

Seraseq[®] ctDNA Complete[™] Reference Materials

Accelerate liquid biopsy assay validation and clinical implementation

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 Reference Materials focus on clinically relevant variants in the most prevalent lung, colorectal, breast, and melanoma cancers, and complements the 40 pan-cancer variants in the Seraseq ctDNA v2 Reference Materials.

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 cGMP-compliant, ISO 13485 certified facilities.

HIGHLIGHTS

Single-sample, multiplexed format; patient-like sample performance.

Broad coverage of clinically actionable snvs, indels, cnvs, and svcs

High-quality manufactured reference material; provides consistent ground truth

ORDERING INFORMATION

Each part code is available for individual purchase.

Product	Format	Catalog #	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

GENES INCLUDED IN THE SERASEQ ctDNA COMPLETE

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

LIST OF VARIANTS

#	Gene	AA Change	HGVS	Variant Type
1	AKT1	p.E17K	c.49G>A	SNV
2	ALK	p.G1202R	c.3604G>A	
3	ALK	p.F1174L	c.3522C>A	
4	BRAF	p.V600E	c.1799T>A	
5	EGFR	p.T790M	c.2369C>T	
6	EGFR	p.L858R	c.2573T>G	
7	KIT	p.D816V	c.2447A>T	
8	KRAS	p.G12C	c.34G>T	
9	KRAS	p.G12D	c.35G>A	
10	KRAS	p.Q61H	c.183A>C	
11	NRAS	p.Q61R	c.182A>G	
12	PIK3CA	p.H1047R	c.3140A>G	
13	BRCA1	p.K654fs*47	c.1961delA	DEL
14	EGFR	p.L747_P753>S	c.2240_2257del18	
15	BRCA2	p.R2645fs*3	c.7934delG	
16	EGFR	p.S752_I759 del SPANKEI	c.2254_2277del24	
17	EGFR	p.E746_A750 del ELREA	c.2235_2249del15	
18	PIK3CA	p.N1068fs*4	c.3204_3205insA	INS
19	ERBB2	p.A775_G776 ins YVMA	c.2324_2325ins12	CNV
20	ERBB2	Amplification	N/A	
21	MET	Amplification		
22	MYC	Amplification		
23	CD74-ROS1	Translocation		
24	EML4-ALKv1	Translocation		
25	NCOA4-RET	Translocation		Translocation

ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit seracare.com**