Seraseq®

FFPE HRD (High-Positive, Low-Positive, Negative) Reference Material

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® FFPE HRD High-Positive, Low-Positive and Negative Reference Material (RM) products are full-process 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 FFPE HRD High-Positive, Low-Positive and Negative RM. Each Material No. is available as an individual product. Information in this Package Insert applies to all three products.

Material No.	Product
0710-2643	Seraseq® FFPE HRD High-Positive RM
0710-2645	Seraseq® FFPE HRD Low-Positive RM
0710-2644	Seraseq® FFPE HRD Negative RM

For each item, 1 vial x 10 µm FFPE curl.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM 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 FFPE HRD High-Positive, Low-Positive and Negative RM products beyond expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM products at 2-8 °C.

PROCEDURE

Materials Provided

Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM products are derived from human cancer cell lines and match normal cell lines blended at ~65% tumor content. Biosynthetic variants in key Homologous Recombination Repair (HRR) genes are added to the High-Positive and Negative reference materials (Table 2). The cells from human cell lines are formalin treated and embedded in paraffin to create an FFPE block, which is then sectioned into 10 µm curls. One 10 µm FFPE curl is provided per vial, and each kit includes 1 vial.

Materials Required but not Provided

Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM products require extraction. Refer to instructions supplied by manufacturers of the extraction kit to be used.

Instructions for Use

Allow the product vial to come to room temperature before use. Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM products must go through an extraction process. Refer to your assay procedures to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM products are compatible with commercially available nucleic acid extraction methods commonly used for FFPE specimens. The product is designed to give a minimum yield of 100 ng per curl when extracted with the QIAamp DNA FFPE Tissue Kit and measured with the Qubit dsDNA HS Assay.

Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM products are measured for Genomic Instability Score (GIS) using an NGS based HRD method. DNA Integrity Number (DIN) is calculated from DNA extracted using the QIAamp DNA FFPE Tissue Kit and assessed using the Agilent gDNA ScreenTape Assay. Batch specific values for GIS and DIN 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 FFPE HRD High-Positive, Low-Positive and Negative RM products may differ. Each laboratory must establish an expected GIS for each Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM 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.

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LIMITATIONS OF THE PROCEDURE

Seraseq FFPE HRD High-Positive, Low-Positive and Negative RM 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 FFPE HRD High-Positive, Low-Positive and Negative RM 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.

Table 2. Biosynthetic variants⁺ present in Seraseq® FFPE HRD High-Positive RM and Seraseq® FFPE HRD Negative RM

#	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® FFPE HRD Low-Positive RM 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.

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