Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description	Seraseq® ctDNA ESR1 Mix WT		
Material Number:	0710-3564	Batch Number:	10714291
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385		
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: 13.0 ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	194 bp		
Acceptance criteria for average fragment size:	150 – 220 bp		
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 7,264. The average on target reads was 96.1%.		

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Gene	Cosmic ID	Nucleic Acid Change	Amino Acid Change	% Allele Frequency (NGS)
ESR1	COSM3829320	c.1138G>C	E380Q	0.00
	COSM4771561	c.1387T>C	S463P	0.04
	COSM5666097	c.1603C>A	P535T	0.00
	COSM6978595	c.1607_1608delinsAT	L536H	0.00
	COSM6843697	c.1607T>A	L536H	0.01
	COSM6906109	c.1607T>C	L536P	0.04
	COSM4774826	c.1607T>G	L536R	0.00
	COSM4766050	c.1607_1608delinsAG	L536Q	0.00
	COSM6971270	c.1610_1611delinsCA	Y537S	0.00
	COSM6948665	c.1609_1610delinsAG	Y537S	0.00
	COSM1074639	c.1610A>C	Y537S	0.00
	COSM1074635	c.1609T>A	Y537N	0.00
	N/A	c.1608_1609delinsTA	Y537N	0.00
	COSM1074637	c.1610A>G	Y537C	0.02
	COSM6918757	c.1609T>G	Y537D	0.00
	COSM94250	c.1613A>G	D538G	0.04
	COSM6948664	c.1610_1615dupATGACC	D538_L539insHD	0.00
	COSM6918537	c.1625A>G	E542G	0.09
PIK3CA	COSM760	c.1624G>A	E542K	0.11
	COSM763	c.1633G>A	E545K	0.03
	COSM775	c.3140A>G	H1047R	0.05
	COSM249879	c.3203dupA	p.N1068Kfs*5	0.00

Approval:

19 AUG 2024

Prepared By Date