

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:	10499589
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:	12 JUN 2020	Expiration Date:	12 JUN 2022
Fill Volume:	One 10 µm curl		
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:	177 ng (Range 131 ng - 242 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:	384 ng (Range 322 ng - 445 ng)		
Test Method for DNA Quality Assessment:	Agilent TapeStation Genomic DNA ScreenTape Analysis		
Average DIN value:	4.30 for QIAamp extracted DNA; 3.95 for Maxwell extracted DNA		
Storage:	4 - 8 °C		

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Digital PCR using BioRad QX200™ Droplet Digital™ PCR System and/or NGS with the Illumina TruSight Oncology 500 Assay (VCF and method details available upon request)¹:

Gene ID	COSMIC Identifier	Amino Acid Change	QIAamp	Maxwell
AKT1	COSM33765	p.E17K	Detected	Detected
ALK	COSM144250	p.G1202R	Detected	Detected
ALK	COSM28055	p.F1175L	Detected	Detected
BRAF	COSM476	p.V600E	Detected	Detected
BRAF	COSM473	p.V600K	Detected	Detected
BRCA1	COSM1383519	p.K654fs*47	Detected	Detected
BRCA2	COSM1738242	p.R2645fs*3	Detected	Detected
CD74-ROS1	N/A	Translocation	Detected	Detected
EGFR	COSM6223	p.E746_A750 del ELREA	Detected	Detected
EGFR	COSM6224	p.L858R	Detected	Detected
EGFR	COSM6240	p.T790M	Detected	Detected
EGFR	COSM6256	p.S752_I759 del SPANKEI	Detected	Detected
EGFR	COSM12370	p.L747_P753>S	Detected	Detected
EGFR	COSM12378	p.D770_N771insG	Detected	Detected
EGFR	COSM6493937	p.C797S	Detected	Detected
EML4-ALK	N/A	Translocation	Detected	Detected
ERBB2	COSM20959	p.Y772_A775dup	Detected	Detected
ERBB2	N/A	Amplification	Detected	Detected
KIT	COSM1314	p.D816V	Detected	Detected
KRAS	COSM516	p.G12C	Detected	Detected
KRAS	COSM521	p.G12D	Detected	Detected
KRAS	COSM554	p.Q61H	Detected	Detected
MET ²	N/A	Amplification	Detected	Detected
MYC	N/A	Amplification	Detected	Detected
NCOA4-RET	N/A	Translocation	Detected	Detected
NRAS	COSM580	p.Q61K	Detected	Detected
NRAS	COSM584	p.Q61R	Detected	Detected
PIK3CA	COSM765	p.E545D	Detected	Detected
PIK3CA	COSM775	p.H1047R	Detected	Detected
TP53	COSM6530	p.C242fs*5	Detected	Detected
TP53	COSM10648	p.R175H	Detected	Detected
TP53	COSM10660	p.R273H	Detected	Detected
TP53	COSM10662	p.R248Q	Detected	Detected
TP53	COSM18610	p.S90fs*33	Detected	Detected

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¹All variants were detected at an allele frequency above 2%. All amplified genes were detected at above 4 total copies.

²The 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.

Approval:

A handwritten signature in black ink, appearing to be "S. R. D.", written over a horizontal line.

Prepared By

19 Jun 2020

Date