

# Revised Technical Product Report

*For Research Use Only; Not for use in Diagnostic Procedures*

Product Description:	SeraSeq <sup>®</sup> ctDNA ESR1 Mutation Mix AF1%		
Material Number:	0710-3565	Batch Number:	10714292
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Fill Volume:	25 µL		
Date of Manufacture:	05 AUG 2024	Expiration Date:	05 AUG 2028
Storage:	-20°C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 13.6 ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	218 bp		
Acceptance criteria for average fragment size:	150 – 220 bp		
ddPCR Test Method:	BioRad QX200 <sup>™</sup> Droplet Digital <sup>™</sup> PCR System		
NGS Assay Test Method:	Next Generation Sequencing testing using ArcherDx LiquidPlex Universal Solid Tumor panel sequenced on a NextSeq 2000. 50 ng of ctDNA mix was used as input. The read depth normalization was 100M reads, variant downstream ROI size was 150. The total read pairs for the sample was 13M and average read depth was 9,963. The average on target reads was 96.1%.		

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Gene	Cosmic ID	Nucleic Acid Change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
ESR1	COSM3829320	c.1138G>C	E380Q	1.06	1.11
	COSM4771561	c.1387T>C	S463P	1.21	1.09
	COSM5666097	c.1603C>A	P535T	1.01	1.05
	COSM6978595	c.1607_1608delinsAT	L536H	1.08	1.04
	COSM6843697	c.1607T>A	L536H	1.07	2.91
	COSM6906109	c.1607T>C	L536P	1.07	1.11
	COSM4774826	c.1607T>G	L536R	1.02	1.05
	COSM4766050	c.1607_1608delinsAG	L536Q	1.01	0.91
	COSM6971270	c.1610_1611delinsCA	Y537S	1.06	1.00
	COSM6948665	c.1609_1610delinsAG	Y537S	1.01	1.04
	COSM1074639	c.1610A>C	Y537S	1.05	1.94
	COSM1074635	c.1609T>A	Y537N	1.13	3.09
	N/A	c.1608_1609delinsTA	Y537N	1.13	1.13
	COSM1074637	c.1610A>G	Y537C	1.08	2.16
	COSM6918757	c.1609T>G	Y537D	0.98	1.06
	COSM94250	c.1613A>G	D538G	1.05	1.00
	COSM6948664	c.1610_1615dupATGACC	D538_L539insHD	1.06	0.91
	COSM6918537	c.1625A>G	E542G	1.09	1.13
PIK3CA	COSM760	c.1624G>A	E542K	0.85	1.19
	COSM763	c.1633G>A	E545K	1.02	1.00
	COSM775	c.3140A>G	H1047R	0.97	0.92
	COSM249879	c.3203dupA	N1068Kfs*5	0.97	0.94

Approval:



03 OCT 2024

Prepared By

Date