Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® Endometrial Cancer DNA Mix		
Material Number:	0710-4125	Batch Number:	10807784
Material Description:	A genomic DNA mutation mix, containing deletions, insertions, duplications, and single nucleotide variants relevant to endometrial cancer, blended with GM24385 DNA as a reference wild-type background		
Fill Volume:	20 µL		
Date of Manufacture:	04 MAR 2026	Expiration Date:	04 MAR 2030
Storage:	-20 °C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 15 ng/µL Average measured value: 16.1 ng/µL		
Digital PCR Method:	Bio-Rad QX200 Droplet Digital™ System		
Digital PCR release criteria:	8.00 – 12.00% for variant allele frequency (VAF) and 5.00 – 6.50 total copies for copy number variants Note: At least 95% of the variants will be within the digital PCR release criteria		
NGS Method:	Next Generation Sequencing testing using Archer™ VARIANTPlex™ Complete Solid Tumor panel with 250 ng of DNA input. Sequencing generated approximately 7.2 million read pairs, achieving an average read depth of 519 and 96.9% on-target reads. Data were produced on a NextSeq 2000 instrument with 88.1% of bases at Q30 or higher. Analysis was performed using Archer Analysis version 7.4.5.		
NGS release criteria:	The DNA is made into a library that is successfully sequenced.		

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Gene	Nucleotide Change	Protein Change	dPCR VAF%	¹NGS VAF%
POLE	c.857C>G	p.P286R	9.51	10.32
POLE	c.1231G>C	p.V411L	9.52	6.51
POLE	c.890C>T	p.S297F	8.60	9.66
POLE	c.1366G>C	p.A456P	9.14	5.13
POLE	c.1376C>T	p.S459F	10.37	6.16
POLE	c.1100T>C	p.F367S	9.51	5.60
POLE	c.1270C>A	p.L424I	9.14	9.45
POLE	c.884T>G	p.M295R	9.69	10.17
POLE	c.1102G>T	p.D368Y	9.69	6.59
POLE	c.1307C>G	p.P436R	10.37	8.15
POLE	c.1331T>A	p.M444K	9.52	7.05
MSH2	c.942+20_942+29delAAAAAAAAAA	MSI BAT-26	11.48	ND
MLH1	c.1852_1854del	p.K618del	11.00	10.74
MSH2	c.942+3A>T	splice site	10.71	ND
MSH6	c.3261dup	p.(F1088Lfs*5)	11.52	8.58
PMS2	c.861_864del	p.R287Sfs*19	10.13	21.13
TP53	c.743G > A	p.R248Q	9.87	9.98
TP53	c.524G>A	p.R175H	10.07	10.06
TP53	c.818G>A	p.R273H	9.87	3.96
TP53	c.723del	p.C242Afs*5	9.87	10.15
PTEN	c.389G>A	p.R130Q	9.26	6.48
PIK3CA	c.3140A>G	p.H1047R	9.99	10.17
PIK3CA	c.3203dup	p.N1068Kfs*5	9.99	9.78
KRAS	c.35G>A	p.G12D	11.57	8.78
CTNNB1	c.98C>T	p.S33F	9.23	8.67
CTNNB1	c.121A>G	p.T41A	8.61	7.45
AKT1	c.49G>A	p.E17K	11.29	7.34
POLD	c.1433G>A	S478N	9.70	10.49
ARID1A	c.5548del	p.D1850Tfs*33	11.55	12.80
FBXW7	c.1513C>T	R505C	9.15	10.24
PPP2R1A	c.536C>G	p.P179R	10.17	8.14

VAF = Variant Allele Frequency. ND = Not detected; further investigation revealed alignment challenges using Archer™ VARIANTPlex Assay.¹NGS was performed as an orthogonal verification step.

CNV	dPCR Total Copies	NGS Total Copies
ERBB2	5.26	6.28

Approval:

Sanchita Jaminden

Prepared By

03 MAR 2026

Date