Seraseq® ctDNA Prostate Reference Materials

Confidently analyze the mutational status of ctDNA from metastatic prostate cancer

INTRODUCTION

While early-stage prostate cancer is often able to be surgically cured, castration resistant metastatic prostate cancer (mCRPC) is a difficult disease to manage with a 5-year survival rate of about 30%. Recent advances have shown that mCRPC can be managed with PARP inhibitor therapy if there are appropriate homologous recombination repair (HRR) gene mutation present in the tumor.

LGC Clinical Diagnostics has produced the Seraseq ctDNA Prostate Mix to aid in labs wanting to know the HRR status of ctDNA from mCRPC as well as survey for canonical mutations to monitor for recurrence of disease. The diverse set of mutations present include SNVs, insertions, deletions, indels, duplications, translocations and CNVs making this the best-in-class reference material on the market.

HIGHLIGHTS

Clinically relevant variants to help evaluate recurrence and HRR status

Simplify analysis by focusing on disease relevant variants

Consistent performance with batch specific VAF information provided

FEATURES AND BENEFITS

- Validate and monitor performance of cfDNA prostate cancer assays using well defined, precisely built reference materials
- Variants present at 1% or 0.5% Variant Allele Frequency (VAF)
- Mutation targets are quantitated using highly sensitive digital PCR
- Orthogonal NGS data as well to support variant allele frequencies present and compare between assays
- Affordably priced for routine use
- All mutations are blended against GM24385 human genomic DNA as background ‘wild type’ material
- Manufactured in GMP-compliant and ISO 13485-certified facilities

ORDERING INFORMATION

Material #	Product	Concentration*	Fill Volume	Total Mass
0710-3327	Seraseq® ctDNA Prostate Mix WT	10 ng/µL	25 µL	250 ng
0710-3328	Seraseq® ctDNA Prostate Mix AF1%	10 ng/µL	25 µL	250 ng
0710-3329	Seraseq® ctDNA Prostate Mix AF0.5%	10 ng/µL	25 µL	250 ng

* Concentration targets are measured by the Qubit dsDNA BR Assay.

MUTATIONS PRESENT IN THE SERASEQ® ctDNA PROSTATE MIX

Genes	Nucleotide Change	Protein Change	Type of Alteration	Variant Size (bp)
APC	c.4348C>T	p.R1450*	SNV	1
APC	c.4666dup	p.T1556fs	Duplication	1
AR	c.2105T>A	p.L702H	SNV	1
AR	c.2623C>T	p.H875Y	SNV	1
AR	c.2632A>G	p.T878A	SNV	1
ATM	c.2543_2571del	p.E848fs	Deletion	29
ATR	c.2320dup	p.I774fs	Duplication	1
BARD1	c.1600_1634delinsGCG	p.T534fs	Indel	35
BRAF	c.1799T>A	p.V600E	SNV	1
BRCA1	c.3481_3491del	p.E1161fs	Deletion	11
BRCA2	c.1813dup	p.I605fs	Insertion	1
BRCA2	c.8954-8_9136del	Deletion	Deletion	284
BRIP1	c.2392C>T	p.R798*	SNV	1
CDK12	c.4382del	p.G1461fs	Deletion	1
CDKN2A	c.9_32dup	p.A4_P11dup	Insertion	24
CHEK1	c.676del	p.T226fs	Deletion	1
CHEK2	c.1116_1117delinsGT	p.K373*	Indel	2
FANCA	c.2778+1G>A	Splice Variant	SNV	1
FANCL	c.1096_1099dup	p.T367fs	Duplication	4
KIT	c.2361+67_2361+72delTTTTTT	MSI BAT-25	Deletion (25T -> 19T)	6

Genes	Nucleotide Change	Protein Change	Type of Alteration	Variant Size (bp)
KRAS	c.34G>T	p.G12C	SNV	1
MAP4K3	c.998-35_998-30delAAAAAA	MSI MONO-27	Deletion (27A -> 21A)	6
MAP4K3	c.246-2475_246-2470delTTTTTT	MSI MONO-27	Deletion (27A -> 21A)	6
MLH1	c.1852_1854del	p.K618del	Deletion	3
MRE11	c.1100_1131del	p.Val367fs	Deletion	32
MSH2	c.942+3A>T	Splice Variant	SNV	1
MSH2	c.942+20_942+29delAAAAAAAAAA	MSI BAT-26	Deletion (27A -> 17A)	10
MSH6	c.3261dup	p.F1088fs	Duplication	1
NBN	c.1396del	p.R466fs	Deletion	1
PALB2	c.1059_1077delinsGG	p.S354fs	Indel	19
PIK3CA	c.3140A>G	p.H1047R	SNV	1
PIK3R1	c.1727_1729del	p.T576del	Deletion	3
PMS2	c.2243_2246del	p.K748fs	Deletion	4
PTEN	c.741dup	p.P248fs	Insertion	1
PTEN	c.800del	p.K267fs	Deletion	1
RAD51B	c.321dup	p.G108fs	Duplication	1
RAD51C	c.706-2A>G	Splice Variant	SNV	1
RAD51D	c.694_715delinsTGAGAGCTGAAGACCCTGGCCT	p.R232*	Indel	22
RAD54L	c.636_637dup	p.K213fs	Duplication	2
RB1	c.751C>T	p.R251*	SNV	1
SLC7A8	c.-231_-224delTTTTTTTT	MSI NR-21	Deletion (21A -> 13A)	9

Genes	Nucleotide Change	Protein Change	Type of Alteration	Variant Size (bp)
SPOP	c.44_47dup	p.P17fs	Duplication	4
TP53	c.743G>A	p.R248Q	SNV	1
ZNF2	c.*1525_*1530delTTTTTT	MSI NR-24	Deletion (23T -> 17T)	6

Translocation	5' Transcript	5' Breakpoint GRCh38	3' Transcript	3' Breakpoint GRCh38
SLC45A3::ETV1	NM_033102.3	1:205666186	NM_004956.5	7:13983465
TMPRSS2::ERG	NM_005656.4	21:41501890	NM_182918.4	21:38510697
0710-3329	Seraseq® ctDNA Prostate Mix AF1%	10 ng/µL	25 µL	250 ng

CNV	GRCh38 Amplified Region
CCND1	11:69634261_69760196
MYC	8:127654539_127799653

ABOUT US

LGC Clinical Diagnostics offers a comprehensive portfolio of reference materials for oncology, reproductive health, and other genomic applications, designed and manufactured to meet the precision demanded by NGS and other molecular 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, inherited diseases and many other assays. **For more information visit seracare.com**

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