleic acid extraction methods commonly used for FFPE specimens. DNA extraction yields per FFPE curl (10 µm) when using either Promega Maxwell RSC FFPE DNA kit or the Qiagen QIAamp DNA FFPE Tissue kit quantitated by Thermo Fisher's Qubit DNA HS assay are provided in Table 1 below.

Table 1: Representative DNA extraction yields per 10 µm FFPE curl.

	Yield per 10 µm curl (ng)	
FFPE Product	QIAamp FFPE DNA Tissue	Maxwell RSC FFPE DNA
TMB Score 26	170	174
TMB Score 20	186	235
TMB Score 7	206	138
TMB Score 9	305	239

Table 2 provides the TMB scores for the Seraseq FFPE TMB RM 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 FFPE TMB RM products may differ. Each laboratory must establish an expected TMB score for each of the Seraseq FFPE TMB RM 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 FFPE TMB RM 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 FFPE TMB RM 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.

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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.

Table 2: Whole Exome Sequencing (WES) generated TMB scores for the Seraseq FFPE TMB RM products.

FFPE TMB Standards	P/N	TMB Score
Seraseq® FFPE TMB RM Score 7	0710-1310	7.2 ± 0.4
Seraseq® FFPE TMB RM Score 9	0710-1308	7.5 ± 1.3
Seraseq® FFPE TMB RM Score 20	0710-1309	18.6 ± 0.5
Seraseq® FFPE TMB RM Score 26	0710-1307	22.8 ± 3.6