Seraseq® Solid Tumor FFPE DNA Reference Material

Comprehensive full-process reference material for development, validation and clinical implementation of solid tumor assays

INTRODUCTION

Tissue biopsy samples that are formalin fixed and paraffin embedded (FFPE) are widely used in comprehensive genomic profiling (CGP) for cancer diagnosis. However, due to the chemical modifications introduced during the fixation process, FFPE samples present unique challenges that can compromise sequencing results starting from pre-analytical extraction steps through to downstream analysis. To ensure the accurate identification of clinically actionable variants, high quality reference materials are essential for guiding and validating data quality and accuracy throughout the sample-to-result assay process.

LGC has developed a comprehensive Solid Tumor FFPE DNA reference material, mimicking patient-like characteristics, enabling clinical labs and assay developers to confidently develop, validate, and routinely assess their solid tumor molecular assays. This unique product contains 74 biosynthetic DNA variants including SNVs, insertions, deletions, and translocations all within a single reference sample. By providing a realistic and reliable benchmark, this positive FFPE reference material enhances the accuracy of CGP assays and patient sample testing, supporting improved clinical decision making in cancer care.

HIGHLIGHTS

Full process reference material to evaluate performance across the entire NGS workflow

Highly multiplexed, containing 74 variants found in solid tumors

High quality reference materials manufactured in GMP-compliant and ISO 13485 certified facilities

FEATURES AND BENEFITS

- 74 unique multiplexed biosynthetic DNA variants across 62 genes covering 37 SNVs, 4 INDELs, 18 deletions, 5 insertions and 10 translocations, associated with solid tumors
- 65 variants are FDA drug targets
- Offered in lightly fixed FFPE format with variants present at clinically relevant allelic frequencies - challenge your assay sensitivity, and limit of detection
- Evaluate assay performance across the entire workflow, including pre-analytic extraction steps
- Includes one 10 µm FFPE curl with DNA yield >100ng per curl
- Mutation targets measured by targeted NGS panel with select key variants further validated by dPCR
- Well-characterized GM24385 human genomic DNA as background wild-type material
- Manufactured under GMP-compliance and ISO 13485-certified facilities

ORDERING INFORMATION

Material #	Product	Concentration	Fill Volume	Total Mass*
0710-3634	Seraseq® Solid Tumor FFPE DNA Reference Material	1 curl/vial	10 µm curl	>100 ng DNA

**Based on AutoGen XTRACT Genomic DNA FFPE One-Step Kit or QIAamp DNA FFPE Tissue Kit and ThermoFisher's Qubit dsDNA HS Assay*

To place an order, please contact us at +1.508.244.6400 and 800.676.1881 or email CDx-CustomerService@lgcgroup.com

For all solid tumor reference materials visit: https://www.seracare.com/Controls---Reference-Materials-NGS-Somatic-Cancer-Solid-Tumors

MUTATIONS PRESENT IN THE SERASEQ® SOLID TUMOR FFPE DNA PRODUCT

Gene	Transcript	Nucleotide Change	COSMIC ID	Variant Type
AR	NM_000044.6	c.2623C>T	COSM238555	SNV
ATM	NM_000051.4	c.1058_1059del	COSM21924	Deletion
BRCA1	NM_007294.4	c.1961del	COSM219054	Deletion
BRCA2	NM_000059.4	c.7934del	COSM1738241	Deletion
CDKN2A	NM_000077.5	c.9_32dup	COSM13442	Insertion
CHEK1	NM_001114122.3	c.676del	COSM1352376*	Deletion
CHEK2	NM_007194.4	c.1116_1117delinsGT	COSM384945	INDEL
EGFR	NM_005228.5	c.2303G>T	COSM6241	SNV
EGFR	NM_005228.5	c.2310_2311insGGT	COSM12378	Insertion
EGFR	NM_005228.5	c.2369C>T	COSM6240	SNV
EGFR	NM_005228.5	c.2389T>A	COSM6493937	SNV
ERBB2	NM_004448.4	c.2313_2324dup	COSM20959	Insertion
ESR1	NM_000125.4	c.1613A>G	COSM94250	SNV
FGFR3	NM_000142.5	c.746C>G	COSM715	SNV
HRAS	NM_005343.4	c.182A>G	COSM499	SNV
HRAS	NM_005343.4	c.37G>C	COSM486	SNV
IDH1	NM_005896.4	c.394C>T	COSM28747	SNV
IDH2	NM_002168.4	c.419G>A	COSM41590	SNV
IDH2	NM_002168.4	c.515G>A	COSM33733	SNV
KIT	NM_000222.3	c.2361+67_2361+72delTTTTTT	N/A	Deletion
KRAS	NM_004985.5	c.34G>T	COSM516	SNV
MAP2K1	NM_002755.4	c.370C>T	COSM235614	SNV
MAP4K3	NM_003618.4	c.246-2475_246-2470delTTTTTT	N/A	Deletion
MAP4K3	NM_003618.4	c.998-35_998-30delAAAAAA	N/A	Deletion
MET	NM_001127500.3	c.3082+1del	COSM6947926	Deletion
MLH1	NM_000249.4	c.232_243delinsATGTAAGG	N/A	INDEL
MSH2	NM_000251.3	c.1662-12_1677del	N/A	Deletion
MSH2	NM_000251.3	c.942+20_942+29delAAAAAAAAAA	N/A	Deletion
MSH6	NM_000179.3	c.2056_2060delinsCTTCTACCTCAAAAA	N/A	INDEL
MTOR	NM_004958.4	c.6644C>A	COSM20417	SNV
NF1	NM_001042492.3	c.3738_3747del	COSM510741	Deletion
NTRK1	NM_002529.4	c.1783G>A	COSM9113104	SNV
NTRK2	NM_006180.6	c.1915G>A	N/A	SNV
NTRK3	NM_001012338.3	c.1867G>A	COSM6951362	SNV
PALB2	NM_024675.4	c.839del	COSM1376815	Deletion
PDGFRA	NM_006206.6	c.2525A>T	COSM736	SNV
PIK3CA	NM_006218.4	c.3140A>G	COSM775	SNV
PIK3CA	NM_006218.4	c.3203dup	COSM249879	Insertion
PIK3CA	NM_006218.4	c.1633G>A	COSM763	SNV
PIK3R1	NM_181523.3	c.1727_1729del	COSM35737	Deletion

