

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® gDNA HRD High-Positive Mix

Material Number: 0710-2879 Batch Number: 10671372

Material Description: Reference standard made from a human breast cancer cell line and its matched "normal" cell line generated from peripheral blood of the same patient. Genomic DNA was extracted, purified, and characterized for HRD status. Biosynthetic variants from key Homologous Recombination Repair (HRR) genes were added to this tumor mix.

Date of Manufacture: 07 JUL 2023 Expiration Date: 07 JUL 2027

Fill Volume: 20 µL

Concentration Test Method: Qubit dsDNA BR Assay

Nominal Concentration: 25 ng/ µL

Measured Concentration: Seraseq gDNA HRD High-Positive Tumor Mix: 32.3 ng/ µL
Seraseq gDNA HRD High-Positive Normal Mix: 30.9 ng/ µL

dPCR Test Method: Allele frequencies of the added biosynthetic variants were measured by construct-specific digital PCR assays run on the Bio-Rad QX-200™ Droplet Digital™ PCR System.

HRD Test Method: 200 ng of gDNA (a blend of 180 ng of tumor and 20 ng of matched normal) was analyzed with the Illumina TruSight™ Oncology 500 HRD RUO Assay (version ruo-ica-2.1.1.5), which calculates a GIS using an algorithm licensed from Myriad Genetics, and sequenced using a NovaSeq6000. Measured allele frequencies of biosynthetic variants appeared lower due to the dilution with matched normal gDNA.

Measured GIScore: 72

| Gene | Nucleic Acid change | Amino Acid Change | % Allele Frequency (dPCR) | % Allele Frequency (NGS) |
|--------|---------------------|-------------------|---------------------------|--------------------------|
| ATM | c.208A>T | p.K70* | 59.47 | 20.35 |
| ATM | c.557delT | p.L186fs | 57.27 | 22.58 |
| BRIP1 | c.107T>G | p.L36* | 59.90 | 34.08 |
| BRIP1 | c.157dup | p.S53Kfs*16 | 59.90 | 30.74 |
| RAD51C | c.242C>A | p.S81* | 63.80 | 29.62 |
| RAD51C | c.338dup | p.G114Wfs*25 | 63.80 | 29.94 |
| RAD51D | c.271A>T | p.K91* | 60.30 | 31.04 |
| RAD51D | c.392dup | p.N131Kfs*23 | 60.30 | 29.37 |

Approval:



09 AUG 2023

Prepared By

Date