

Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq ctDNA Myeloid Mix, AF 0.5%		
Material Number:	0710-2648	Batch Number:	10640957
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Storage:	-20°C		
Fill Volume:	25 µL		
Date of Manufacture:	28 SEP 2022	Expiration Date:	28 SEP 2026
Concentration:	Nominal value: 15 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 22.9 ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	193bp		
Acceptance criteria for average size:	150-220 bp		
dPCR Test Method:	BioRad QX200™ Droplet Digital™ PCR System [Next Generation Sequencing testing using custom ArcherDx LiquidPlex panel for ctDNA Myeloid Assays sequenced on NextSeq 2000 using P1 reagent Kit (2X 150bp). 50 ng of ctDNA mix was used as input. The read depth normalization was 100M reads, variant downstream ROI size was 450. The total read pairs for the sample was 11.3 M and average read depth was 8586. The average on target reads was 88.3%.		
NGS Assay Test Method:			

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Gene ID	HGVS	Protein variant	COSMIC ID	AF% dPCR	AF% ¹ NGS
ABL1	c.944C>T	p.T315I	12560	0.63	0.64
ASXL1	c.1900_1922del	p.E635Rfs*15	36165	0.62	0.77
ASXL1	c.1934dup	p.G646Wfs*12	34210	0.65	0.00
BRAF	c.1799T>A	p.V600E	476	0.63	0.83
CALR	c.1099_1150del	p.L367Tfs*46	1738055	0.45	0.42
CBL	c.1139T>C	p.L380P	34055	0.45	0.61
CBL	c.1259G>A	p.R420Q	34077	0.45	0.52
CEBPA	c.68dup	p.H24Afs*84	18922	0.52	0.70
CEBPA	c.937_939dup	p.K313dup	6152	0.52	0.45
CSF3R	c.1853C>T	p.T618I	1737962	0.53	0.77
EZH2	c.1937A>T	p.Y646F	37028	0.66	0.62
FLT3	c.1759_1800dup	p.N587_D600dup	250173	0.64	0.59
FLT3	c.1806_1807insGGGGCTTTCAGAGAA TATGAATATGATCTCAAA	p.K602_W603insGAFR EYEYDLK	NA	0.63	0.62
FLT3	c.2503G>T	p.D835Y	783	0.53	0.43
IDH1	c.394C>T	p.R132C	28747	0.64	0.69
IDH2	c.419G>A	p.R140Q	41590	0.50	0.71
IDH2	c.515G>A	p.R172K	33733	0.64	0.67
JAK2	c.1624_1629del	p.N542_E543del	24440	0.63	0.29
JAK2	c.1849G>T	p.V617F	12600	0.68	0.57
MPL	c.1544G>T	p.W515L	18918	0.65	0.62
MYD88	c.755T>C	p.L252P	85940	0.64	0.59
NPM1	c.860_863dup	p.W288Cfs*12	17559	0.64	0.69
SF3B1	c.1998G>T	p.K666N	131557	0.65	0.30
SF3B1	c.2098A>G	p.K700E	84677	0.65	0.52
SRSF2	c.284_307del	p.P95_R102del	146289	0.57	0.27

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

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

¹NGS was performed as an orthogonal verification step. Some variants were not easily detected due to variant complexity and limitations of the assay.

Approval:

M H A

09 OCT 2024

Prepared By

Date