

LiquidHALLMARK® 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 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	FGFR2	FGFR3	NTRK1/2/3	PD-L1 (CD274)	RET	ROS1	TMPRSS2
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Fusions ctRNA (*Add-on option)	ALK	AR AR-V7 Splice Variant	BRAF	CTNNB1-PLAG1	EGFR	ERBB4	ERG	ESR1
	ETV1/4/5	FGFR1	FGFR2	FGFR3	FLI1 ^R	MET <i>include exon 14 skipping</i>		MYB-NFIB
	NRG1	NTRK1/2/3	PAX3-FOXO1	PAX8-PPARG	RET	ROS1	SSX1	SSX2

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. Fusions highlighted in orange are analyzed using both ctDNA and ctRNA. ctRNA currently investigational – provided for informational, non-diagnostic purposes only.

Test Specifications

Methodology	Amplicon-based next generation sequencing
Targets	Single nucleotide variants (SNVs), including cis-trans), insertions and deletions (indels), copy number variations (CNVs), microsatellite instability (MSI), fusions, and viruses
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	2 x 9mL Streck Tubes of Blood (18mL)
Turnaround Time	7 working days

Performance Specifications ^{1,2,3,4}

	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	> 99 %	> 99 %

- Results presented for Horizon Discovery™ cell-free DNA (cfDNA) standard and reference genomic DNA standards tested at specified Mutant Allele Frequencies (MAF), or using Seracare RNA Fusion standards at known fusion copy numbers
 - Sensitivity reported for true variants in the Horizon Discovery™ cfDNA standards and Seracare RNA fusions 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).
 - 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. ^{5,6,7,8}

References [1] Poh J. et al. 2022. PLoS ONE 17(4): e0267389 [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] 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] Cher, C. Y. et al. J Clin Oncol 38: 2020 (suppl; abstr e19511) [8] Ngeow, K.C. et al. J Clin Oncol 38: 2020 (suppl; abstr 3572)