PRODUCT SHEET

Seraseq® Circulating Tumor DNA v2 Reference Materials

MOST PATIENT-LIKE REFERENCE MATERIALS FOR CTDNA ASSAY DEVELOPMENT, VALIDATION AND QC

HIGHLIGHTS

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

40 UNIQUE TUMOR DRIVER MUTATIONS QUANTITATED WITH DIGITAL PCR; ASSURES ACCURATE, PRECISE AND CONSISTENT DETECTION OF SOMATIC MUTATIONS

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL; GUARANTEES CONSISTENT GROUND TRUTH

INTRODUCTION

The analysis of circulating tumor DNA (ctDNA), commonly referred to as Liquid Biopsy, is gaining tremendous traction as a non-invasive method to assess cancer. The ability to detect and monitor mutations by next-generation sequencing (NGS) and PCR offers tremendous clinical potential. However, a major challenge for those developing and validating new assays is clearly and easily defining key performance characteristics for detection of genomic alterations at very low frequencies. As it is extremely difficult to source, produce, and maintain materials which are well-matched to ctDNA derived from clinical specimens, there is a need for high quality reference materials for these types of tests.

In order to overcome the lack of patient-like reference materials, including shortcomings of existing methodologies used to produce ctDNA-like materials such as sonication, SeraCare has developed a unique patent-pending technology that produces the most patient-like size distribution and performance characteristics compared to native ctDNA. The portfolio of Seraseq Circulating Tumor DNA v2 reference materials is a highly multiplexed, patient-like offering for NGS-based ctDNA assays targeting cancer-relevant somatic mutations. This first product of its kind consists of 40 variants in a well-characterized genomic background across a range of allele frequencies down to 0.125% that can be used to significantly expedite assay development and validation, or as a routine assay quality control.

KEY GENES INCLUDED IN SERASEQ CTDNA V2 REFERENCE MATERIALS

AKT1	APC	BRAF	CTNNB1	EGFR	ERBB2
FGFR3	GNA11	GNAQ	GNAS	IDH1	JAK2
KIT	KRAS	MPL	NPM1	PDGFRA	PIK3CA
PTEN	RET	SMAD4	TP53	NRAS	

FEATURES AND BENEFITS

- Develop your assay with confidence using patient-like reference materials that are more consistent with native ctDNA than any other commercially available solution
- Ensure robust sensitivity using a single sample with clinically-relevant mutations across a range of variant allele frequencies that establish and challenge your limit of detection (LOD)
- Offered as a purified DNA mixture for ease of use, or as a full-process plasma-like material capable of assessing the entire workflow from extraction through data analysis
- Mutation targets precisely quantitated with digital PCR and blended with single well-characterized GM24385 human genomic DNA as background ‘wild-type’ material
- Manufactured in cGMP-compliant, ISO 13485-certified facilities

Gene ID	HGVS	Amino Acid Change	Mutation Type
AKT1	c.49G>A	p.E17K	SNV
APC	c.4666_4667insA	p.T1556fs*3	Insertion in homopolymer (7N)
APC	c.4348C>T	p.R1450*	SNV
ATM	c.1058_1059delGT	p.C353fs*5	Deletion
BRAF	c.1799T>A	p.V600E	SNV
CTNNB1	c.121A>G	p.T41A	SNV
EGFR	c.2236_2250del15	p.E746_A750delELREA	Deletion
EGFR	c.2310_2311insGGT	p.D770_N771insG	Insertion
EGFR	c.2573T>G	p.L858R	SNV
EGFR	c.2369C>T	p.T790M	SNV
ERBB2	c.2324_2325ins12	p.A775_G776insYVMA	Insertion
FGFR3	c.746C>G	p.S249C	SNV
FLT3	c.2503G>T	p.D835Y	SNV
FOXL2	c.402C>G	p.C134W	SNV
GNA11	c.626A>T	p.Q209L	SNV
GNAQ	c.626A>C	p.Q209P	SNV
GNAS	c.601C>T	p.R201C	SNV
IDH1	c.394C>T	p.R132C	SNV
JAK2	c.1849G>T	p.V617F	SNV
KIT	c.2447A>T	p.D816V	SNV
KRAS	c.35G>A	p.G12D	SNV
MPL	c.1544G>T	p.W515L	SNV
NCOA4-RET	NCOA4{NC_000010.10}:r.1_1014+1312_ RET{NC_000010.10}:r.2327-1437_5659	N/A	Gene Fusion (DNA)
NPM1	c.863_864insTCTG	p.W288fs*12	Insertion
NRAS	c.182A>G	p.Q61R	SNV
PDGFRA	c.1694_1695insA	p.S566fs*6	Insertion
PDGFRA	c.2525A>T	p.D842V	SNV
PIK3CA	c.3204_3205insA	p.N1068fs*4	Insertion
PIK3CA	c.1633G>A	p.E545K	SNV
PIK3CA	c.3140A>G	p.H1047R	SNV
PTEN	c.800delA	p.K267fs*9	Deletion in homopolymer (6N>5N)
PTEN	c.741_742insA	p.P248fs*5	Insertion
RET	c.2753T>C	p.M918T	SNV
SMAD4	c.1394_1395insT	p.A466fs*28	Insertion
TP53	c.723delC	p.C242fs*5	Deletion
TP53	c.263delC	p.S90fs*33	Deletion in homopolymer (5N>4N)
TP53	c.524G>A	p.R175H	SNV
TP53	c.818G>A	p.R273H	SNV
TP53	c.743G>A	p.R248Q	SNV
TPR-ALK	TPR{NC_000001.10}:r.1_2185+246_ ALK{NC_000002.11}:r.4125-550_6265	N/A	Gene Fusion (DNA)

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

ORDERING INFORMATION

Each part code is available for individual purchase.

Product	Format	Catalog	Part Code	Concentration	Volume	Total Mass
Seraseq ctDNA v2 Reference Material	FULL-PROCESS, REQUIRES EXTRACTION ctDNA stabilized and blended in a synthetic plasma matrix	0710-0203	2.0%	25 ng/mL	5 mL	125 ng
		0710-0204	1.0%	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
Seraseq ctDNA v2 Mutation Mix	NO EXTRACTION REQUIRED Purified ctDNA in buffer	0710-0139	2.0%	10 ng/uL	25 uL	250 ng
		0710-0140	1.0%	10 ng/uL	25 uL	250 ng
		0710-0141	0.50%	10 ng/uL	25 uL	250 ng
		0710-0142	0.25%	10 ng/uL	25 uL	250 ng
		0710-0143	0.125%	10 ng/uL	25 uL	250 ng

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

MKT-00404-01