

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® FFPE HRD Negative Reference Material

Material Number: 0710-2644 Batch Number: 10683417

Material Description: Mixture of human breast cancer cells and matched normal B lymphoblast cells carrying synthetic DNA variants (mixed at 65% tumor) fixed with 10% formalin and embedded in paraffin.

Storage: 2 - 8 °C

Fill Volume: One 10 µm curl

Date of Manufacture: 10 OCT 2023 Expiration Date: 10 OCT 2025

Test Method for Yield per Curl: DNA was extracted using the Qiagen QIAamp DNA FFPE Tissue Kit and quantified using the Qubit dsDNA HS Assay.

Average DNA yield per curl: 504.6 ng

Test Method for DNA Quality Assessment: Agilent TapeStation Genomic DNA ScreenTape Analysis

Average DIN value: 5.6 for QIAamp extracted DNA

dPCR Test Method: Variant and wild-type specific PCR assays run on the BioRad QX-200 digital PCR system using DNA extract from FFPE curls using the Qiagen QIAamp DNA FFPE Tissue Kit.

HRD Test Method: Illumina TruSight™ Oncology 500 HRD RUO Assay which calculates a GIS using an algorithm licensed from Myriad Genetics

Measured GIScore: 31 ± 2

Gene	Nucleic Acid change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
ATM	c.208A>T	p.K70*	5.9	7.3
ATM	c.557delT	p.L186fs	7.8	9.0
BRIP1	c.107T>G	p.L36*	7.1	ND
BRIP1	c.157dup	p.S53Kfs*16	7.1	ND
RAD51C	c.242C>A	p.S81*	7.1	2.6
RAD51C	c.338dup	p.G114Wfs*25	7.1	2.2
RAD51D	c.271A>T	p.K91*	8.1	3.2
RAD51D	c.392dup	p.N131Kfs*23	8.1	4.9

ND = not detected; BRIP1 is amplified to ~60 total copies, diluting the variant to a very low allele frequency.

Approval:

A handwritten signature in black ink, appearing to be 'H. S. S. S.' or similar, written over a horizontal line.

Prepared By

13 DEC 2023

Date