



Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description	Seraseq® ctDNA Lymphoma Mix AF1%		
Material Number:	0710-3182	Batch Number:	10688078
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Fill Volume:	25 µL		
Date of Manufacture:	21 DEC 2023	Expiration Date:	21 DEC 2027
Storage:	-20°C		
Concentration	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 12.1 ng/µL		
Average fragment size	193 bp		
(Agilent Bioanalyzer High			
Sensitivity DNA Analysis):			
Acceptance criteria for	150 – 220 bp		
average fragment size:			
ddPCR Test Method:	BioRad QX200™ Droplet Digital™ PCR System		
NGS Assay Test Method:	Next Generation Sequencing testing using ArcherDx LiquidPlex Custom panel for ctDNA Lymphoma Assays sequenced on MiSeq System sequencer. 50 ng of ctDNA mix was used as input. The read depth normalization was set to 100M reads and the variant downstream ROI size was 150. The total read pairs for the sample was 5.0M and average read depth was 7,971. The average on target reads was 19.8%.		



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Structural Variant	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
NPM1-ALK	0.85	0.56
HSP90AA1-BCL6	1.18	0.74
CCND1-CDC42BPB	0.92	0.42
BIRC3-MALT1	0.92	0.53
MYC-IGH	1.17	0.84
TBL1XR1-TP63	0.87	0.51

Gene	Cosmic ID	Nucleic Acid Change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
BCL2	COSM5653732	c.302G>C	p.G101A	0.95	1.28
BRAF	COSM476	c.1799T>A	p.V600E	0.98	1.66
CXCR4	COSM5981986	c.1013C>G	p.S338X	0.90	1.16
CXCR4	COSM5981985	c.1013C>A	p.S338X	0.83	1.00
DNMT3A	COSM52944	c.2645G>A	p.R882H	0.98	1.17
EZH2	COSM85769	c.1922A>T	Y641F	1.05	1.10
IDH2	COSM33733	c.515G>A	p.R172K	1.03	0.84
MYD88	COSM85940	c.794T>C	p.L265P	1.02	1.05
NOTCH1	COSM12774	c.7541_7542del	p.P2514Rfs*4	1.00	1.06
NOTCH2	COSM36210	c.7198C>T	p.R2400*	1.01	1.22
RHOA	COSM78415	c.50G>T	p.G17V	0.91	0.86
SF3B1	COSM133591	c.2098A>G	p.K700E	1.12	1.08
STAT3	COSM1155743	c.1919A>T	p.Y640F	1.10	1.23
STAT3	COSM1155730	c.1982A>T	p.D661V	0.96	1.10
STAT3	COSM1155744	c.1940A>T	p.N647I	0.89	1.27
STAT5B	COSM1716592	c.1994A>T	p.Y665F	0.92	0.91
STAT5B	COSM1716590	c.1924A>C	p.N642H	0.84	0.90
TP53	COSM10662	c.743G>A	p.R248Q	1.24	0.88
TP53	COSM43974	c.820del	p.V274Ffs*71	1.31	1.22
TP53	COSM10660	c.818G>A	p.R273H	1.18	1.27

NA = not applicable; NGS assay does not cover specified variant.

ND = not detected; NGS assay did not reveal specified variant above 0.1%.

Approval:

08 JAN 2024

Prepared By

Date