

Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® FFPE BRCA1/2 LGR Reference Material		
Material Number:	0730-0564	Batch Number:	10641898
Material Description:	Formalin-fixed Paraffin Embedded (FFPE) reference cells carrying synthetic DNA variants, including small and large INDELs as well as large genomic re-arrangements (LGRs) in BRCA1 and BRCA2 genes.		
Date of Manufacture:	25 OCT 2022	Expiration Date:	25 OCT 2025
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:	188.1 ng		
Test Method for DNA Quality Assessment:	Agilent TapeStation Genomic DNA ScreenTape Analysis		
Average DIN value:	4.2		
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.		
NGS Assay Test Method:	20ng DNA was used to prepare NGS libraries using CleanPlex® BRCA1 & BRCA2 Kit v3 from Paragon Genomics. Variant Allelic frequencies were determined by searching sequence reads for 18-20 bp sequences specific to the expected mutations and their corresponding normal sequences.		

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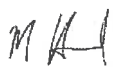
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Gene	Nucleic Acid change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
BRCA1	c.1961del	p.K654Sfs*47	22.9	9.6
BRCA1	c.2071_2171del	p.R691_P724delins*	22.9	3.5
BRCA1	c.2820_2830delinsAAGATAAGCCAGTTTGATAA	p.D940_C944delinsER*	22.9	4.9
BRCA1	c.4186_4357dup	p.R1397Yfs*2	20.7	9.9
BRCA1	c.4327C>T	p.R1443*	20.7	9.0
BRCA1	c.441+2T>G	Splice variant	21.9	3.2
BRCA1	c.4487_4675+2del	Splice variant	21.6	3.7
BRCA1	c.4987_5074del	p.V1665Sfs*8	21.9	ND
BRCA1	c.5209_5248delinsTC	p.R1737Sfs*81	21.0	1.3
BRCA1	c.5279_5332del	p.I1760_D1778delinsN	22.1	ND
BRCA2	c.2407dup	p.Y803Lfs*2	12.0	5.2
BRCA2	c.2886_3144del	p.H962Qfs*6	12.0	ND
BRCA2	c.5150_5226delinsTACTTAATACTTATTAAGTATTA	p.E1717_N1742delinsVLNTY*	12.0	6.2
BRCA2	c.5436del	p.E1812Dfs*3	12.0	5.6
BRCA2	c.68_316del	p.D23_L105del	12.2	ND
BRCA2	c.8167G>C	p.D2723H	12.8	5.3
BRCA2	c.8331+2T>A	Splice variant	12.8	4.5
BRCA2	c.8755-2_9023del	Splice variant	11.7	5.4
BRCA2	c.891_899delinsGATACTTCAG	p.T298Ifs*7	13.8	6.3
BRCA2	c.910G>T	p.E304*	13.8	0.1

ND – Not detected. BRCA 1 c.5279_5332del, BRCA2 c.68_316del and BRCA2 c.2886_3144del mutations were detected in some chimeric amplicon reads

Approval:



23 SEP 2024

Prepared By

Date