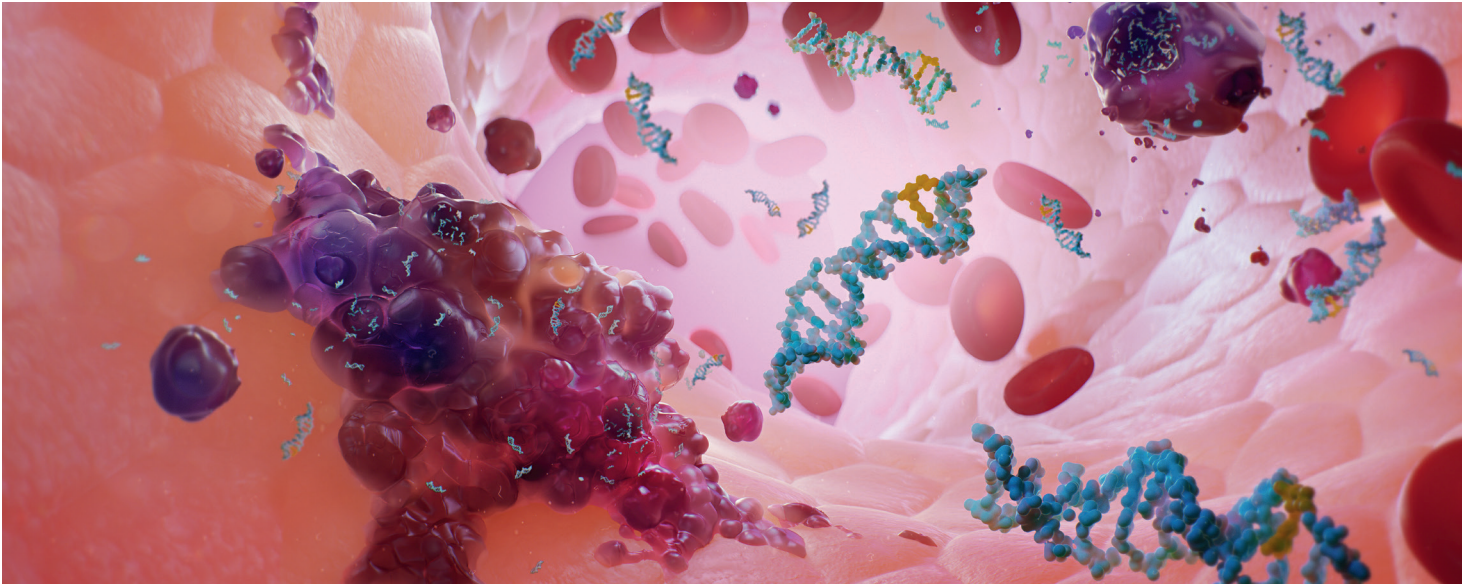


Master the sensitivity in ctDNA detection

Plasma-SeqSensei™ Breast Cancer IVD Kit



Plasma-SeqSensei™* Breast Cancer IVD Kit offers next-generation sequencing technology (NGS-)based assays that enable highly sensitive and quantitative detection of mutations in circulating tumour DNA (ctDNA) from plasma and delivers results within two days as easy-to-read reports using Plasma-SeqSensei™ IVD Software.

Plasma-SeqSensei™ Breast Cancer IVD Kit detects gene mutations in breast cancer biomarkers including AKT1, ERBB2, ESR1, KRAS, PIK3CA and TP53 to support clinicians with detection of minimal residual disease, recurrence surveillance, and (neo-)adjuvant therapy response monitoring.

Unique benefits for clinicians



High sensitivity at low MAF

Plasma-SeqSensei™ workflow reduces NGS error rates over 100-fold employing unique molecular identifiers (UID), enabling detection of 0.06% and higher mutant allele fractions (MAF) with 95% certainty in a background of 10,000 wildtype copies.

→ Confident low MAF reporting.



Absolute quantification

Internal quantifier Quantispike enables absolute quantification of ctDNA molecules down to a limit of detection of six mutant molecules independent of actual sample DNA input.

→ Consistent quantification in longitudinal monitoring.

Unique benefits for clinical laboratories



Short and standardised workflow

From cell-free DNA (cfDNA) to results in two days, including sequencing time.



Fast and convenient data analysis

Locally hosted software automates data analysis and provides a mutation report designed for clinicians.

Key facts

- ✓ IVD-certified reagents and software
- ✓ High sensitivity down to 0.06 % MAF
- ✓ Beyond MAF: absolute quantification down to six mutant molecules
- ✓ Two days turnaround time – from cfDNA sample to report



Target regions for Plasma-SeqSensei™ Breast Cancer IVD Kit

Gene ID#	Transcript ID#	CDS start	CDS end	Most frequent mutation(s) detected (AA change)
AKT1	ENST00000554581	47	69	E17K
ERBB2	ENST00000269571	907	947	S310F
ERBB2	ENST00000269571	2,308	2,360	L755S, D769Y
ERBB2	ENST00000269571	2,258	2,307	V777L
ESR1	ENST00000440973	1,108	1,143	E380Q
ESR1	ENST00000440973	1,378	1,420	S463P
ESR1	ENST00000440973	1,583	1,614	D538G, Y537S/C/N
KRAS	ENST00000256078	8	43	G12D/V/C/R/A/S, G13D
PIK3CA	ENST00000263967	254	278	R88Q
PIK3CA	ENST00000263967	329	352	K111E
PIK3CA	ENST00000263967	353	367	G118D
PIK3CA	ENST00000263967	1,033	1,058	E345K
PIK3CA	ENST00000263967	1,085	1,115	P366R
PIK3CA	ENST00000263967	1,252	1,264	C420R
PIK3CA	ENST00000263967	1,348	1,387	E453K
PIK3CA	ENST00000263967	1,611	1,659	E545K/A, E542K
PIK3CA	ENST00000263967	2,138	2,184	E726K
PIK3CA	ENST00000263967	3,118	3,169	H1047R/L
TP53	ENST00000269305	144	232	W53*
TP53	ENST00000269305	293	375	R110P
TP53	ENST00000269305	376	423	C141Y, C135Y
TP53	ENST00000269305	451	537	R175H, H179R
TP53	ENST00000269305	574	659	R213*, Y220C, R196*
TP53	ENST00000269305	695	782	R248Q/W, G245S
TP53	ENST00000269305	783	856	R273H/C, R282W
TP53	ENST00000269305	888	919	R306*
TP53	ENST00000269305	920	993	Q331*
TP53	ENST00000269305	994	1,080	R342*

Product specifications

Feature	Description
Starting sample	Whole blood and plasma
Sample capacity	2–16 samples per kit and up to 32 samples with Plasma-SeqSensei™ Extension IVD Kit
QC function	Positive control and no template control (NTC) applied to every run
Input DNA required	4.3–86 ng / 116 µL
Number of amplicons	28
Sensitivity	0.06% allele frequency with 95% certainty in 10,000 wildtype copies
Cut-off	6 mutant molecules
Compatible sequencing instruments	Illumina NextSeq 500/550™

* Plasma-SeqSensei™ Breast Cancer IVD Kit is for In Vitro Diagnostic Use.