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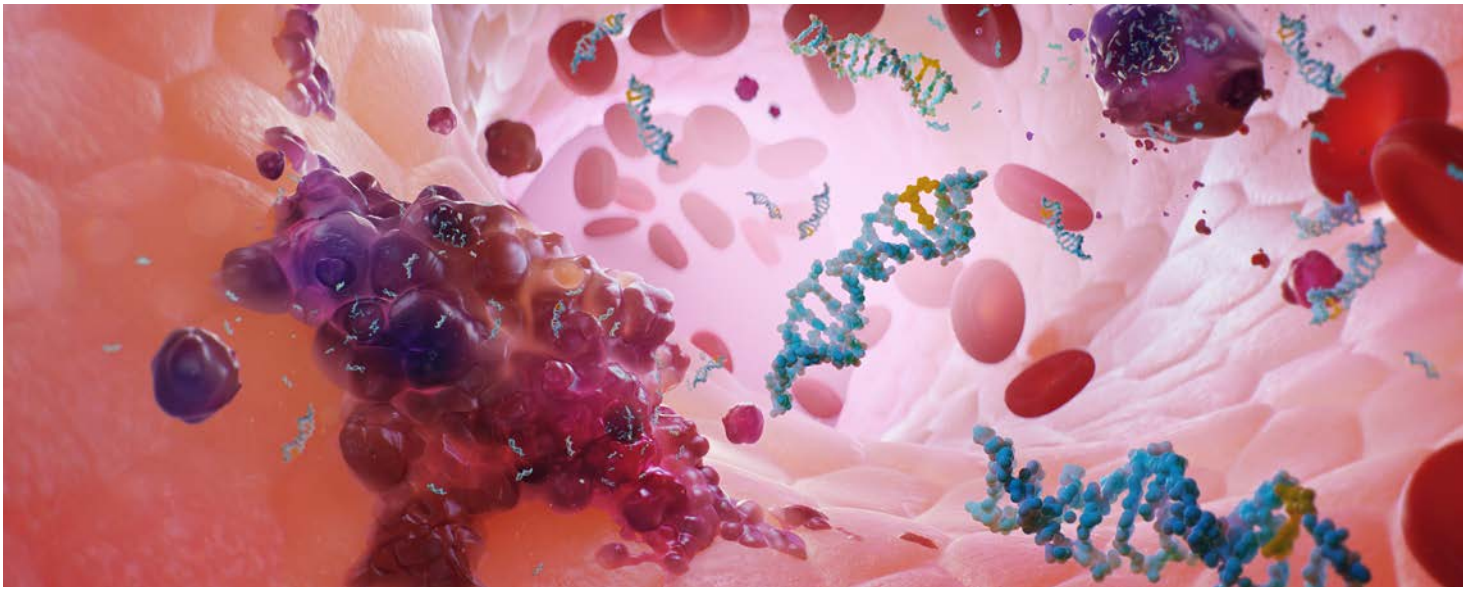
Master the sensitivity in ctDNA detection

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

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) 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 seven mutant molecules independent of actual sample DNA input.

➔ Consistent quantification in longitudinal monitoring.

www.sysmex-europe.com/liquidbiopsy

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 0.07 % MAF
- ✔ Beyond MAF: absolute quantification down to seven 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 ID#	Transcript ID#	CDS start	CDS end	Most frequent mutation(s) detected (AA change)
BRAF	ENST00000288602	1,383	1,431	G469A/R/V/E, G466V/E
BRAF	ENST00000288602	1,742	1,813	V600E/K/R/M, K601E, D594G
EGFR	ENST00000275493	2,116	2,177	G719A/S
EGFR	ENST00000275493	2,565	2,620	L858R, L861Q
EGFR	ENST00000275493	2,225	2,279	E746_A750del, L747_P753delinsS, L747_T751del, L747_A750delinsP, E746_S752delinsV
EGFR	ENST00000275493	2,361	2,403	T790M
EGFR	ENST00000275493	2,284	2,325	S768I
KRAS	ENST00000256078	419	445	A146T/V
KRAS	ENST00000256078	326	352	K117N
KRAS	ENST00000256078	34	102	G12D/V/C/A/S/R/F, G13D/C/R/V/A
KRAS	ENST00000256078	169	228	Q61H/R/L/H/K, A59T
NRAS	ENST00000369535	162	210	Q61R/K/L/H
NRAS	ENST00000369535	420	449	A146V/T
NRAS	ENST00000369535	1	52	G12D/C/S/A/V/R, G13R/V/C/S
NRAS	ENST00000369535	341	364	L120D, K117R
PIK3CA	ENST00000263967	3,118	3,195	H1047R/L/Y, G1049R, M1043I/V
PIK3CA	ENST00000263967	1,611	1,659	E545K/A/G/Q, E542K, Q546K/R/P

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
Sensitivity	0.07 % allele frequency with 95 % certainty in 10,000 wildtype copies
Cut-off	7 mutant molecules
Compatible sequencing instruments	Illumina NextSeq 500/550™

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

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