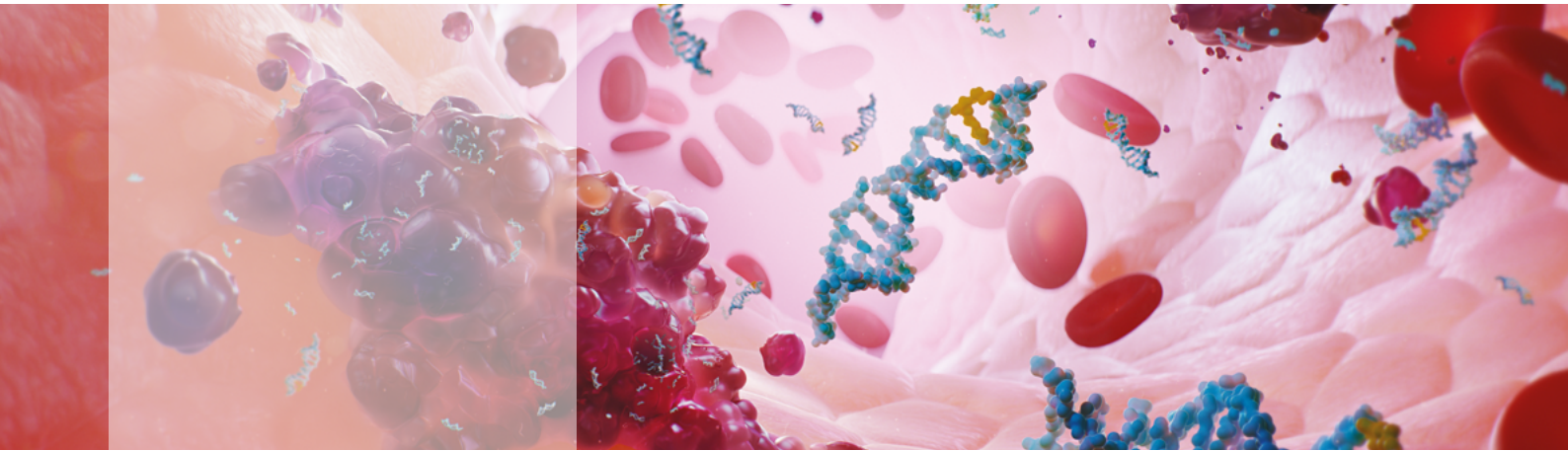


Master the sensitivity in ctDNA detection

Plasma-SeqSensei™ Breast Cancer IVD Kit



Plasma-SeqSensei™* Breast Cancer IVD Kit offers next-generation sequencing (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 and clinical laboratories



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).



Absolute quantification

Internal quantifier Quantispike enables absolute quantification of ctDNA molecules independent of the variable amount of wild-type cfDNA molecules. This allows for consistent quantification in longitudinal ctDNA monitoring.



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 reported as mutant molecules
- Two days turnaround time – from cfDNA sample to report



Target regions for Plasma-SeqSensei™ Breast Cancer IVD Kit

| Gene | Transcript ¹ | Amino acid start | Amino acid end | Most frequent mutations detected ² |
|--------|-------------------------|------------------|----------------|---|
| AKT1 | ENST00000554581.1 | 17 | 23 | E17K |
| ERBB2 | ENST00000269571.5 | 303 | 315 | S310F |
| ERBB2 | ENST00000269571.5 | 754 | 769 | L755S, D769Y |
| ERBB2 | ENST00000269571.5 | 770 | 786 | V777L |
| ESR1 | ENST00000440973.1 | 370 | 381 | E380Q |
| ESR1 | ENST00000440973.1 | 460 | 473 | S463P, L469V, F461V, L466Q |
| ESR1 | ENST00000440973.1 | 529 | 538 | D538G, Y537S/C/N/D, L536H, N532K, V534E/L |
| KRAS | ENST00000256078.4 | 4 | 14 | G12D/V/C/R/A/S, G13D |
| PIK3CA | ENST00000263967.3 | 86 | 92 | R88Q |
| PIK3CA | ENST00000263967.3 | 111 | 117 | K111E |
| PIK3CA | ENST00000263967.3 | 119 | 122 | G118D |
| PIK3CA | ENST00000263967.3 | 345 | 352 | E345K |
| PIK3CA | ENST00000263967.3 | 363 | 371 | P366R |
| PIK3CA | ENST00000263967.3 | 418 | 421 | C420R |
| PIK3CA | ENST00000263967.3 | 450 | 462 | E453K |
| PIK3CA | ENST00000263967.3 | 538 | 553 | E545K/A, E542K |
| PIK3CA | ENST00000263967.3 | 714 | 728 | E726K |
| PIK3CA | ENST00000263967.3 | 1,040 | 1,056 | H1047R/L |
| TP53 | ENST00000269305.4 | 49 | 77 | W53* |
| TP53 | ENST00000269305.4 | 99 | 125 | R110P |
| TP53 | ENST00000269305.4 | 126 | 141 | C141Y, C135Y |
| TP53 | ENST00000269305.4 | 151 | 179 | R175H, H179R |
| TP53 | ENST00000269305.4 | 192 | 219 | R213*, Y220C, R196* |
| TP53 | ENST00000269305.4 | 233 | 260 | R248Q/W, G245S |
| TP53 | ENST00000269305.4 | 262 | 285 | R273H/C, R282W |
| TP53 | ENST00000269305.4 | 297 | 306 | R306* |
| TP53 | ENST00000269305.4 | 308 | 331 | Q331* |
| TP53 | ENST00000269305.4 | 332 | 360 | R342* |

¹ Sequence source: Ensemble database

² This list does not include all possible mutations that can occur in listed regions. For complete nucleotide coverage, please refer to the Plasma-SeqSensei™ Instruction for Use.

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 |
| Analytical sensitivity | Down to 0.06% allele frequency |
| Compatible sequencing instruments | Illumina NextSeq 500/550™ |

Mastering liquid biopsy with Plasma-SeqSensei™



Distributor EMEA: Sysmex Europe SE · www.sysmex-europe.com
 Manufacturer: Sysmex Inostics GmbH · www.sysmex-inostics.com
 You will find your local Sysmex representative's address under www.sysmex-europe.com/contacts

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