

Seraseq® ctDNA MRD Mix

Reference material designed for NGS MRD assay validation and routine monitoring of clinically actionable variants in various solid tumor cancers.

INTRODUCTION

MRD monitoring typically involves measuring signs of a cancer in order to inform decisions about treatment escalation and de-escalation. Typically, this can be facilitated by use of less invasive techniques such as liquid biopsy (ctDNA), to monitor cancer-specific somatic variants. A patient-derived approach to the application of ctDNA-based MRD monitoring starts with a tumor profiling analysis to identify clinically relevant tumor variants that constitute the patient's genomic profile. Following this, a targeted panel/assay containing a subset of the gene variants can be designed for disease monitoring by detecting presence or absence of circulating tumor (ct) DNA variants in the patient's blood sample. These patient-derived MRD analyses represent a paradigm shift in disease monitoring and are rapidly being developed by many assay vendors while best clinical practices are being developed in parallel.

SeraCare has developed a novel ctDNA MRD mutation mix designed to support the development, validation and clinical deployment of a ctDNA-based patient derived MRD monitoring NGS assays. The new Seraseq ctDNA MRD Mix product is constructed from a combination of a diseased human cell line, its SNP-matched normal cell line, and biosynthetic DNA containing variants commonly targeted by therapeutic drugs (see list below). The blended DNA is fragmented, sized to mimic ctDNA fragment sizes, and serially diluted to tumor fractions (TF) of 0%, 0.5%, 0.05% and 0.005%.

ADDITIONAL DNA GENES INCLUDED IN THE SERASEQ® CTDNA MRD MIX

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

HIGHLIGHTS

Highly multiplexed reference material containing clinically-significant variants primarily found in solid tumors.

First-to-market reference standard for mrd monitoring.

High-quality manufactured reference material; guarantees consistent ground truth.

ORDERING INFORMATION

Material #	Product	Concentration	Fill Volume	Total Mass
0710-2146	Seraseq ctDNA MRD Mix (Kit contains 4 vials: 0%, 0.5%, 0.05% & 0.005% tumor fractions)	10ng/μL	20 μL	200 ng (x4)
0710-3670	Seraseq ctDNA MRD 0% Tumor	10ng/μL	20 μL	200 ng
0710-3671	Seraseq ctDNA MRD 0.5% Tumor	10ng/μL	20 μL	200 ng
0710-3672	Seraseq ctDNA MRD 0.05% Tumor	10ng/μL	20 μL	200 ng
0710-3673	Seraseq ctDNA MRD 0.005% Tumor	10ng/μL	20 μL	200 ng

FEATURES AND BENEFITS

- Combination of diseased human cancer cell line, its SNP-matched normal and biosynthetic DNA variants.
- Fragmented, sized (ctDNA), and blended at four tumor levels: 0% (WT), 0.5%, 0.05% and 0.005%.
- Develop, validate and routinely determine presence/absence of patient-derived disease variants with high precision (against a matched normal (WT) background).
- Variant detection and VAF analysis by digital PCR and targeted cfDNA NGS assay.
- Available as a purified DNA mix ready for targeted sequencing library prep.
- Manufactured in GMP-compliant and ISO 13485-certified facilities.

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