

# Seraseq<sup>®</sup> Compromised FFPE Tumor DNA Reference Material

**HIGHLY MULTIPLEXED FFPE REFERENCE MATERIAL FOR NGS-BASED ASSAY DEVELOPMENT, VALIDATION AND CLINICAL TESTING**

## HIGHLIGHTS

SINGLE-SAMPLE,  
MULTIPLEXED FORMAT;  
PATIENT-LIKE SAMPLE  
PERFORMANCE

ALL CANCER DISEASE  
ACTIONABLE VARIANTS;  
ALL VARIANT TYPES  
— SNVs, INDELS, CNVs,  
SVs; dPCR AND NGS  
QUANTITATED

HIGH-QUALITY  
MANUFACTURED  
REFERENCE MATERIAL;  
PROVIDES CONSISTENT  
GROUND TRUTH

## INTRODUCTION

**Comprehensive genomic profiling (CGP) is an important part of an integrated clinical management of cancer patients, where cancer patients harboring variants/biomarkers of clinical utility are determined by highly multiplexed targeted NGS assay testing. Precise analysis of these patient samples requires high quality sample-to-result assay workflow controls to guide and validate the accurate identification of these actionable variants.**

LGC SeraCare has developed a highly multiplexed Compromised FFPE Tumor DNA reference material imbibing “patient-like” characteristics to support end-to-end NGS workflows performed by clinical labs in the analysis of cancer patient samples. This product consists of 17 genes and 34 variants, incorporating all variant types – SNVs, INDELS, CNVs, and SVs. These variants were precisely quantitated by digital PCR and targeted NGS against a single well-characterized genomic background (GM24385).

## GENES INCLUDED IN THE SERASEQ<sup>®</sup> COMPROMISED FFPE TUMOR DNA

AKT1	EGFR	MYC	CD74-ROS1
ALK	ERBB2	NRAS	NCOA4-RET
BRAF	KIT	PIK3CA	
BRCA1	KRAS	TP53	
BRCA2	MET		

## FEATURES AND BENEFITS

- 34 highly multiplexed variants across 17 genes, covering 18 SNVs, 10 INDELS, 3 CNVs, and 3 SVs, in FFPE format
- Evaluate performance across the entire workflow, including pre-analytic extraction steps
- Mutation targets assessed with dPCR and NGS
- Well-characterized GM24385 human genomic DNA as background ‘wild-type’ material
- Manufactured within cGMP compliant and ISO 13485 certified facilities

## ABOUT 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

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## GENE VARIANTS

#	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_1799delins AA	
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_2311insGG T	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	

## ORDERING INFORMATION

Product	Format	Material No	Conc.	Volume	Total Mass
SeraSeq Compromised FFPE Tumor DNA RM	Extraction Required - FFPE	0710-1492	1 FFPE curl/vial	10 µm	> 100 ng*

\*QIAamp FFPE Tissue DNA Kit.

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

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