

Technical Product Report - REVISED

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: 10641623

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: 28 OCT 2022 Expiration Date: 28 OCT 2026

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: 164.8 ng

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

Average DIN value: 4.2 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 which calculates a GIS using an algorithm licensed from Myriad Genetics.

Measured GIScore: 72 ± 3

Gene	Nucleic Acid change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
ATM	c.208A>T	p.K70*	35.2	15.7
ATM	c.557delT	p.L186fs	43.7	18.4
BRIP1	c.107T>G	p.L36*	42.8	9.6
BRIP1	c.157dup	p.S53Kfs*16	42.8	11.1
RAD51C	c.242C>A	p.S81*	39.3	11.8
RAD51C	c.338dup	p.G114Wfs*25	39.3	15.3
RAD51D	c.271A>T	p.K91*	42.8	19.7
RAD51D	c.392dup	p.N131Kfs*23	42.8	22.2

Approval:


Prepared By

9.3.2024
Date