

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:	10819443
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:	29 JUL 2026	Expiration Date:	29 JUL 2030
Concentration: (Qubit dsDNA BR Assay):	Nominal value: 15 ng/µL Average measured value: 21 ng/µL		
Main peak size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	212 bp	Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	231 bp
Acceptance criteria for main peak 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). 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 8.2M and average read depth was 10,867. The average on target reads was 87.3%.		

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Gene ID	HGVS	Protein variant	AF% ¹ dPCR	AF% ² NGS
ABL1	c.944C>T	p.T315I	0.00	0.01
ASXL1	c.1900_1922del	p.E635Rfs*15	0.00	0.00
ASXL1	c.1934dup	p.G646Wfs*12	0.00	1.81
BRAF	c.1799T>A	p.V600E	0.00	0.03
CALR	c.1099_1150del	p.L367Tfs*46	0.00	0.00
CBL	c.1139T>C	p.L380P	0.00	0.03
CBL	c.1259G>A	p.R420Q	0.00	0.05
CEBPA	c.68dup	p.H24Afs*84	0.00	0.00
CEBPA	c.937_939dup	p.K313dup	0.00	0.00
CSF3R	c.1853C>T	p.T618I	0.00	0.01
EZH2	c.1937A>T	p.Y646F	0.00	0.00
FLT3	c.1759_1800dup	p.N587_D600dup	0.00	0.00
FLT3	c.1806_1807insGGGGCTTTCAGAGA ATATGAATATGATCTCAAA	p.K602_W603insGAFRE YEYDLK	0.00	0.00
FLT3	c.2503G>T	p.D835Y	0.00	0.00
IDH1	c.394C>T	p.R132C	0.01	0.04
IDH2	c.419G>A	p.R140Q	0.00	0.05
IDH2	c.515G>A	p.R172K	0.00	0.08
JAK2	c.1624_1629del	p.N542_E543del	0.00	0.00
JAK2	c.1849G>T	p.V617F	0.00	0.00
MPL	c.1544G>T	p.W515L	0.00	0.00
MYD88	c.755T>C	p.L252P	0.00	0.01
NPM1	c.860_863dup	p.W288Cfs*12	0.00	0.00
SF3B1	c.1998G>T	p.K666N	0.00	0.01
SF3B1	c.2098A>G	p.K700E	0.00	0.01
SRSF2	c.284_307del	p.P95_R102del	0.01	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.

Approval:



Prepared By

27 Aug 2016

Date