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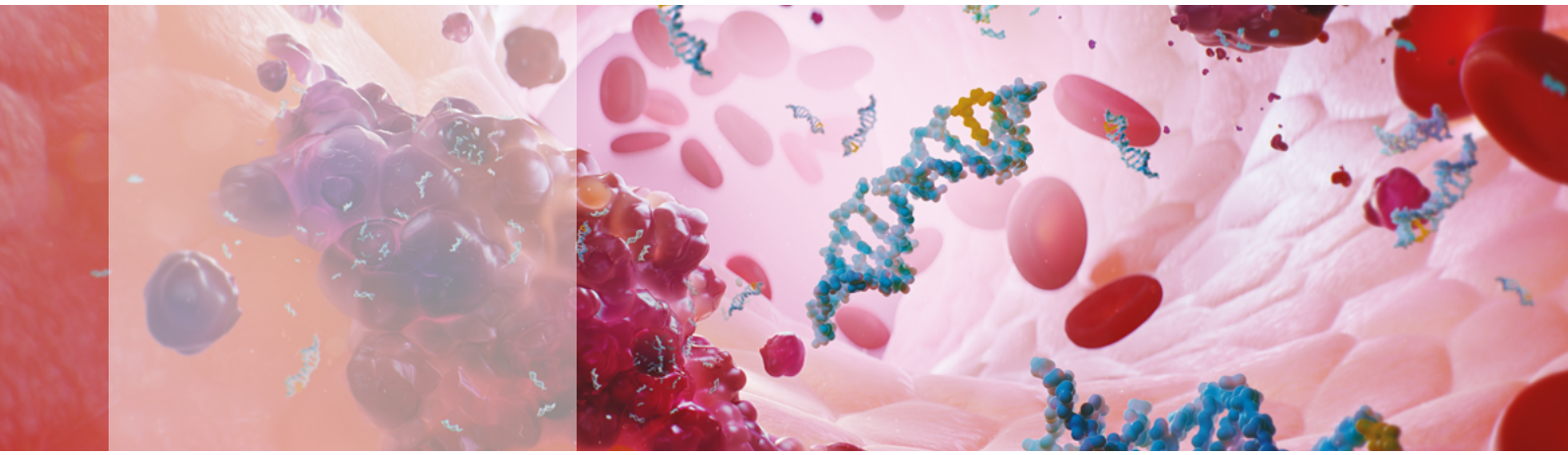
Master the sensitivity in ctDNA detection

Plasma-SeqSensei™ Solid Cancer IVD Kit



Plasma-SeqSensei™* Solid 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™ Solid Cancer IVD Kit detects gene mutations across solid cancer biomarkers including BRAF, EGFR, KRAS, NRAS and PIK3CA to support clinicians with detection of minimal residual disease, recurrence surveillance and (neo-)adjuvant therapy response monitoring. Additionally, this kit is intended to analyse the RAS mutation status to determine the potential benefit of anti-epidermal growth factor receptor (EGFR) therapy for colorectal cancer patients.

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 0.07 % 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.

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

Key facts

- IVD-certified reagents and software
- High sensitivity down to 0.07 % MAF
- Beyond MAF: absolute quantification reported as mutant molecules
- Two days turnaround time – from cfDNA sample to report
- CDx indication: assessing potential benefit of anti-EGFR therapy in colorectal cancer patients

Target regions for Plasma-SeqSensei™ Solid Cancer IVD Kit

Gene	Transcript1	Amino acid start	Amino acid end	Most frequent mutations detected²
BRAF	ENST00000288602.6	462	477	G469A/R/V/E, G466V/E
BRAF	ENST00000288602.6	582	604	V600E/K/R/M, K601E, D594G
EGFR	ENST00000275493.2	706	725	G719A/S
EGFR	ENST00000275493.2	743	759	E746_A750del, L747_P753delinsS, L747_T751del, L747_A750delinsP, E746_S752delinsV
EGFR	ENST00000275493.2	762	775	S768I
EGFR	ENST00000275493.2	788	801	T790M
EGFR	ENST00000275493.2	856	873	L858R, L861Q
KRAS	ENST00000256078.4	12	34	G12D/V/C/A/S/R/F, G13D/C/R/V/A
KRAS	ENST00000256078.4	57	76	Q61H/R/L/H/K, A59T
KRAS	ENST00000256078.4	110	117	K117N
KRAS	ENST00000256078.4	141	148	A146T/V
NRAS	ENST00000369535.4	1	17	G12D/C/S/A/V/R, G13R/V/C/S
NRAS	ENST00000369535.4	55	70	Q61R/K/L/H
NRAS	ENST00000369535.4	115	121	L120D, K117R
NRAS	ENST00000369535.4	141	149	A146V/T
PIK3CA	ENST00000263967.3	538	553	E545K/A/G/Q, E542K, Q546K/R/P
PIK3CA	ENST00000263967.3	1,040	1,065	H1047R/L/Y, G1049R, M1043I/V

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	5.7–95 ng / 116 µL
Number of amplicons	17
Analytical sensitivity	Down to 0.07% allele frequency
Compatible sequencing instruments	Illumina NextSeq 500/550™

Mastering liquid biopsy with Plasma-SeqSensei™

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.

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