

# Technical Product Report

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

Product Description: Seraseq® ctDNA Mutation Mix v2 AF1%

Material Number: 0710-0140      Batch Number: 10611225

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): 15.1 ng/μL

Volume: 25 μL

Date of Manufacture: 08 MAR 2022      Expiration Date: 08 MAR 2024

Storage: -20°C

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

| Gene ID   | COSMIC Identifier      | AF%                     |
|-----------|------------------------|-------------------------|
| AKT1      | COSM33765              | 1.05                    |
| APC       | COSM13127              | 1.02                    |
| APC       | COSM18561              | 0.87                    |
| ATM       | COSM21924              | 1.26                    |
| BRAF      | COSM476                | 1.05                    |
| CTNNB1    | COSM5664               | 1.33                    |
| EGFR      | COSM6224               | 1.23                    |
| EGFR      | COSM12378              | 1.13                    |
| EGFR      | COSM6225               | 1.16                    |
| EGFR      | COSM6240               | 1.13                    |
| ERBB2     | COSM20959              | 0.98                    |
| FGFR3     | COSM715                | 1.10                    |
| FLT3      | COSM783                | 0.98                    |
| FOXL2     | COSM33661              | 0.96                    |
| GNA11     | COSM52969              | 1.38                    |
| GNAQ      | COSM28758              | 0.98                    |
| GNAS      | COSM27887              | 1.17                    |
| IDH1      | COSM28747              | 1.33                    |
| JAK2      | COSM12600              | 1.00                    |
| KIT       | COSM1314               | 1.11                    |
| KRAS      | COSM521                | 0.98                    |
| MPL       | COSM18918              | 1.09                    |
| NCOA4-RET | N/A                    | 1.07                    |
| NPM1      | COSM17559              | 0.79                    |
| NRAS      | COSM584                | 1.25                    |
| PDGFRA    | COSM736                | 1.13                    |
| PDGFRA    | COSM28053              | 1.14                    |
| PIK3CA    | COSM763                | 0.85                    |
| PIK3CA    | COSM12464 <sup>2</sup> | 0.92                    |
| PIK3CA    | COSM775                | 1.11                    |
| PTEN      | COSM4986               | 1.08                    |
| PTEN      | COSM5809               | 1.08                    |
| RET       | COSM965                | 1.07                    |
| SMAD4     | COSM14105              | 1.00                    |
| TP53      | COSM10648              | 1.14                    |
| TP53      | COSM10660              | 1.05                    |
| TP53      | COSM10662              | 1.06                    |
| TP53      | COSM6530               | 0.94                    |
| TP53      | COSM18610              | Not Tested <sup>1</sup> |
| TPR-ALK   | N/A                    | 0.92                    |

<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 AF1%

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              | 0.92 |
| BRAF   | COSM476                | 0.91 |
| CTNNB1 | COSM5664               | 0.97 |
| EGFR   | COSM6225               | 1.41 |
| EGFR   | COSM12378              | 0.85 |
| EGFR   | COSM6240               | 0.72 |
| EGFR   | COSM6224               | 0.90 |
| ERBB2  | COSM20959              | 0.75 |
| IDH1   | COSM28747              | 1.11 |
| KIT    | COSM1314               | 0.84 |
| KRAS   | COSM521                | 1.44 |
| NRAS   | COSM584                | 1.06 |
| PDGFRA | COSM28053              | 1.24 |
| PDGFRA | COSM736                | 1.05 |
| PIK3CA | COSM763                | 0.68 |
| PIK3CA | COSM775                | 0.94 |
| PIK3CA | COSM12464 <sup>1</sup> | 0.78 |
| RET    | COSM965                | 1.01 |
| TP53   | COSM10660              | 1.06 |
| TP53   | COSM10662              | 0.82 |
| TP53   | COSM6530               | 0.83 |
| TP53   | COSM10648              | 1.25 |
| TP53   | COSM18610              | 1.24 |

<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 = 1

# of total reads / sample = 15.9 M

Average read depth = 9772X

On-target reads = 97.2%

Q30 score = 89.9%

Analysis = Archer Analysis Suite v6.2.2

Default analysis settings except for the following:

- NORMALIZATION\_LEVEL is set to 1000000 (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 "ERJ".

09 MAR 2022

Prepared By

Date