Gene	Transcript	Nucleotide Change	COSMIC ID	Variant Type
PMS2	NM_000535.7	c.861_864del	COSM5547641	Deletion
PTCH1	NM_000264.5	c.2307_2308delinsTT	COSM17587	INDEL
PTEN	NM_000314.8	c.741dup	COSM4986	Insertion
PTEN	NM_000314.8	c.800del	COSM5809	Deletion
RAD51C	NM_058216.3	c.242C>A	N/A	SNV
RAD51C	NM_058216.3	c.338dup	N/A	SNV
RAD51D	NM_002878.4	c.392dup	N/A	SNV
RAD51D	NM_002878.4	c.271A>T	N/A	SNV
RAF1	NM_002880.4	c.770C>T	COSM181063	SNV
RB1	NM_000321.3	c.751C>T	COSM878	SNV
RET	NM_020975.6	c.2753T>C	COSM965	SNV
SLC7A8	NM_012244.4	c.-231_-224delTTTTTTTT	N/A	Deletion
SMARCB1	NM_003073.5	c.118C>T	COSM1002	SNV
STK11	NM_000455.5	c.734+1G>T	COSM51523	SNV
TERT	NM_198253.3	c.-124C>T	N/A	SNV
TERT	NM_198253.3	c.-146C>T	N/A	SNV
TP53	NM_000546.6	c.524G>A	COSM10648	SNV
TP53	NM_000546.6	c.723del	COSM6530	Deletion
TP53	NM_000546.6	c.743G>A	COSM10662	SNV
TP53	NM_000546.6	c.818G>A	COSM10660	SNV
TSC1	NM_000368.5	c.1263+1G>T	COSM1738312	SNV
TSC2	NM_000548.5	c.2640-1G>A	COSM3361675	SNV
VHL	NM_000551.4	c.481C>T	COSM17612	SNV
ZNF2	NM_021088.4	c.*1525_*1530delTTTTTT	N/A	Deletion
CD74::NRG1	Intron 6::Intron 5	NM_001025159.3::NM_013964.5	Translocation	N/A
CD74::ROS1	Intron 6::Intron 34	NM_001025159.3::NM_001378902.1	Translocation	N/A
COL1A1::PDGFB	Intron 25::Intron 1	NM_000088.3::NM_002608.3	Translocation	N/A
EML4::ALK	Intron 13::Intron 19	NM_019063.5::NM_004304.5	Translocation	N/A
ETV6::NTRK3	Intron 5::Intron 14	NM_001987.5::NM_002530.4	Translocation	N/A
FGFR2::BICC1	Intron 17::Intron 2	NM_000141.5::NM_001080512.3	Translocation	N/A
FGFR3::TACC3	Exon 18::Intron 7	NM_000142.5::NM_006342.3	Translocation	N/A
NCOA4::RET	Intron 7::Intron 11	NM_001145263.2::NM_020975.6	Translocation	N/A
PML::NTRK2	Intron 2::Intron 12	NM_002675.4::NM_006180.6	Translocation	N/A
TPM3::NTRK1	Intron 7::Intron 9	NM_153649.4::NM_002529.4	Translocation	N/A

**COSMIC uses transcript ENST00000427383.6*

NOTE: Above list does not include variants present in the GM24385 background. SNV refers to single nucleotide variant; INDEL is defined as insertion/deletion. Genomic coordinates use the 1-based coordinate system.

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