

# Technical Product Report

*For Research Use Only; Not for use in Diagnostic Procedures*

Product Description: Seraseq™ ctDNA Mutation Mix v2 AF0.125%

Material No: 0710-0143

Batch No: 10269364

Material Description: Mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs

Date of Manufacture: 11Jul2017

Expiration Date: 11Jul2018

Concentration (Qubit dsDNA BR Assay): 13.6 ng/μL

Volume: 25 μL

Storage: -20 °C

Digital PCR testing using BioRad  
QX200™ Droplet Digital™ PCR System:

| Gene ID    | COSMIC Identifier | AF%                     |
|------------|-------------------|-------------------------|
| AKT1       | COSM33765         | 0.16                    |
| APC        | COSM13127         | 0.18                    |
| APC        | COSM18561         | 0.11                    |
| ATM        | COSM21924         | 0.16                    |
| BRAF       | COSM476           | 0.14                    |
| CTNNB1     | COSM5664          | 0.17                    |
| EGFR       | COSM6224          | 0.17                    |
| EGFR       | COSM12378         | 0.18                    |
| EGFR       | COSM6225          | 0.12                    |
| EGFR       | COSM6240          | 0.18                    |
| ERBB2      | COSM682/20959     | 0.14                    |
| FGFR3      | COSM715           | 0.12                    |
| FLT3       | COSM783           | 0.13                    |
| FOXL2      | COSM33661         | 0.14                    |
| GNA11      | COSM52969         | 0.15                    |
| GNAQ       | COSM28758         | 0.20                    |
| GNAS       | COSM27887         | 0.20                    |
| IDH1       | COSM28747         | 0.19                    |
| JAK2       | COSM12600         | 0.12                    |
| KIT        | COSM1314          | 0.13                    |
| KRAS       | COSM521           | 0.15                    |
| MPL        | COSM18918         | 0.14                    |
| NCOA4-RET  | N/A               | 0.13                    |
| NPM1       | COSM17559         | 0.10                    |
| NRAS/CSDE1 | COSM584           | 0.21                    |
| PDGFRA     | COSM736           | 0.14                    |
| PDGFRA     | COSM28053         | 0.14                    |
| PIK3CA     | COSM763           | 0.13                    |
| PIK3CA     | COSM12464         | 0.13                    |
| PIK3CA     | COSM775           | 0.17                    |
| PTEN       | COSM4986          | 0.10                    |
| PTEN       | COSM5809          | 0.10                    |
| RET        | COSM965           | 0.14                    |
| SMAD4      | COSM14105         | 0.18                    |
| TP53       | COSM10648         | 0.20                    |
| TP53       | COSM10660         | 0.16                    |
| TP53       | COSM10662         | 0.20                    |
| TP53       | COSM6530          | 0.14                    |
| TP53       | COSM18610         | Not Tested <sup>1</sup> |
| TPR-ALK    | N/A               | 0.13                    |

<sup>1</sup> NGS testing alone is used for QC of variant COSM18610.

Next Generation Sequencing testing  
 using Archer<sup>®</sup> Reveal ctDNA<sup>™</sup> 28 Kit run  
 on an Illumina<sup>®</sup> MiSeq<sup>™</sup>:

| Gene   | COSMIC Identifier | AF% <sup>2</sup> |
|--------|-------------------|------------------|
| AKT1   | COSM33765         | 0.14             |
| BRAF   | COSM476           | 0.25             |
| CTNNB1 | COSM5664          | 0.12             |
| EGFR   | COSM6225          | 0.23             |
| EGFR   | COSM12378         | 0.08             |
| EGFR   | COSM6240          | 0.15             |
| EGFR   | COSM6224          | NMD              |
| ERBB2  | COSM20959         | NMD              |
| IDH1   | COSM28747         | 0.26             |
| KIT    | COSM1314          | 0.10             |
| KRAS   | COSM521           | 0.16             |
| NRAS   | COSM584           | 0.13             |
| PDGFRA | COSM28053         | 0.25             |
| PDGFRA | COSM736           | 0.18             |
| PIK3CA | COSM763           | 0.24             |
| PIK3CA | COSM775           | 0.11             |
| PIK3CA | COSM12464         | NMD              |
| RET    | COSM965           | 0.26             |
| TP53   | COSM10660         | 0.11             |
| TP53   | COSM10662         | 0.17             |
| TP53   | COSM6530          | NMD              |
| TP53   | COSM10648         | 0.28             |
| TP53   | COSM18610         | 0.14             |

<sup>2</sup> NMD = No Mutation Detected. Results presented in this table represent a single QC test run. Variants listed as NMD here were successfully detected in other rounds of QC testing. Stochastic failures are expected for this 0.125% allele frequency tier under the run conditions that were used for QC testing of Seraseq ctDNA Mutation Mix v2.

Approval:



Prepared By

24 Jul 2017

Date