

Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® FFPE HRD High-Positive Reference Material

Material Number: 0710-2643 Batch Number: 10743938

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.

Date of Manufacture: 12 MAR 2025 Expiration Date: 12 MAR 2029

Storage: 2 - 8°C

Fill Volume: One 10 µm curl

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: 331 ng

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

Average DIN value: 5.2 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 extracted from FFPE curls using the Qiagen QIAamp DNA FFPE Tissue Kit.

HRD Test Method: Illumina TruSight™ Oncology 500 HRD RUO Assay

Measured GIScore: 76

Gene	Nucleic Acid change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
ATM	c.208A>T	p.K70*	12.0	9.5
ATM	c.557delT	p.L186fs	13.5	11.3
BRIP1	c.107T>G	p.L36*	15.3	7.0
BRIP1	c.157dup	p.S53Kfs*16	15.3	8.0
RAD51C	c.242C>A	p.S81*	14.8	6.9
RAD51C	c.338dup	p.G114Wfs*25	14.8	7.7
RAD51D	c.271A>T	p.K91*	12.4	9.1
RAD51D	c.392dup	p.N131Kfs*23	12.4	10.5

Approval:

Brianne O'Leary
Prepared By

15 OCT 2025
Date