

Seraseq[®] ctDNA Complete[™] Reference Materials

ACCELERATE LIQUID BIOPSY ASSAY VALIDATION AND CLINICAL IMPLEMENTATION

HIGHLIGHTS

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

BROAD COVERAGE OF
CLINICALLY ACTIONABLE
SNVs, INDELS, CNVs,
AND SVs

HIGH-QUALITY
MANUFACTURED
REFERENCE MATERIAL;
PROVIDES CONSISTENT
GROUND TRUTH

INTRODUCTION

As liquid biopsy assays gain acceptance for a growing variety of clinical applications, an acute need for highly multiplexed reference materials bearing a broad range of clinically relevant variant types has arisen. But searching for useful remnant patient specimens is prohibitively time-consuming, and singleplex cell lines are inefficient and add unnecessary expense.

Seraseq ctDNA Complete reference materials are purpose-built to accelerate the thorough validation and clinical implementation of NGS-based ctDNA assays. These orthogonally validated truth-set materials can trim weeks or even months off your assay validation timeline with the most complete coverage of actionable variant types in a single reference sample. With the input of recognized clinical genomics experts, the Seraseq ctDNA Complete materials focus on clinically relevant variants in the most prevalent lung, colorectal, breast, and melanoma cancers, and complement the 40 pan-cancer variants in the Seraseq ctDNA v2 reference materials.

KEY GENES INCLUDED

AKT1	BRCA2	EML4-ALK	MYC
ALK	CD74-ROS1	KIT	NCOA4-RET
BRAF	ERBB2	KRAS	NRAS
BRCA1	EGFR	MET	PIK3CA

FEATURES AND BENEFITS

- 25 unique multiplexed variants in 16 genes, covering 12 SNVs, seven INDELS, three CNVs, and three SVs for the broadest coverage of clinically relevant variant types in a single reference material
- Six different allele frequencies (AF) – WT (0%), 0.1%, 0.5%, 1%, 2.5%, and 5% - challenge your limit-of-detection or match typical AF of solid tumor NGS assays
- Allows end-to-end evaluation of assay performance across the entire workflow, including pre-analytic extraction steps
- Variants precisely quantitated with digital PCR and orthogonally validated by NGS
- Blended with well-characterized GM24385 human genomic DNA as background wild-type material
- Manufactured in GMP-compliant, 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.

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM.



VARIANT LIST

#	Gene	Gene ID	AA Change	HGVS	Variant Type
1	AKT1	COSM33765	p.E17K	c.49G>A	SNV
2	ALK	COSM144250	p.G1202R	c.3604G>A	
3	ALK	COSM28055	p.F1174L	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	KIT	COSM1314	p.D816V	c.2447A>T	
8	KRAS	COSM516	p.G12C	c.34G>T	
9	KRAS	COSM521	p.G12D	c.35G>A	
10	KRAS	COSM554	p.Q61H	c.183A>C	
11	NRAS	COSM584	p.Q61R	c.182A>G	
12	PIK3CA	COSM775	p.H1047R	c.3140A>G	
13	BRCA1	COSM1383519	p.K654fs*47	c.1961delA	
14	EGFR	COSM12370	p.L747_P753>S	c.2240_2257del18	
15	BRCA2	COSM1738242	p.R2645fs*3	c.7934delG	
16	EGFR	COSM6256	p.S752_I759 del SPANKEI	c.2254_2277del24	DEL
17	EGFR	COSM6223	p.E746_A750 del ELREA	c.2235_2249del15	
18	PIK3CA	COSM12464	p.N1068fs*4	c.3204_3205insA	INS
19	ERBB2	COSM20959	p.A775_G776 ins YVMA	c.2324_2325ins12	
20	ERBB2	N/A	Amplification		CNV
21	MET	N/A	Amplification		
22	MYC	N/A	Amplification		
23	CD74-ROS1	N/A	Translocation		Translocation
24	EML4-ALKv1	N/A	Translocation		
25	NCOA4-RET	N/A	Translocation		

ORDERING INFORMATION

Each part code is available for individual purchase.

Product	Format	Material #	AF	Concentration	Fill Volume	Total Mass
Seraseq ctDNA Complete Mutation Mix	NO EXTRACTION REQUIRED Purified ctDNA in buffer	0710-0528	5%	10 ng/μL	25 μL	250 ng
		0710-0529	2.5%	10 ng/μL	25 μL	250 ng
		0710-0530	1%	10 ng/μL	25 μL	250 ng
		0710-0531	0.5%	10 ng/μL	25 μL	250 ng
		0710-0532	0.1%	10 ng/μL	25 μL	250 ng
		0710-0533	0%	10 ng/μL	25 μL	250 ng
Seraseq ctDNA Complete Reference Material	FULL-PROCESS, REQUIRES EXTRACTION ctDNA stabilized and blended in a synthetic plasma matrix	0710-0669	5%	25 ng/mL	5 mL	125 ng
		0710-0670	2.5%	25 ng/mL	5 mL	125 ng
		0710-0671	1%	25 ng/mL	5 mL	125 ng
		0710-0672	0.5%	25 ng/mL	5 mL	125 ng
		0710-0673	0.1%	25 ng/mL	5 mL	125 ng
		0710-0674	0%	25 ng/mL	5 mL	125 ng

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