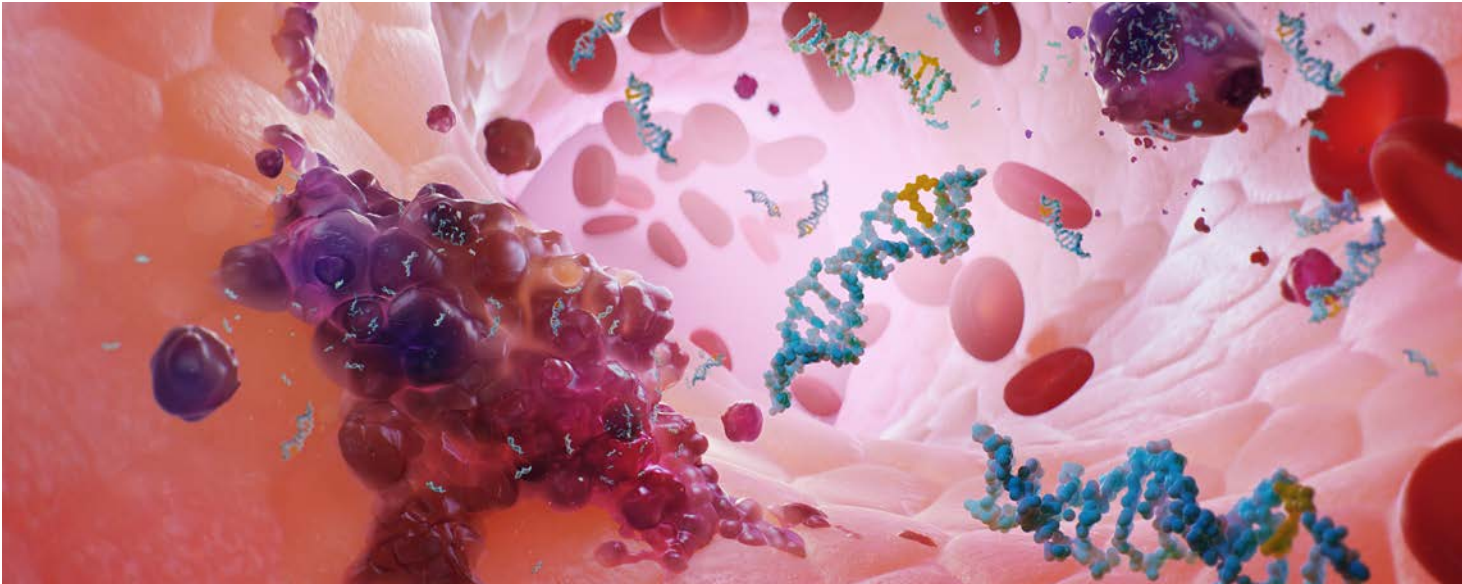


Master the sensitivity in ctDNA detection

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.