

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® FFPE Lymphoma DNA Reference Material		
Material Number:	0710-2202	Batch Number:	10571804
Material Description:	Formalin-fixed paraffin-embedded reference cells (GM24385) carrying synthetic DNA variants.		
Date of Manufacture:	06 AUG 2021	Expiration Date:	06 AUG 2023
Storage:	2 - 8°C		
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:	193 ng (Range 156 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:	124 ng (Range 111 ng - 131 ng)		
Test Method for DNA Quality Assessment:	Agilent TapeStation Genomic DNA ScreenTape Analysis.		
Average DIN value:	6.1 for QIAamp extracted DNA.		
dPCR Test Method:	Variant and wild-type specific PCR assays run on the BioRad QX-200 digital PCR system using DNA extracted from FFPE curls using the Qiagen QIAamp DNA FFPE Tissue Kit.		
NGS Assay Test Method:	200 ng of FFPE extracted DNA was analyzed in triplicate using a custom ArcherDX VariantPlex panel and Illumina MiSeq™ v2 (2x150 bp) PE chemistry. Default Archer Analysis 6.2.2 settings were used for SNV and indel calls. For translocations, allele frequency was calculated by dividing the number of observations of the translocation by the sum of observations of the translocation and the breakpoints of the two normal genes.		

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Variant	Variant Type	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
NPM1-ALK	Translocation	10.6	4.8
HSP90AA1-BCL6	Translocation	5.8	4.5
CCND1-CDC42BPB	Translocation	10.4	5.4
BIRC3-MALT1	Translocation	10.8	2.9
MYC-IGH	Translocation	8.4	2.0
TBL1XR1-TP63	Translocation	11.1	7.0

Gene	COSMIC ID	Nucleic Acid change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
BCL2	COSM5653732	c.302G>C	p.G101A	7.2	8.3
BRAF	COSM476	c.1799T>A	p.V600E	7.9	12.4
CXCR4	COSM5981986	c.1013C>G	p.S338X	9.2	6.4
CXCR4	COSM5981985	c.1013C>A	p.S338X	10.4	6.4
DNMT3A	COSM52944	c.2645G>A	p.R882H	8.5	10.1
EZH2	COSM85769	c.1922A>T	Y641F	8.1	5.5
IDH2	COSM33733	c.515G>A	p.R172K	9.7	9.0
MYD88	COSM85940	c.794T>C	p.L265P	9.1	9.2
NOTCH1	COSM12774	c.7541_7542del	p.P2514Rfs*4	11.5	13.7
NOTCH2	COSM36210	c.7198C>T	p.R2400*	9.4	9.4
RHOA	COSM78415	c.50G>T	p.G17V	13.3	10.2
SF3B1	COSM133591	c.2098A>G	p.K700E	9.2	10.0
STAT3	COSM1155743	c.1919A>T	p.Y640F	12.9	6.8
STAT3	COSM1155730	c.1982A>T	p.D661V	7.7	6.1
STAT3	COSM1155744	c.1940A>T	p.N647I	9.7	5.5
STAT5B	COSM1716592	c.1994A>T	p.Y665F	8.3	7.5
STAT5B	COSM1716590	c.1924A>C	p.N642H	11.7	6.0
TP53	COSM10662	c.743G>A	p.R248Q	9.9	10.2
TP53	COSM43974	c.820del	p.V274Ffs*71	8.5	8.5
TP53	COSM10660	c.818G>A	p.R273H	11.6	9.0

Approval:



12 AUG 2021

Prepared By

Date