

Seraseq[®] Methylated ctDNA Mutation Mix

Comprehensive reference materials for development, validation and performance monitoring of genomic assays measuring methylation status

INTRODUCTION

CLINICAL

DIAGNOSTICS

The use of ctDNA in the study and treatment of cancer continues to expand. Recent advances have highlighted CpG methylation of cell-free DNA as a biomarker with multiple utilities. Methylation status gives insight to tumor recurrence, epigenetic regulation of gene expression and may also indicate tissue of origin of circulating tumor DNA (ctDNA).

Despite the impactful information methylation status adds to base-pair level sequencing data and the proliferation of assays to incorporate methylation data, commercial reference materials for methylated ctDNA have been limited.

FEATURES

- Global methylation of CpG sites to support all CpG methylation assays
- Methylated ctDNA and unmethylated ctDNA to blend to a desired percent methylated ctDNA
- Enzymatically fragmented ctDNA for low background noise and physiologically relevant fragment sizes
- Methylation status precisely quantified using highly sensitive digital PCR assays in a well-characterized genomic background (GM24385)
- Validated by targeted NGS panels
- Manufactured in GMP-compliant, ISO 13485-certified facilities

| Gene | Percent Methylation- Unmethylated | Percent Methylation- Methylated | | |
|-------|--------------------------------------|------------------------------------|--|--|
| CCND2 | 0.44 | 100 | | |
| EGFR | 0.74 | 99 | | |
| ETV6 | 0.63 | 114 | | |
| FANCA | 0.78 | 95 | | |
| МҮВ | 1.1 | 103 | | |
| RET | 0.90 | 104 | | |
| TFRC | 0.70 | 90 | | |

Table 1 Percent methylation observed at specific SNPs in the genes indicated above for a representative batch of materials in both the unmethylated and methylated products.



Multiplexed format; patient-like sample performance

Quantitated with digital PCR and validated with NGS; assures accurate and consistent detection of clinically relevant mutations

High-quality manufactured reference material



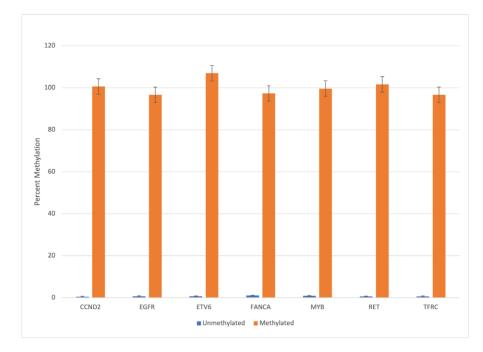


Figure 1 Percent methylation observed across three representative batches of methylated and unmethylated product at the 7 indicated SNPs.

ORDERING INFORMATION

| Product | Format | Catalog Number | Percent Methylated | Conc. | Fill Volume | Total Mass |
|--|---------------------------|-------------------|-----------------------|----------|-------------|---------------|
| Seraseq Unmethylated ctDNA Mutation Mix | Purified DNA in buffer | 0710-3088 | <2% | 10 ng/µL | 25 μL | 250 ng |
| Seraseq Methylated ctDNA Mutation Mix | Purified DNA in buffer | 0710-3089 | >90% | 10 ng/µL | 25 μL | 250 ng |

To place an order, please contact us at **+1.508.244.6400** and **800.676.1881** or email **CDx-CustomerService@lgcgroup.com** For all liquid biopsy reference material, visit **https://www.seracare.com/liquid-biopsy**

ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit seracare.com.**



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