

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

| | | | |
|----------------------------|---|------------------|-------------|
| Product Description: | Seraseq ctDNA Myeloid Mix, AF 0.1% | | |
| Material Number: | 0710-2647 | Batch Number: | 10640956 |
| 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 2024 |
| Test Method: | Qubit dsDNA BR Assay | | |
| Concentration Test Method: | Nominal value: 15 ng/µL Average measured value: 23.6 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% dPCR | AF% NGS |
|---------|---|-------------------------------|-----------|----------|---------|
| ABL1 | c.944C>T | p.T315I | 12560 | 0.13 | 0.16 |
| ASXL1 | c.1900_1922del | p.E635Rfs*15 | 36165 | 0.13 | 0.13 |
| ASXL1 | c.1934dup | p.G646Wfs*12 | 34210 | 0.13 | 0.00 |
| BRAF | c.1799T>A | p.V600E | 476 | 0.08 | 0.02 |
| CALR | c.1099_1150del | p.L367Tfs*46 | 1738055 | 0.13 | 0.00 |
| CBL | c.1139T>C | p.L380P | 34055 | 0.12 | 0.16 |
| CBL | c.1259G>A | p.R420Q | 34077 | 0.12 | 0.10 |
| CEBPA | c.68dup | p.H24Afs*84 | 18922 | 0.12 | 0.28 |
| CEBPA | c.937_939dup | p.K313dup | 6152 | 0.12 | 0.03 |
| CSF3R | c.1853C>T | p.T618I | 1737962 | 0.10 | 0.07 |
| EZH2 | c.1937A>T | p.Y646F | 37028 | 0.13 | 0.34 |
| FLT3 | c.1759_1800dup | p.N587_D600dup | 250173 | 0.13 | 0.00 |
| FLT3 | c.1806_1807insGGGGCTTTCAGA GAATATGAATATGATCTCAAA | p.K602_W603insGAF REYEYDLK | NA | 0.12 | 0.20 |
| FLT3 | c.2503G>T | p.D835Y | 783 | 0.11 | 0.09 |
| IDH1 | c.394C>T | p.R132C | 28747 | 0.12 | 0.08 |
| IDH2 | c.419G>A | p.R140Q | 41590 | 0.10 | 0.17 |
| IDH2 | c.515G>A | p.R172K | 33733 | 0.12 | 0.14 |
| JAK2 | c.1624_1629del | p.N542_E543del | 24440 | 0.12 | 0.08 |
| JAK2 | c.1849G>T | p.V617F | 12600 | 0.14 | 0.16 |
| MPL | c.1544G>T | p.W515L | 18918 | 0.12 | 0.12 |
| MYD88 | c.755T>C | p.L252P | 85940 | 0.14 | 0.09 |
| NPM1 | c.860_863dup | p.W288Cfs*12 | 17559 | 0.13 | 0.07 |
| SF3B1 | c.1998G>T | p.K666N | 131557 | 0.13 | 0.04 |
| SF3B1 | c.2098A>G | p.K700E | 84677 | 0.13 | 0.09 |
| SRSF2 | c.284_307del | p.P95_R102del | 146289 | 0.11 | 0.07 |

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.

NGS Parameters:

DNA input = 50 ng
Archer analysis version = v7.0
Read depth norm = 100 M
Variant downstream ROI size = 450
On Target = 87.7%
Total # read pairs = 10.0 M
Average read depth = 4380
Average %AF = 0.11

Approval:

A handwritten signature in black ink, appearing to be 'DRJ'.

17 OCT 2022

Prepared By

Date