

Seraseq[®] gDNA HRD Mutation Mixes

Comprehensive reference materials for development, validation and clinical application of targeted NGS assays evaluating genomic instability resulting from HRD

INTRODUCTION

Genomic instability resulting from homologous recombination DNA repair deficiency (HRD) is a response biomarker to assess ovarian and breast cancer patient eligibility for PARP inhibitor and platinum-based therapies. HRD measurements have the potential to improve cancer therapy, however standardizing and democratizing HRD measurements remains challenging due to their inherent complexity.

SeraCare has developed contrived cell line-derived HRD reference materials to support the development, validation, and routine use of assays determining HRD status in cancer patients.

FEATURES

- Derived from tumor and matched-normal human cell lines
- Allows blending to desired % tumor content with included SNP-matched normal cell line gDNA
- 20 µL of both tumor and matched normal gDNA at 25 ng/µL
- Additional biosynthetic single-nucleotide variants (SNVs) of 4 homologous recombination repair (HRR) genes
- HRD status validated by targeted Next Generation Sequencing (NGS)
- Manufactured in GMP-compliant, ISO 13485-certified facilities

HIGHLIGHTS

Reference material validated by NGS HRD assays

Derived from tumor and matched-normal human cell lines

High-quality manufactured reference material in mutation mix format

Product	GIS*
Seraseq HRD gDNA High-Positive Mix +	72
Seraseq HRD gDNA Low-Positive Mix	58
Seraseq HRD gDNA Negative Mix +	33

+ Includes HRR gene variants at VAF 10-50%

See the Package Insert for more details.

*200 ng of gDNA (a blend of 180 ng tumor and 20 ng of matched normal) was assigned a Genomic Instability Score (GIS) using Illumina TruSight™ Oncology (TSO) 500 HRD RUO assay which calculates a GIS using an algorithm licensed from Myriad Genetics. Batch-specific GIS score information is provided on the Technical Product Report, this product sheet reflects representative measured values

BIOSYNTHETIC VARIANTS PRESENT IN SERASEQ HRD gDNA HIGH-POSITIVE MIX AND SERASEQ HRD gDNA NEGATIVE MIX

#	Gene ID	HGVS	Protein Variant
1	ATM	c.208A>T	p.K70*
2	ATM	c.557del	p.L186fs
3	BRIP1	c.107T>G	p.L36*
4	BRIP1	c.157dup	p.S53Kfs*16
5	RAD51C	c.242C>A	p.S81*
6	RAD51C	c.338dup	p.G114Wfs*25
7	RAD51D	c.271A>T	p.K91*
8	RAD51D	c.392dup	p.N131Kfs*23

See the Technical Spreadsheet for more details.

ORDERING INFORMATION

Product	Material #	Concentration	Fill	Mass
Seraseq® HRD gDNA High-Positive Mix	0710-2879	25 ng/μL	20 μL	500 ng DNA*
Seraseq® HRD gDNA Low-Positive Mix	0710-2880			
Seraseq® HRD gDNA Negative Mix	0710-2881			

*Values are for each vial, note each kit contains one tumor and one matched normal vial of DNA. See the Technical Product Report for more details.

To place an order, please contact us at **+1.508.244.6400** and **800.676.1881** or email **CDx-CustomerService@lgcgroup.com**

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.**