

## PRODUCT SHEET

# Seraseq® FFPE HRD Reference Materials

**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 assessment has the potential to improve cancer therapy, however standardizing and democratizing HRD measurements remains challenging.

LGC SeraCare has developed HRD reference materials to support the development, validation, and routine determination of HRD status in cancer patients.

## FEATURES

- Derived from tumor and matched-normal human cell lines
- Blended to ~65% tumor content with SNP-matched normal cell lines
- Additional biosynthetic single-nucleotide variants (SNVs) of 4 homologous recombination repair (HRR) genes
- 10 µm FFPE curl with DNA yield >100 ng per curl
- Full-process FFPE format reference material validated by NGS and microarray assays with various HRD algorithms<sup>§</sup>
- Manufactured in GMP-compliant, ISO 13485-certified facilities

## HIGHLIGHTS

Validated by NGS and Microarray assays with various HRD algorithms

Derived from tumor and matched-normal human cell lines; in FFPE format

High-quality manufactured reference material

Product	GIS <sup>‡</sup>
Seraseq® FFPE HRD High-Positive RM <sup>†</sup>	72 ± 3
Seraseq® FFPE HRD Low-Positive RM	54 ± 2
Seraseq® FFPE HRD Negative RM <sup>†</sup>	31 ± 2

<sup>§</sup>See the Data Sheet for more details. <sup>†</sup>Includes HRR gene variants at VAF 10–50%. <sup>‡</sup> Genomic Instability Score (GIS) calculated using Illumina TruSight™ Oncology (TSO) 500 HRD RUO assay which calculates a GIS using an algorithm licensed from Myriad Genetics. Illumina TSO 500 HRD is not available in the U.S. or Japan.

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

Biosynthetic SNVs present in Seraseq® FFPE HRD High-Positive RM and Seraseq® FFPE HRD Negative RM. See the Technical Spreadsheet for more details.

## ORDERING INFORMATION

Product	Material	Conc.	Fill	Yield
Seraseq® FFPE HRD High-Positive RM	0710-2643	1 FFPE curl/vial	10 µm curl	>100 ng DNA*
Seraseq® FFPE HRD Low-Positive RM	0710-2645			
Seraseq® FFPE HRD Negative RM	0710-2644			

\*Based on Qiagen QIAamp DNA FFPE Tissue Kit and the Qubit dsDNA HS Assay. See the Technical Product Report for more details.

Beratung und Vertrieb in Deutschland und Österreich:



**HiSS Diagnostics GmbH**  
Tullastr. 70  
79108 Freiburg  
Germany

Telefon: +49 761 389 49 0  
Fax: +49 761 389 49 20  
Email: [hiss@hiss-dx.de](mailto:hiss@hiss-dx.de)  
Web: [www.hiss-dx.de](http://www.hiss-dx.de)

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.  
Seraseq® is a registered trademark of LGC Clinical Diagnostics, Inc.  
© 2022 LGC Clinical Diagnostics, Inc. All rights reserved. MKT-00835-01