

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® Compromised FFPE Tumor DNA RM product is a full-process reference material formulated for use with Next Generation Sequencing (NGS) assays that detect somatic mutations in human cancer patient samples. This product is intended for use as a reference material for analysis of somatic mutations 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

Table 1. Seraseq Compromised FFPE Tumor DNA RM

Material No.	Product
0710-1492	Seraseq® Compromised FFPE Tumor DNA RM

One 10 µm FFPE curl per vial

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle Seraseq Compromised FFPE Tumor DNA RM product as though it is capable of transmitting infectious agents. This product is formulated using an engineered human cell line derived from GM24385, which is a B-lymphocytic, male cell line from the Genome in a Bottle (GIAB) Project.

Safety Precautions

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens. 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 Compromised FFPE Tumor DNA RM beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

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

PROCEDURE

Materials Provided

Seraseq Compromised FFPE Tumor DNA RM consists of engineered cells which have been formalin treated and embedded in paraffin to create an FFPE block, which is then sectioned into 10 µm curls. One 10 µm FFPE curl is provided per vial.

Materials Required but not Provided

Seraseq Compromised FFPE Tumor DNA RM product 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 Compromised FFPE Tumor DNA 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 Compromised FFPE Tumor DNA RM product is 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's Maxwell RSC FFPE DNA kit or Qiagen's QIAamp DNA FFPE Tissue kit, quantitated by Thermo Fisher's Qubit DNA HS assay, are provided in Table 2 below.

Table 2. Representative DNA extraction yields per 10 µm FFPE curl.

FFPE Curl	Yield per 10 µm curl (ng)	
	Qiagen QIAamp DNA FFPE Tissue	Promega Maxwell RSC DNA FFPE
1	190	445
2	242	322
3	148	390
4	131	378
Average (ng)	177.7 ± 49.8	383.6 ± 50.5

Table 3 lists the DNA variants (SNVs, INDELS, CNVs and SVs) in the Seraseq Compromised FFPE Tumor DNA RM product. Detection of mutations may differ across different NGS panels and different test reagent lots. While the presence and frequency of each mutation in this product is confirmed during manufacture using functional NGS and/or digital PCR assays, there may be differences in observed allele frequencies due to assay characteristics. Each laboratory must establish an assay-specific expected value for each mutation and lot of the Seraseq Compromised FFPE Tumor DNA RM. 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 are available online at www.seracare.com/oncology.

LIMITATIONS OF THE PROCEDURE

Seraseq Compromised FFPE Tumor DNA 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 Compromised FFPE Tumor DNA RM is not a calibrator and should not be used for assay calibration. This material is not whole-process control and does not evaluate the method 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.

Table 3. List of DNA variants in Seraseq Compromised FFPE Tumor DNA RM.

#	Gene	COSMIC ID	AA change	AA Mutation	Variant Type
1	AKT1	COSM33765	p.E17K	c.49G>A	SNV
2	ALK	COSM144250	p.G1202R	c.3604G>A	
3	ALK	COSM28055	p.F1175L	c.3522C>A	
4	BRAF	COSM476	p.V600E	c.1799T>A	
5	EGFR	COSM6240	p.T790M	c.2369C>T	
6	EGFR	COSM6224	p.L858R	c.2573T>G	
7	EGFR	COSM6493937	p.C797S	c.2389T>A	
8	KIT	COSM1314	p.D816V	c.2447A>T	
9	KRAS	COSM521	p.G12D	c.35G>A	
10	KRAS	COSM516	p.G12C	c.34G>T	
11	KRAS	COSM554	p.Q61H	c.183A>C	
12	NRAS	COSM584	p.Q61R	c.182A>G	
13	NRAS	COSM580	p.Q61K	c.181C>A	
14	PIK3CA	COSM775	p.H1047R	c.3140A>G	
15	PIK3CA	COSM765	p.E545D	c.1635G>T	
16	TP53	COSM10648	p.R175H	c.524G>A	
17	TP53	COSM10660	p.R273H	c.818G>A	
18	TP53	COSM10662	p.R248Q	c.743G>A	
19	BRAF	COSM473	p.V600K	c.1798_1799delinsAA	Del
20	BRCA1	COSM1383519	p.K654fs*47	c.1961del	
21	BRCA2	COSM1738242	p.R2645fs*3	c.7934del	
22	EGFR	COSM6223	p.E746_A750 del ELREA	c.2235_2249del	
23	EGFR	COSM12370	p.L747_P753>S	c.2240_2257del	
24	EGFR	COSM6256	p.S752_I759 del SPANKEI	c.2254_2277del	
25	TP53	COSM6530	p.C242fs*5	c.723delC	
26	TP53	COSM18610	p.S90fs*33	c.263delC	
27	EGFR	COSM12378	p.D770_N771insG	c.2310_2311insGGT	Ins
28	ERBB2	COSM20959	p.Y772_A775dup	c.2313_2324dup	
29	ERBB2	N/A	Amplification	N/A	CNV
30	MET	N/A	Amplification	N/A	
31	MYC	N/A	Amplification	N/A	
32	CD74-ROS1	N/A	translocation	N/A	SV
33	NCOA4-RET	N/A	Gene Fusion	N/A	
34	EML4-ALK	N/A	translocation	N/A	