

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:	10683410
Material Description:	Formalin-fixed paraffin-embedded reference cells (GM24385) carrying synthetic DNA variants.		
Date of Manufacture:	15 MAR 2024	Expiration Date:	15 MAR 2026
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:	492 ng (Range 283 ng - 601 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:	278 ng (Range 214 ng - 330 ng)		
Test Method for DNA Quality Assessment:	Agilent TapeStation Genomic DNA ScreenTape Analysis.		
Average DIN value:	6.7 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:	250 ng of FFPE extracted DNA was analyzed in triplicate using custom ArcherDX VariantPlex panel. Default Archer Analsys v7.3.2 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 gene.		

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Variant	Variant Type	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
NPM1-ALK	Translocation	18.3	2.8
HSP90AA1-BCL6	Translocation	19.7	7.5
CCND1-CDC42BPB	Translocation	22.6	4.3
BIRC3-MALT1	Translocation	20.3	7.3
MYC-IGH	Translocation	33.8	5.6
TBL1XR1-TP63	Translocation	25.9	2.9

Gene	COSMIC ID	Nucleic Acid change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
BCL2	COSM5653732	c.302G>C	p.G101A	17.8	16.4
BRAF	COSM476	c.1799T>A	p.V600E	18.7	22.6
CXCR4	COSM5981986	c.1013C>G	p.S338X	19.9	14.7
CXCR4	COSM5981985	c.1013C>A	p.S338X	19.9	15.3
DNMT3A	COSM52944	c.2645G>A	p.R882H	19.5	21.1
EZH2	COSM85769	c.1922A>T	Y641F	18.8	18.9
IDH2	COSM33733	c.515G>A	p.R172K	17.9	19.8
MYD88	COSM85940	c.794T>C	p.L265P	24.0	21.3
NOTCH1	COSM12774	c.7541_7542del	p.P2514Rfs*4	20.3	22.6
NOTCH2	COSM36210	c.7198C>T	p.R2400*	23.9	20.6
RHOA	COSM78415	c.50G>T	p.G17V	23.4	23.7
SF3B1	COSM133591	c.2098A>G	p.K700E	25.1	18.3
STAT3	COSM1155743	c.1919A>T	p.Y640F	21.6	15.7
STAT3	COSM1155730	c.1982A>T	p.D661V	19.9	15.4
STAT3	COSM1155744	c.1940A>T	p.N647I	19.4	13.5
STAT5B	COSM1716592	c.1994A>T	p.Y665F	20.2	18.7
STAT5B	COSM1716590	c.1924A>C	p.N642H	19.3	18.9
TP53	COSM10662	c.743G>A	p.R248Q	13.1	22.5
TP53	COSM43974	c.820del	p.V274Ffs*71	22.5	17.9
TP53	COSM10660	c.818G>A	p.R273H	18.3	18.7

Approval:



Prepared By

20 MAR 2024

Date