

Liquid Biopsy Product Overview

The most patient-like reference materials for ctDNA assays

INTRODUCTION

Expedite the clinical implementation and standardization of next-generation sequencing (NGS)-based liquid biopsy assays with patient-like ctDNA reference samples featuring broad coverage of clinically relevant genomic alterations and variant types. Trust the industry-leading portfolio of Seraseq™ circulating tumor DNA (ctDNA) reference materials to, accelerate, validate and standardize the clinical application of targeted NGS-based cell-free DNA assays.

FEATURES AND BENEFITS

- Easy access to the broadest range of clinically relevant oncology biomarkers
- More comprehensive analytical validations compared to using natural cfDNA alone
- Cost-effective testing with highly multiplexed mixes (up to 40 variants in a single reference sample) featuring the broadest selection of variant types - SNVs, INDELS, CNVs, SVs/gene fusions
- Better genomic coverage and improved library complexity (molecular diversity)

HIGHLIGHTS

Natural cfDNA-like size distribution ~170 bp and library performance

Clinically relevant variants in a well-characterized WT background

VAFs confirmed by ddPCR and NGS assays

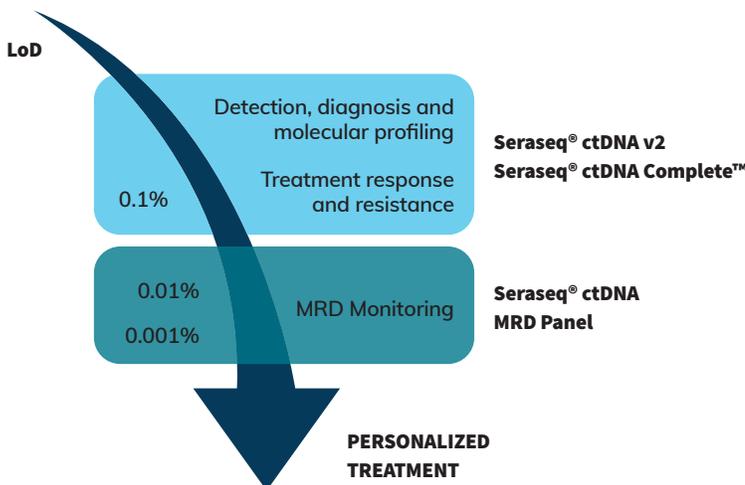


Figure 1: Different applications of Seraseq ctDNA reference materials in clinical cfDNA NGS assays

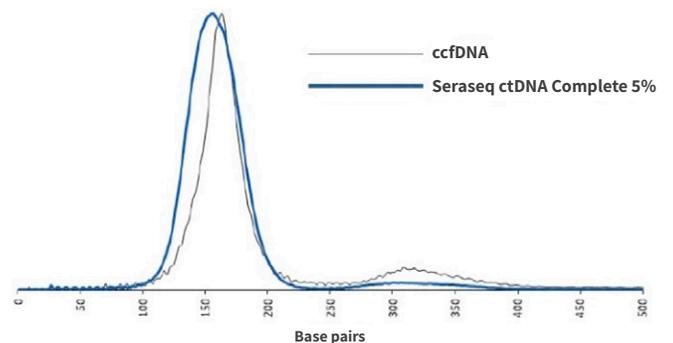


Figure 2: cfDNA fragment size comparisons. Black line represents natural circulating cell free DNA, and blue line is Seraseq ctDNA Complete™ Mutation Mix AF5%.

COMPREHENSIVE SOLUTION FOR cfDNA NGS ASSAY WORKFLOWS

Seraseq® ctDNA Reference Materials

Seraseq ctDNA v2

- Pan-cancer ctDNA reference sample with 40 variants (SNVs, INDELS, and SVs) in 28 genes
- Available in a broad range of VAFs – WT (0%), 0.125%, 0.25%, 0.5%, 1%, 2% - both as purified DNA mix and full-process reference material encapsulated in plasma matrix.

