

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

21

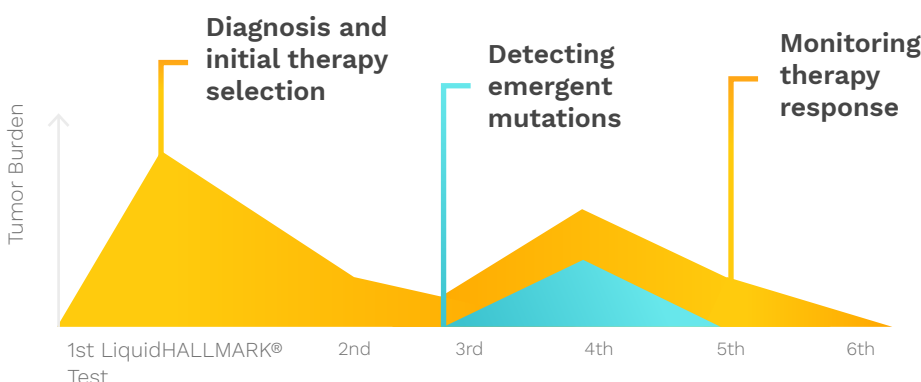
ctDNA - only
approach

30

ctDNA + ctRNA
approach

How LiquidHALLMARK® helps

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



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
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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
	RSP02	RSP03	SLC45A3	SSX1	SSX2	TFE3	THADA	TMPRSS2

MSI	BAT25	BAT26	NR21	NR24	NR27	MONO27
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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 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)

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

BREAST & OVARIAN

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

COLON

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

PANCREAS & BILE DUCT

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

PROSTATE

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

Fusions ctRNA (Add-on option)

ALK	AR (AR-3/4/7/9 splice variant)	AXL-MBIP	BRAF	CLIP1-LTK	CTNNB1-PLAG1	DNAJB1-PRKACA	
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RSP02	RSP03	SLC45A3	SSX1	SSX2	TFE3	THADA	TMPRSS2

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