

Simple. Swift. Sensitive.

LiquidHALLMARK® is a comprehensive next-generation sequencing (NGS) assay for ultrasensitive biomarker detection. LiquidHALLMARK examines plasma circulating tumor DNA (ctDNA) mutations in 80 genes, including fusions in 10 genes.

97.4% Proven concordance with allele-specific PCR for EGFR mutation detection in advanced lung cancer

Methods

Ultra-deep sequencing using Lucence's proprietary AmpliMark™ technology

Targets

SNVs (including cis-trans), insertions and deletions, copy number variations (CNVs), microsatellite instability (MSI), fusions, and viruses

Accuracy

> 99%

Analytical Limit of Detection

0.1% for single nucleotide variants and insertions/deletions, 0.5% for fusions

Sample requirement

2 Streck tubes of blood (18ml in total)

Turnaround time

7 working days

Targets list

Genes*	ABL1	CCND2 #	FBXW7 #	IDH1	MED12	PDGFRA #	RIT1
	AKT1	CDH1	FGFR1	IDH2	MET #	PIK3CA #	ROS1
	ALK #	CDK6 #	FGFR2	JAK1	MLH1	PIK3R1	SF3B1
	APC	CDKN2A #	FGFR3	JAK2	MTOR	PPP2R1A	SMAD4 ^
	AR	CREBBP	FLT3	JAK3	MYC #	PTEN #	SMO
	ARAF	CTNNB1	GATA3	KEAP1 #	NF1	PTPN11	SPOP
	ATM	EGFR †	GNA11	KIT #	NFE2L2	RAF1	STK11
	BRAF	ERBB2 (HER2)#	GNAQ	KRAS #	NOTCH1	RB1	TERT Promoter
	BRCA1 #1	ERCC2	GNAS	MAP2K1 (MEK1)	NRAS #	RET	TP53 ^
	BRCA2 #2	ESR1	HNF1A	MAP2K2 (MEK2)	NTRK1	RHEB	U2AF1
	CCND1 #	EZH2	HRAS	MAPK1 (ERK2)	NTRK3	RHOA	VHL

Fusions	ALK	FGFR2	FGFR3	NTRK1	NTRK2	NTRK3	PD-L1	RET	ROS1	TMPRSS2
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MSI	BAT25	BAT26	NR21	NR24	NR27	MONO27
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Viruses	Epstein-Barr Virus (EBV)	Hepatitis B Virus (HBV)	Human Herpesvirus (HHV-8)
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* Targeted regions selected to maximize detection of known hotspot mutations.
 # Includes detection of gene copy number changes. † Includes sequencing of EGFR kinase and extracellular domain mutations.
 ^ Full coverage. 1 >99% coverage. 2 >98.4% coverage of coding exons.

Test Performance Specifications ^{2,3,4}

	Mutant Allele Frequency Limit of Detection	Sensitivity	Specificity
Single Nucleotide Variants (SNVs)	0.1 %	>99 %	>99 %
Insertions/ Deletions (Indels)	0.1 %	>95 %	>99 %
Fusions	0.5 %	>90 %	>99 %

- Results presented for Horizon Discovery™ cell-free DNA (cfDNA) standard and reference genomic DNA standards tested at specified Mutant Allele Frequencies (MAF).
- Sensitivity reported for true variants in the Horizon Discovery™ cfDNA standards and genomic DNA.
- Specificity reported is the per-base specificity across the LiquidHALLMARK® panel (detection of true negatives).
- Clinical performance data in Lung, Breast, Hematological cancers presented in 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program and 2020 American Association for Cancer Research (AACR) Advances in Liquid Biopsies. ^{1,5,6,7}

[1] Choudhury, Y. et al. J Clin Oncol 38: 2020 (suppl; abstr e21516) [2] Choudhury, Y. et al. Ann. Oncol., 29, 2018 (suppl_9; mdy441.010) [3] Choudhury, Y. et al. J Clin Oncol 36: 2018 (suppl; abstr e24107) [4] Choudhury, Y. et al. AACR; Clin Cancer Res 2020;26(11_Suppl): Abstract nr A41 [5] Lim, J. S. et al. J Clin Oncol 38: 2020 (suppl; abstr 1035) [6] Cher, C. Y. et al. J Clin Oncol 38: 2020 (suppl; abstr e19511) [7] Ngeow, K.C. et al. J Clin Oncol 38: 2020 (suppl; abstr 3572)

Customer support: +1 888 LUCENCE sales.us@lucence.com

lucence.com

Lucence Service Laboratory 3520W Bayshore Rd, Palo Alto, CA94303

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