

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq ctDNA Myeloid Mix, 0% (WT)		
Material Number:	0710-2646	Batch Number:	10640955
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385.		
Storage:	-20°C		
Fill Volume:	25 µL		
Date of Manufacture:	28 SEP 2022	Expiration Date:	28 SEP 2024
Test Method:	Qubit dsDNA BR Assay		
Concentration Test Method:	Nominal value: 15 ng/µL Average measured value: 23.2 ng/µL		
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).		

Gene ID	HGVS	Protein variant	COSMIC ID	AF% ¹ dPCR	AF% ² NGS
ABL1	c.944C>T	p.T315I	12560	0.00	0.02
ASXL1	c.1900_1922del	p.E635Rfs*15	36165	0.00	0.00
ASXL1	c.1934dup	p.G646Wfs*12	34210	0.00	0.00
BRAF	c.1799T>A	p.V600E	476	0.00	0.05
CALR	c.1099_1150del	p.L367Tfs*46	1738055	0.00	0.00
CBL	c.1139T>C	p.L380P	34055	0.00	0.04
CBL	c.1259G>A	p.R420Q	34077	0.00	0.02
CEBPA	c.68dup	p.H24Afs*84	18922	0.00	0.00
CEBPA	c.937_939dup	p.K313dup	6152	0.00	0.00
CSF3R	c.1853C>T	p.T618I	1737962	0.00	0.00
EZH2	c.1937A>T	p.Y646F	37028	0.00	0.02
FLT3	c.1759_1800dup	p.N587_D600dup	250173	0.00	0.00
FLT3	c.1806_1807insGGGGCTTTCAGA GAATATGAATATGATCTCAAA	p.K602_W603insGAF REYEYDLK	NA	0.00	0.00
FLT3	c.2503G>T	p.D835Y	783	0.00	0.00
IDH1	c.394C>T	p.R132C	28747	0.00	0.04
IDH2	c.419G>A	p.R140Q	41590	0.00	0.05
IDH2	c.515G>A	p.R172K	33733	0.00	0.02
JAK2	c.1624_1629del	p.N542_E543del	24440	0.00	0.00
JAK2	c.1849G>T	p.V617F	12600	0.00	0.00
MPL	c.1544G>T	p.W515L	18918	0.00	0.01
MYD88	c.755T>C	p.L252P	85940	0.00	0.04
NPM1	c.860_863dup	p.W288Cfs*12	17559	0.00	0.00
SF3B1	c.1998G>T	p.K666N	131557	0.00	0.00
SF3B1	c.2098A>G	p.K700E	84677	0.00	0.03
SRSF2	c.284_307del	p.P95_R102del	146289	0.00	0.00

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

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

¹Variant allele frequencies > 0.00% for this wild-type negative control are within the expected range for stochastic positive dPCR reactions.

²NGS was performed as an orthogonal verification step. Some background variants are detected due to the sensitivity of NGS methodology.

NGS Parameters:

DNA input = 50 ng
Archer analysis version = v7.0
Read depth norm = 100 M
Variant downstream ROI size = 450
On Target = 87.0
Total # read pairs = 9.3 M
Average read depth = 9605
Average %AF = 0.01

Approval:

A handwritten signature in black ink that reads 'Catherine Huang'.

19 OCT 2022

Prepared By

Date