



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, now also including methylation
- Low-cost ctDNA extraction reference materials
- 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

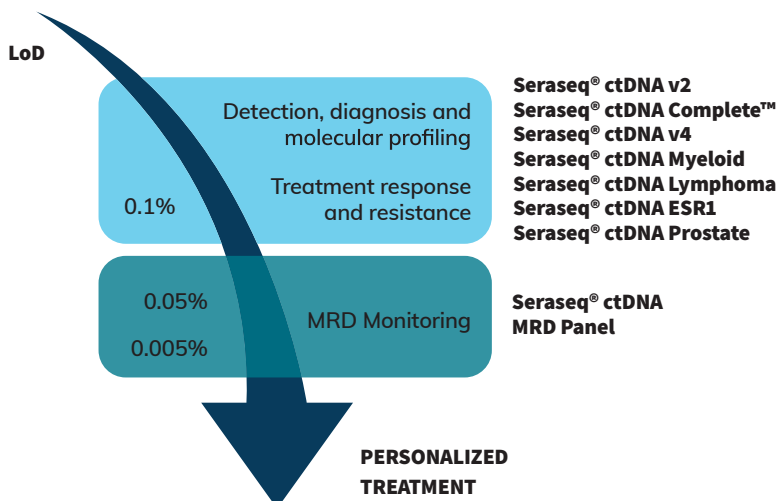


Figure 1: Different applications of Seraseq ctDNA reference materials in clinical cfDNA NGS assays

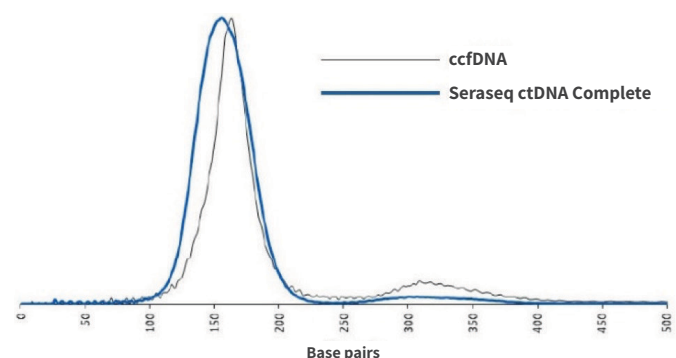


Figure 2: cfDNA fragment size comparisons. Black line represents natural circulating cell free DNA, and blue line is Seraseq ctDNA Complete™ Mutation Mix AF5%.

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 ctDNAComplete™

- 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 v4

- 93 unique multiplexed variants relevant to a range of solid tumors in 71 genes, covering 43 SNVs, 19 deletions, 5 insertions, 4 INDELs, 12 CNVs, and 10 translocations for the broadest coverage of clinically relevant variant types in a single reference material
- Four different variant allele frequencies (VAF) – WT (0%), 0.1%, 0.5%, and 5% - challenge your limit-of-detection or match typical AF of solid tumor NGS assays
- Clinically actionable focus - 83 variants are FDA drug targets

Seraseq ctDNA MRD Panel

- Based on a well-characterized TMB Score 26 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 WES analysis of primary tumor
- 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
- Proprietary low background fragmentation to ensure clean signal to noise for highly sensitive MRD assays
- Companion FFPE TMB Score 26 and gDNA TMB Score 26 material available for full process tumor informed applications

Seraseq Myeloid ctDNA

- Myeloid-focused content spanning 25 variants (SNVs and INDELs including ITDs) in 17 genes
- Available in a broad range of VAFs - WT (0%), 0.1%, 0.5%, 1% as purified DNA mix

