LUCENCE

Simple. Swift. Sensitive.

LiquidHALLMARK® is a comprehensive next-generation sequencing (NGS) assay for ultrasensitive biomarker detection. Requiring only a simple draw of blood, LiquidHALLMARK® provides important information for cancer care especially when tissue-invasive biopsy is insufficient or inaccessible.

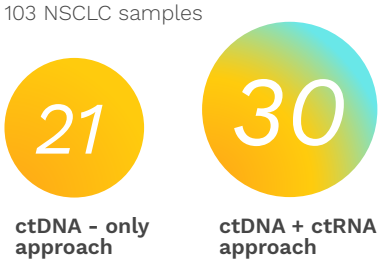
Highly sensitive profiling and analysis

LiquidHALLMARK® profiles plasma circulating tumor DNA (ctDNA) mutations in 80 genes, at a 0.1% limit of detection.

LiquidHALLMARK® Tissue Concordance is 93.1% - 100% [1]

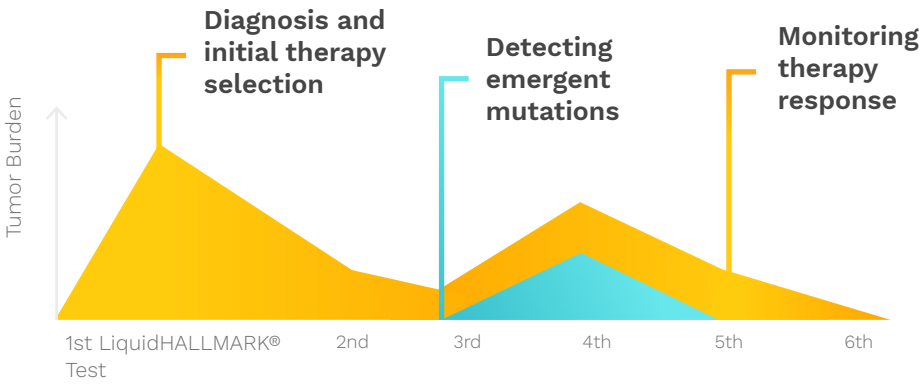
Combined with circulating tumor RNA (ctRNA) sequencing to detect fusions, LiquidHALLMARK® identifies more clinically actionable mutations allowing doctors to make better informed decisions.

43% more fusions detected [2]
103 NSCLC samples



How LiquidHALLMARK® helps

With just a simple blood draw, serial monitoring can be achieved using LiquidHALLMARK® to inform clinical decisions.



Information for non-US medical professionals only

Targets List

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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* [1]	*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 **ctDNA**	*ALK*	*CD274* (*PD-L1*)	*FGFR2*	*FGFR3*	*NTRK1/2/3*	*RET*	*ROS1*	*TMPRSS2*

Fusions **ctRNA** *(Add-on option)*	*ALK*	*AR* (*AR-3/4/7/9 splice variant*)	*AXL-MBIP*	*BRAF*	*CLIP1-LTK*	*CTNNB1-PLAG1*	*DNAJB1-PRKACA*	
	EGFR	*ERBB4*	*ERG*	*ESR1*	*ETV1/4/5*	*FGFR1/2/3*	*FLI1*	*MET* (*including exon 14 skipping*)
	MYB-NFIB	*NRG1*	*NTRK1/2/3*	*NUTM1*	*PAX3-FOXO1*	*PAX8-PPARG*	*RET*	*ROS1*
	RSPO2	*RSPO3*	*SLC45A3*	*SSX1*	*SSX2*	*TFE3*	*THADA*	*TMPRSS2*

MSI	BAT25	BAT26	NR21	NR24	NR27	MONO27

*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 Specifications

Methodology	Ultra-deep sequencing using Lucence's proprietary AmpliMARK™ technology
Targets	Single nucleotide variants (SNVs, including cis-trans), insertions and deletions (indels), copy number variations (CNVs), microsatellite instability (MSI) and fusions
Accuracy	>99%
Analytical limit of detection (LOD)	0.1% for SNVs and indels 0.5% for ctDNA fusions 10 copies for ctRNA fusions
Sample Required	3 x 9mL Streck Tubes of Blood (27mL)
Turnaround Time	8 working days

Performance Specifications [3]

	LOD	Sensitivity	Specificity
Single Nucleotide Variants (SNVs)	0.1 % MAF	> 99 %	> 99 %
Insertions / Deletions (Indels)	0.1 % MAF	> 95 %	> 99 %
Fusions (ctDNA)	0.5 % MAF	> 90 %	> 99 %
Fusions (ctRNA)	10 copies	> 97.4 %	> 99 %

- Sensitivity reported for true variants in the Horizon Discovery cell-free DNA (cfDNA), genomic DNA Reference Standards, and Seracare RNA fusion standards.
- Specificity reported is the per-base specificity across the LiquidHALLMARK® panel (detection of true negatives) for ctDNA, and panel-wide specificity for ctRNA (number of false positives detected) in non-cancer samples.
- Pan-cancer clinical performance data in 1,592 samples, including Lung, Breast and Colorectal cancers. [3-9]

