

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® Compromised FFPE Tumor DNA Reference Material		
Material Number:	0710-1492	Batch Number:	10747256
Material Description:	Formalin-fixed paraffin-embedded reference cells (GM24385) carrying synthetic DNA constructs manufactured to more closely mimic the quality of patient tissue		
Date of Manufacture:	07 APR 2025	Expiration Date:	07 APR 2027
Fill Volume:	One 10 µm curl		
Storage:	2 - 8 °C		
Test Method for Yield per Curl:	DNA was extracted using the Qiagen QIAamp DNA FFPE Tissue Kit and quantified using the Qubit dsDNA HS Assay.		
Average DNA yield per curl:	483.9 ng (Range 306.0 ng - 680.0 ng)		
Test Method for Yield per Curl:	DNA was extracted using the Promega Maxwell RSC DNA FFPE Kit and quantified using the Qubit dsDNA HS Assay.		
Average DNA yield per curl:	497.2 ng (Range 273.5 ng - 612.5 ng)		
Test Method for DNA Quality Assessment:	Agilent TapeStation Genomic DNA ScreenTape Analysis		
Average DIN value:	6.0 for QIAamp extracted DNA; 4.9 for Maxwell extracted DNA		
Test Method for Variant Assessment:	200 ng of DNA extracted from FFPE curls using the Qiagen QIAamp DNA FFPE Tissue Kit was used as input for the Illumina TruSight Oncology 500 panel and prepared libraries were sequenced on a NovaSeq 6000. The total read pairs for each sample was >80M and the coverage was >150X.		

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Gene ID	COSMIC Identifier	Amino Acid Change	Variant Allele Frequency (%)
AKT1	COSM33765	p.E17K	20.9
ALK	COSM144250	p.G1202R	17.2
ALK	COSM28055	p.F1174L	16.7
BRAF	COSM476	p.V600E	6.8
BRAF	COSM473	p.V600K	7.5
BRCA1	COSM1383519	p.K654fs*47	16.5
BRCA2	COSM1738242	p.R2645fs*3	11.2
CD74-ROS1	N/A	Translocation	6.4
EGFR	COSM6223	p.E746_A750 del ELREA	11.3
EGFR	COSM6224	p.L858R	22.1
EGFR	COSM6240	p.T790M	16.6
EGFR	COSM6256	p.S752_I759 del SPANKEI	10.2
EGFR	COSM12370	p.L747_P753>S	13.8
EGFR	COSM12378	p.D770_N771insG	12.7
EGFR	COSM6493937	p.C797S	14.0
EML4-ALK	N/A	Translocation	8.8
ERBB2	COSM20959	p.Y772_A775dup	2.3
KIT	COSM1314	p.D816V	18.8
KRAS	COSM516	p.G12C	8.4
KRAS	COSM521	p.G12D	9.0
KRAS	COSM554	p.Q61H	9.6
NCOA4-RET	N/A	Translocation	18.0
NRAS	COSM580	p.Q61K	7.5
NRAS	COSM584	p.Q61R	10.3
PIK3CA	COSM765	p.E545D	12.8
PIK3CA	COSM775	p.H1047R	9.0
TP53	COSM6530	p.C242fs*5	10.9
TP53	COSM10648	p.R175H	5.4
TP53	COSM10660	p.R273H	7.8
TP53	COSM10662	p.R248Q	10.0
TP53	COSM18610	p.S90fs*33	5.2

Gene	Total Copy Number
ERBB2	28.2
MET	10.2
MYC	5.6

NA = not part of the assay; ND = not detected

Note: The MET gene is amplified using two synthetic constructs with a small region of overlap between the constructs (see package insert for genomic coordinates). Assays which target this region of overlap may report higher amplification levels.

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Approval:



Prepared By

30 Apr 2025

Date

