

# Technical Product Report

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

Product Description: Seraseq® ctDNA Mutation Mix v2 AF0.5%

Material Number: 0710-0141      Batch Number: 10480285

Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs

Concentration  
(Qubit dsDNA BR Assay): 14.8 ng/μL

Volume: 25 μL

Date of Manufacture: 11 JUN 2018      Expiration Date: 11 JUN 2021

Storage: -20°C

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

| Gene ID   | COSMIC Identifier      | AF%                     |
|-----------|------------------------|-------------------------|
| AKT1      | COSM33765              | 0.53                    |
| APC       | COSM13127              | 0.50                    |
| APC       | COSM18561              | 0.43                    |
| ATM       | COSM21924              | 0.59                    |
| BRAF      | COSM476                | 0.54                    |
| CTNNB1    | COSM5664               | 0.63                    |
| EGFR      | COSM6224               | 0.63                    |
| EGFR      | COSM12378              | 0.54                    |
| EGFR      | COSM6225               | 0.56                    |
| EGFR      | COSM6240               | 0.54                    |
| ERBB2     | COSM20959              | 0.53                    |
| FGFR3     | COSM715                | 0.62                    |
| FLT3      | COSM783                | 0.51                    |
| FOXL2     | COSM33661              | 0.54                    |
| GNA11     | COSM52969              | 0.69                    |
| GNAQ      | COSM28758              | 0.52                    |
| GNAS      | COSM27887              | 0.58                    |
| IDH1      | COSM28747              | 0.75                    |
| JAK2      | COSM12600              | 0.48                    |
| KIT       | COSM1314               | 0.60                    |
| KRAS      | COSM521                | 0.53                    |
| MPL       | COSM18918              | 0.59                    |
| NCOA4-RET | N/A                    | 0.54                    |
| NPM1      | COSM17559              | 0.38                    |
| NRAS      | COSM584                | 0.54                    |
| PDGFRA    | COSM736                | 0.53                    |
| PDGFRA    | COSM28053              | 0.55                    |
| PIK3CA    | COSM763                | 0.45                    |
| PIK3CA    | COSM12464 <sup>2</sup> | 0.47                    |
| PIK3CA    | COSM775                | 0.60                    |
| PTEN      | COSM4986               | 0.34                    |
| PTEN      | COSM5809               | 0.34                    |
| RET       | COSM965                | 0.55                    |
| SMAD4     | COSM14105              | 0.53                    |
| TP53      | COSM10648              | 0.39                    |
| TP53      | COSM10660              | 0.56                    |
| TP53      | COSM10662              | 0.59                    |
| TP53      | COSM6530               | 0.42                    |
| TP53      | COSM18610              | Not Tested <sup>1</sup> |
| TPR-ALK   | N/A                    | 0.56                    |

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

<sup>2</sup> As of June 2019 this mutation is no longer listed in the COSMIC database

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Product Description: Seraseq® ctDNA Mutation Mix v2 AF0.5%

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents:

| Gene   | COSMIC Identifier      | AF%  |
|--------|------------------------|------|
| AKT1   | COSM33765              | 0.52 |
| BRAF   | COSM476                | 0.74 |
| CTNNB1 | COSM5664               | 0.55 |
| EGFR   | COSM6225               | 0.46 |
| EGFR   | COSM12378              | 0.29 |
| EGFR   | COSM6240               | 0.54 |
| EGFR   | COSM6224               | 0.46 |
| ERBB2  | COSM20959              | 0.28 |
| IDH1   | COSM28747              | 0.64 |
| KIT    | COSM1314               | 0.60 |
| KRAS   | COSM521                | 0.40 |
| NRAS   | COSM584                | 0.76 |
| PDGFRA | COSM28053              | 0.51 |
| PDGFRA | COSM736                | 0.60 |
| PIK3CA | COSM763                | 0.20 |
| PIK3CA | COSM775                | 0.60 |
| PIK3CA | COSM12464 <sup>1</sup> | 0.98 |
| RET    | COSM965                | 0.47 |
| TP53   | COSM10660              | 0.37 |
| TP53   | COSM10662              | 0.49 |
| TP53   | COSM6530               | 0.30 |
| TP53   | COSM10648              | 0.59 |
| TP53   | COSM18610              | 0.60 |

<sup>1</sup> As of June 2019 this mutation was no longer listed in the COSMIC database.

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NGS was performed as an orthogonal verification step. Parameters used:

**NGS Parameters:**

DNA input = 50 ng

# of samples / flow cell = 2

# of total reads / sample = 9.3 M

Average read depth = ~8000X

On-target reads = ~93%

Q30 score = ~89%

Analysis = Archer Analysis Suite v5.1.7

Default analysis settings except for the following:

- ERROR\_CORRECTION is turned to ON (default=OFF; cfDNA pipeline)
- NORMALIZATION\_LEVEL is set to 10000000 (default is 3500000; cfDNA pipeline)
- VARIANT\_DOWNSTREAM\_ROI\_SIZE is set to 150 (default=400; cfDNA pipeline)

Please see the poster from NIST for more information about assay sensitivity:

<https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018>

Approval:

A handwritten signature in black ink, appearing to be "S. B. R.", written over a horizontal line.

03/31/2020

Prepared By

Date