References [1] Dawar, R. et al. Amplicon-Based Liquid Biopsy Prospectively Detects More Tissue-Confirmed Guideline-Recommended Biomarkers in Lung Cancer. WCLC 2023. [2] Choudhury, Y. et al. J Clin Oncol 2022 40:16_suppl, 3040-3040 [3] Poh J. et al. 2022. PLoS ONE 17(4): e0267389 [4] Poh J. et al. J Clin Oncol 39: 2021 (suppl; abstr 3062) [5] Choudhury, Y. et al. J Clin Oncol 38: 2020 (suppl; abstr e21516) [6] Lim, J. S. et al. J Clin Oncol 38: 2020 (suppl; abstr 1035) [7] Ngeow, K.C. et al. J Clin Oncol 38: 2020 (suppl; abstr 3572) [8] Choudhury, Y. et al. Ann. Oncol., 29, 2018 (suppl_9; mdy441.010) [9] Choudhury, Y. et al. J Clin Oncol 36: 2018 (suppl; abstr e24107)

LiquidMARK™ Focused Panels

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Focused sub-panels for targeted cancer types.
All sub-panels include microsatellite instability (MSI) testing. Full ctRNA fusion panel is available as an add-on for all sub-panels.

LUNG

Genes*	*ALK* [#]	*CDKN2A* [#]	*FGFR2*	*MTOR*	*NTRK3*	*RB1*	*STK11*
	ARAF	*CTNNB1*	*FGFR3*	*NF1*	*PDGFRA* [#]	*RET*	*TP53* [#^]
	BRAF	*EGFR* [†#]	*KEAP1* [¤]	*NFE2L2*	*PIK3CA* [#]	*RIT1*	*U2AF1*
	BRCA1 [#¤]	*ERBB2* [#(HER2)]	*KRAS* [#]	*NRAS* [#]	*PIK3R1*	*ROS1*	
	BRCA2 [#b]	*FGFR1*	*MET* [#]	*NTRK1*	*PTEN* [#]	*SF3B1*	
Fusions ctDNA	*ALK* [#]	*CD274* (PD-L1)	*FGFR2*	*FGFR3*	*NTRK 1/2/3*	*RET*	*ROS1*

BREAST & OVARIAN

Genes*	*AKT1*	*BRCA1*	*CTNNB1*	*FGFR1*	*GNAS*	*NTRK1*	*PTEN*	*TP53*
	APC	*BRCA2*	*ERBB2*	*FGFR2*	*KRAS*	*NTRK3*	*RB1*	
	ATM	*CDH1*	*ESR1*	*FGFR3*	*MYC*	*PIK3CA*	*RET*	
	BRAF	*CDK6*	*FBXW7*	*GATA3*	*NF1*	*PIK3R1*	*SF3B1*	
Fusions ctDNA	*CD274* (PD-L1)	*FGFR2*	*FGFR3*	*NTRK 1/2/3*	*RET*			

COLON

Genes*	*APC*	*CTNNB1*	*FGFR1*	*KRAS*	*NRAS*	*PIK3R1*	*SMAD4*	
	ATM	*EGFR*	*FGFR2*	*MLH1*	*NTRK1*	*PTEN*	*TP53*	
	BRAF	*ERBB2*	*FGFR3*	*MTOR*	*NTRK3*	*RAF1*		
	CREBBP	*FBXW7*	*JAK1*	*MYC*	*PIK3CA*	*RET*		
Fusions ctDNA	*CD274* (PD-L1)	*FGFR2*	*FGFR3*	*NTRK 1/2/3*	*RET*			

PANCREAS & BILE DUCT

Genes*	*AKT1*	*BRCA1*	*CDKN2A*	*FGFR2*	*IDH1*	*MYC*	*PIK3CA*	*STK11*
	APC	*BRCA2*	*CTNNB1*	*FGFR3*	*IDH2*	*NRAS*	*PIK3R1*	*SMAD4*
	ATM	*CCND1*	*ERBB2*	*GNAS*	*KRAS*	*NTRK1*	*PTEN*	*TP53*
	BRAF	*CCND2*	*FGFR1*	*HRAS*	*MET*	*NTRK3*	*RET*	*VHL*
Fusions ctDNA	*CD274* (PD-L1)	*FGFR2*	*FGFR3*	*NTRK 1/2/3*	*RET*			

PROSTATE

Genes*	*AR*	*BRCA1*	*FGFR1*	*KRAS*	*NTRK3*	*PTEN*	*SPOP*
	ATM	*BRCA2*	*FGFR2*	*MYC*	*PIK3CA*	*RB1*	*TP53*
	BRAF	*ERBB2*	*FGFR3*	*NTRK1*	*PIK3R1*	*RET*	
Fusions ctDNA	*CD274* (PD-L1)	*FGFR2*	*FGFR3*	*NTRK 1/2/3*	*RET*	*TMPRSS2*	

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Fusions ctRNA *(Add-on option)*

ALK	*AR (AR-3/4/7/9 splice variant)*	*AXL-MBIP*	*BRAF*	*CLIP1-LTK*	*CTNNB1-PLAG1*	*DNAJB1-PRKACA*	
EGFR	*ERBB4*	*ERG*	*ESR1*	*ETV1/4/5*	*FGFR1/2/3*	*FLI1*	*MET (including exon 14 skipping)*
MYB-NFIB	*NRG1*	*NTRK1/2/3*	*NUTM1*	*PAX3-FOXO1*	*PAX8-PPARG*	*RET*	*ROS1*
RSPO2	*RSPO3*	*SLC45A3*	*SSX1*	*SSX2*	*TFE3*	*THADA*	*TMPRSS2*

*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.

M1010E-SG-07. July 2023