Seraseq ctDNA Complete™

- Solid tumor focused content with coverage of 25 variants (SNVs, CNVs, INDELS and SVs) in 16 genes
- Available in a broad range of VAFs – WT (0%), 0.1%, 0.5%, 1%, 2.5%, 5% - both as purified DNA mix and full-process reference material encapsulated in plasma matrix.

Seraseq ctDNA MRD Panel NEW

- Based on a well-characterized cancer cell line, its SNP-matched normal cell line and 22 targetable solid tumor focused DNA variants
- Enables validation of ultra-high sensitivity MRD assays based on patient-specific disease markers determined from tissue biopsy WES analysis.
- Includes tumor fraction (TF) blends of 0%, 0.5%, 0.05% and 0.005% for assay LoD determinations from a tumor-normal matched reference sample
- Variant information data available for WES and targeted panel verification of variants at dilution levels.

ORDERING INFORMATION

Material #	Product	Format	VAF	Concentration	Fill Volume	Total Mass
0710-0203	Seraseq ctDNA v2 Reference Material	FULL-PROCESS, REQUIRES EXTRACTION ctDNA stabilized and blended in a synthetic plasma matrix	2%	25 ng/mL	5 mL	125 ng
0710-0204			1%	25 ng/mL	5 mL	125 ng
0710-0205			0.50%	25 ng/mL	5 mL	125 ng
0710-0206			0.25%	25 ng/mL	5 mL	125 ng
0710-0207			0.125%	25 ng/mL	5 mL	125 ng
0710-0208			WT (0%)	25 ng/mL	5 mL	125 ng
0710-0139			Seraseq ctDNA v2 Mutation Mix	NO EXTRACTION REQUIRED Purified ctDNA in Buffer	2%	10 ng/μL
0710-0140	1%	10 ng/μL			25 μL	250 ng
0710-0141	0.50%	10 ng/μL			25 μL	250 ng
0710-0142	0.25%	10 ng/μL			25 μL	250 ng
0710-0143	0.125%	10 ng/μL			25 μL	250 ng
0710-0144	WT (0%)	10 ng/μL			25 μL	250 ng

For research use only. Not for use in diagnostic procedures.

Material #	Product	Format	VAF	Concentration	Fill Volume	Total Mass
0710-0669	Seraseq ctDNA Complete™ Reference Material	FULL-PROCESS, REQUIRES EXTRACTION ctDNA stabilized and blended in a synthetic plasma matrix	5%	25 ng/mL	5 mL	125 ng
0710-0670			2.50%	25 ng/mL	5 mL	125 ng
0710-0671			1%	25 ng/mL	5 mL	125 ng
0710-0672			0.50%	25 ng/mL	5 mL	125 ng
0710-0673			0.10%	25 ng/mL	5 mL	125 ng
0710-0674			W T (0%)	25 ng/mL	5 mL	125 ng
0710-0528	Seraseq ctDNA Complete™ Mutation Mix	NO EXTRACTION REQUIRED Purified ctDNA in Buffer	5%	10 ng/μL	25 μL	250 ng
0710-0529			2.50%	10 ng/μL	25 μL	250 ng
0710-0530			1%	10 ng/μL	25 μL	250 ng
0710-0531			0.50%	10 ng/μL	25 μL	250 ng
0710-0532			0.10%	10 ng/μL	25 μL	250 ng
0710-0533			W T (0%)	10 ng/μL	25 μL	250 ng
0710-2146	Seraseq ctDNA MRD Panel Mix	Purified ctDNA in Buffer	0% TF	10 ng/μL	20 μL	200 ng
			0.5% TF	10 ng/μL	20 μL	200 ng
			0.05% TF	10 ng/μL	20 μL	200 ng
			0.005% TF	10 ng/μL	20 μL	200 ng

For research use only. Not for use in diagnostic procedures.

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**