

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:	10724378
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:	05 NOV 2024	Expiration Date:	05 NOV 2026
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:	514.0 ng (Range 240.5 ng - 672.5 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:	487.8 ng (Range 159.0 ng - 847.5 ng)		
Test Method for DNA Quality Assessment:	Agilent TapeStation Genomic DNA ScreenTape Analysis		
Average DIN value:	5.7 for QIAamp extracted DNA; 4.7 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 an 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. Mutations not covered by NGS were tested by digital PCR using BioRad Q200™ Droplet Digital™ PCR System.		

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Gene ID	COSMIC Identifier	Amino Acid Change	Variant Allele Frequency (%)
AKT1	COSM33765	p.E17K	29.6
ALK	COSM144250	p.G1202R	26.8
ALK	COSM28055	p.F1174L	21.1
BRAF	COSM476	p.V600E	9.8
BRAF	COSM473	p.V600K	8.5
BRCA1	COSM1383519	p.K654fs*47	21.6
BRCA2	COSM1738242	p.R2645fs*3	14.9
CD74-ROS1	N/A	Translocation	9.3
EGFR	COSM6223	p.E746_A750 del ELREA	14.7
EGFR	COSM6224	p.L858R	26.5
EGFR	COSM6240	p.T790M	23.9
EGFR	COSM6256	p.S752_I759 del SPANKEI	15.5
EGFR	COSM12370	p.L747_P753>S	17.2
EGFR	COSM12378	p.D770_N771insG	14.0
EGFR	COSM6493937	p.C797S	14.9
EML4-ALK	N/A	Translocation	13.0
ERBB2	COSM20959	p.Y772_A775dup	4.5
KIT	COSM1314	p.D816V	25.4
KRAS	COSM516	p.G12C	12.3
KRAS	COSM521	p.G12D	9.8
KRAS	COSM554	p.Q61H	14.3
NCOA4-RET	N/A	Translocation	17.8
NRAS	COSM580	p.Q61K	10.9
NRAS	COSM584	p.Q61R	16.4
PIK3CA	COSM765	p.E545D	17.5
PIK3CA	COSM775	p.H1047R	14.2
TP53	COSM6530	p.C242fs*5	9.3
TP53	COSM10648	p.R175H	6.7
TP53	COSM10660	p.R273H	7.4
TP53	COSM10662	p.R248Q	9.7
TP53	COSM18610	p.S90fs*33	5.2

Gene	Total Copy Number
ERBB2	14.3
MET	15.1
MYC	9.1

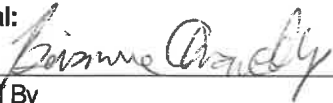
Note: The MET gene is amplified using two synthetic constructs with a small region of overlap between the constructs (see package insert for genomic coordinates). Assays which target this region of overlap may report higher amplification levels.

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Approval:

A handwritten signature in black ink, appearing to read 'Lizanne Brandy'.

Prepared By

12/23/2024

Date