



Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq ctDNA Myeloid Mix, AF1%		
Material Number:	0710-2649	Batch Number:	10640958
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: 22.9ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	193 bp		
Acceptance criteria for average size:	150-220 bp		
dPCR Test Method:	BioRad QX200™ Droplet Digital™ PCR System		
NGS Assay Test Method:	Next Generation Sequencing testing using custom ArcherDx LiquidPlex panel for ctDNA Myeloid Assays sequenced on NextSeq 2000 using P1 reagent Kit (2X 150bp).		



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Gene ID	HGVS	Protein variant	COSMIC ID	AF% dPCR	AF% ¹ NGS
ABL1	c.944C>T	p.T315I	12560	0.99	1.05
ASXL1	c.1900_1922del	p.E635Rfs*15	36165	1.31	0.85
ASXL1	c.1934dup	p.G646Wfs*12	34210	1.33	0.00
BRAF	c.1799T>A	p.V600E	476	0.89	1.07
CALR	c.1099_1150del	p.L367Tfs*46	1738055	1.09	0.76
CBL	c.1139T>C	p.L380P	34055	1.14	1.26
CBL	c.1259G>A	p.R420Q	34077	1.14	1.04
CEBPA	c.68dup	p.H24Afs*84	18922	1.25	0.91
CEBPA	c.937_939dup	p.K313dup	6152	1.25	0.89
CSF3R	c.1853C>T	p.T618I	1737962	1.17	1.17
EZH2	c.1937A>T	p.Y646F	37028	1.18	1.25
FLT3	c.1759_1800dup	p.N587_D600dup	250173	1.27	1.29
FLT3	c.1806_1807insGGGGCTTTCAGAGAA TATGAATATGATCTCAAA	p.K602_W603insGAFR EYEDLK	NA	1.28	1.39
FLT3	c.2503G>T	p.D835Y	783	1.19	0.96
IDH1	c.394C>T	p.R132C	28747	1.27	1.13
IDH2	c.419G>A	p.R140Q	41590	1.15	0.96
IDH2	c.515G>A	p.R172K	33733	1.23	1.29
JAK2	c.1624_1629del	p.N542_E543del	24440	1.31	0.49
JAK2	c.1849G>T	p.V617F	12600	1.24	1.15
MPL	c.1544G>T	p.W515L	18918	1.25	1.19
MYD88	c.755T>C	p.L252P	85940	1.34	1.13
NPM1	c.860_863dup	p.W288Cfs*12	17559	0.98	1.03
SF3B1	c.1998G>T	p.K666N	131557	1.27	0.82
SF3B1	c.2098A>G	p.K700E	84677	1.27	1.04
SRSF2	c.284_307del	p.P95_R102del	146289	1.24	0.76

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:

23 SEP 2024

Prepared By

Date