Seraseq®
gDNA HRD (High-Positive, Low-Positive, Negative) Mixes

Package Insert

PLEASE NOTE:
THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE
Seraseq® gDNA HRD High-Positive, Low-Positive and Negative Mix products are reference materials formulated for use with targeted Next Generation Sequencing (NGS) assays that detect somatic mutations in human cancer patient samples. These products are intended as reference materials for measuring homologous recombination deficiency (HRD) status via genomic instability in cancer patient samples analyzed by NGS assays under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS
Table 1. Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mixes. Each Material No. is available as an individual product. Information in this Package Insert applies to all three products.

Material No.	Product
0710-2879	Seraseq® gDNA HRD High-Positive Mix
0710-2880	Seraseq® gDNA HRD Low-Positive Mix
0710-2881	Seraseq® gDNA HRD Negative Mix

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products as though they are capable of transmitting infectious agents.

Safety Precautions
Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens[1]. Do not pipette by mouth; do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions
Do not use Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products beyond expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS
Store Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products at -20°C.

PROCEDURE
Materials Provided
Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products consist of genomic DNA purified from tumor and SNP-matched normal human cancer cell lines. Biosynthetic variants in key Homologous Recombination Repair (HRR) genes are added to the High-Positive and Negative reference materials (Table 2). The DNA is in 1 mM Tris, 0.1 mM EDTA pH 8.0. Each kit contains 2 vials, containing 1 tumor gDNA vial and 1 SNP-matched normal gDNA (WT) vial, with 20 µL provided per vial at a concentration of 25 ng/µL.

Instructions for Use
Allow the product vial to come to room temperature before use. Refer to your assay procedures to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS
Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products are measured for Genomic Instability Score (GIS) using an NGS based HRD method. Batch specific values for GIS can be found in batch specific Technical Product Report. Detection of somatic mutations may differ across whole genome sequencing (WGS) or different NGS panels, and concomitantly GIS determined by WGS or targeted NGS panels for Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products may differ. Each laboratory must establish an expected GIS for each Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix product. When results for the product are outside of the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error include deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, or changes in bioinformatics pipeline parameters. Additional support documents (VCFs of filtered mutations from analysis pipeline) are available by contacting us at CDx-info@lgcgroup.com. Additional support documents are available online at www.seracare.com/oncology.

LIMITATIONS OF THE PROCEDURE
Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. These products are offered for Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC Clinical Diagnostics SeraCare does not claim that others can duplicate test results exactly. Note that based on your particular assay protocol and regions interrogated, variants other than the 8 annotated in these products may be detected at varying allele frequencies. Seraseq gDNA HRD High-Positive, Low-Positive and Negative Mix products are not calibrators and should not be used for assay calibration. These materials are not whole-process controls and do not evaluate the methods used for specimen extraction. Adverse shipping and/or storage conditions or use of outdated product may produce erroneous results.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

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Table 2. Biosynthetic variants[+] present in Seraseq® gDNA HRD High-Positive Mix and Seraseq® gDNA HRD Negative Mix

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

[+] For additional variant information, refer to the Technical Spreadsheet (document number MKT-00820). Seraseq® gDNA HRD Low-Positive Mix does not contain the biosynthetic variants in Table 2.

NOTE: Above list does not include variants present in the respective cell line background of each reference material.