Seraseq Lymphoma ctDNA

- Lymphoma-focused content spanning 26 variants (SNVs, INDELs and translocations) in 20 genes
- Available in a broad range of VAFs - WT (0%), 0.1% 1% as purified DNA mix

ctDNA ESR1

- 22 clinically relevant mutations in ESR1 and PIK3CA
- All variants present at 1% variant allele frequency (VAF) with WT sample available to dilute and challenge limit of detection
- All DNA mutations leading to clinically relevant amino acid substitutions in the ligand binding domain of ESR1 (e.g. 3 different DNA sequences leading to a Y537S amino acid substitution) are present

ctDNA Prostate

- 48 clinically relevant mutations including SNVs, INDELs, translocations and CNVs.
- Emphasis on homologous recombination repair (HRR) pathway mutations typically found in castration resistant metastatic prostate cancer (mCRPC)
- Variants present at 1% or 0.5% Variant Allele Frequency (VAF)

Seraseq ctDNA Extraction Reference Material

- Calibrated cfDNA spiked into synthetic plasma at 3 different cfDNA concentrations (20 ng / ml , 50 ng / ml, 80 ng/ml), with extraction data from 4 commonly used methods provided
- Designed for extraction kit validation and automation workflow optimization, and as an affordable run control for routine use in performance monitoring of extraction protocols

Seraseq Methylated and Unmethylated ctDNA

- First-to-market ctDNA reference materials to validate the sensitivity and performance of liquid biopsy assays measuring CpG methylation. Available as unmethylated (<2%) or methylated (>90%) on genome-wide CpG sites.
- Validate and monitor performance of methylation detection at your desired percentage of methylated ctDNA

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			0.13%	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	25 µL	250 ng
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			0.13%	10 ng/µL	25 µL	250 ng
0710-0144			WT (0%)	10 ng/µL	25 µL	250 ng
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			WT (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			WT (0%)	10 ng/µL	25 µL	250 ng
0710-3097	SeraSeq ctDNA Mutation Mix v4	Purified ctDNA in Buffer	0.10%	10 ng/µL	25 µL	250 ng
0710-3099			0.50%	10 ng/µL	25 µL	250 ng
0710-3100			5%	10 ng/µL	25 µL	250 ng
0710-3101			WT (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.



Material #	Product	Format	VAF	Concentration	Fill Volume	Total Mass
0710-3089	Seraseq Methylated ctDNA Mix	Purified ctDNA in Buffer	N/A	10 ng/μL	25 μL	250 ng
0710-3088	Seraseq Unmethylated ctDNA Mix	Purified ctDNA in Buffer	N/A	10 ng/μL	25 μL	250 ng
0710-2646	Seraseq Myeloid ctDNA Mix	Purified ctDNA in Buffer	0.10%	15 ng/μL	25 μL	375 ng
0710-2647			0.50%	15 ng/μL	25 μL	375 ng
0710-2648			1%	15 ng/μL	25 μL	375 ng
0710-2649			WT (0%)	15 ng/μL	25 μL	375 ng
0710-3184	Seraseq ctDNA Lymphoma Mix	Purified ctDNA in Buffer	0.10%	10 ng/μL	25 μL	375 ng
0710-3183			0.50%	10 ng/μL	25 μL	375 ng
0710-3182			1%	10 ng/μL	25 μL	375 ng
0710-3181			WT (0%)	10 ng/μL	25 μL	375 ng
0710-3294	Seraseq ctDNA Extraction Reference Material	FULL-PROCESS, REQUIRES EXTRACTION ctDNA in a synthetic plasma matrix	1%	20 ng/mL	4 x 1 mL	80 ng
0710-3295			1%	50 ng/mL	4 x 1 mL	200 ng
0710-3296			1%	80 ng/mL	4 x 1 mL	320 ng
0710-3327	Seraseq ctDNA Prostate Mix	Purified ctDNA in Buffer	WT (0%)	10 ng/μL	25 μL	250 ng
0710-3328			1%	10 ng/μL	25 μL	250 ng
0710-3329			0.50%	10 ng/μL	25 μL	250 ng
0710-3565	Seraseq ctDNA ESR1 Mix	Purified ctDNA in Buffer	1%	10 ng/μL	25 μL	250 ng
0710-3564			WT (0%)	10 ng/μL	25 μL	250 ng

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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**

