Hedera Profiling 2 ctDNA test panel
A compendium of pure actionability

Hedera Profiling 2 ctDNA test panel : 32-gene assay optimized to run cfDNA samples with NGS across > 6 solid tumor types

Unique Design

The **assay's unique design** allows it to assess a **broad range of biomarkers,** including **SNVs, Indels, CNVs, Fusions** and **MSI** in a single DNA-only, streamlined and robust lab-to-report workflow. It contains **>80% of all ESCAT Level I genes** included to date in the guidelines.

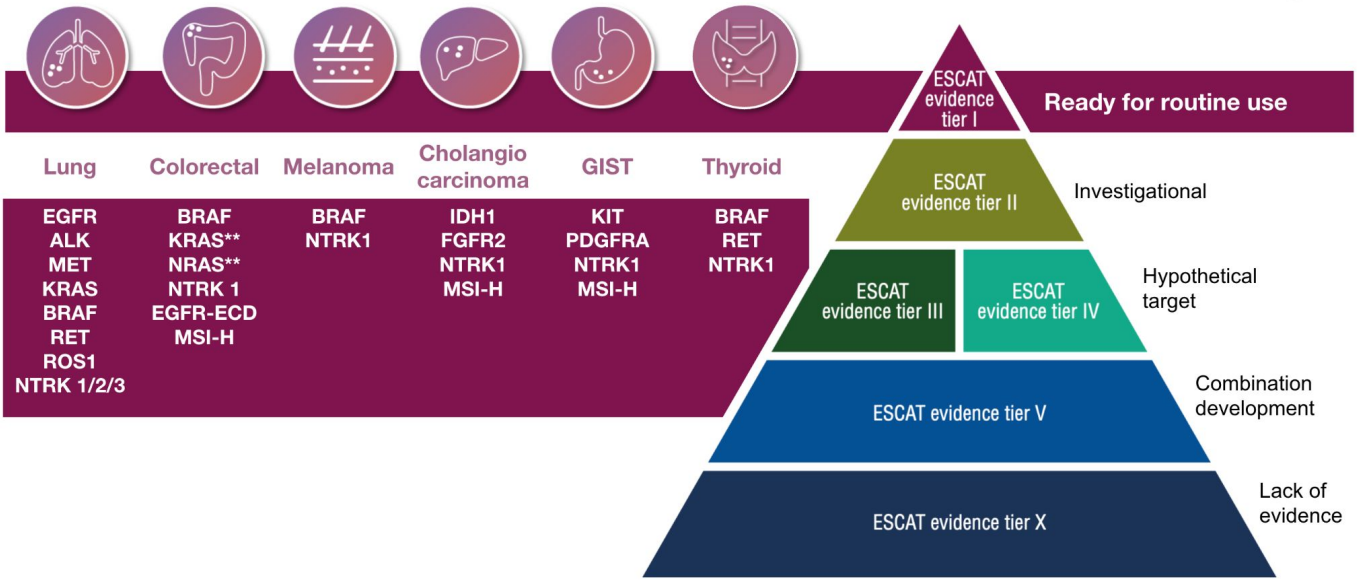
Specifications for use

- **Panel size:** 90 kb
- **Instruments supported:** Illumina NextSeq and NovaSeq Series
- **Multiplexing**: up to 6 samples on a NextSeq 500/550 instrument (MID Output flow cell)
- **Sample size:** min 5mL plasma required (cfDNA BCT by Streck recommended)
- **cfDNA input:** min 10 ng cfDNA, 30 ng cfDNA recommended
- **Library preparation method:** hybrid-capture chemistry
- **UMI/UDI technologies:** allowing error correction and preventing index hopping for enhanced sensitivity and specificity

Hedera Profiling 2 ctDNA test panel is labelled for Performance Studies Only. Not available in all countries including the United States. The clinical performance evaluation of Hedera Profiling 2 ctDNA test panel has not been established and users can run a local validation under CE-IVDR to use the assay as in-house IVD.

> 80% of all ESCAT Level I genes are included in the Hedera Profiling 2 ctDNA test panel*

Most genes included in the panel are classified as ESCAT Level I



As a result, most genes included in the panel are druggable*

AKT1	FGFR3	KEAP1	NTRK3
ALK	FGFR4	KIT	PDGFRA
BRAF	GNA11	KRAS	PIK3CA
EGFR	GNAQ	MAP2K1	PTEN
ERBB2	GNAS	MET	RET
ESR1	HRAS	NRAS	ROS1
FGFR1	IDH1	NTRK1	STK11
FGFR2	IDH2	NTRK2	TP53

The panel also integrates:

- MSI (18 markers)
- METex14 skipping

EGFR variant VIII

SNVs, Indels	SNVs, Indels, CNVs	SNVs, Indels, CNVs, Fusions	SNVs, Indels, Fusions	Druggable

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** Mechanism of resistance, non applicable for ESCAT. ESCAT: ESMO Scale of Clinical Actionability for molecular Targets

Hedera Profiling 2 ctDNA test panel: robustly pre-validated and eases your local verification step

78 validation samples were run covering 2150 variants for SNVs/Indels and 54 for Fusions in 27 genes across > 6 cancer types

Performance characteristics at a glance

Alteration type	Variant subset	N different samples / Total N replicates	Number positive / Number expected	Analytical sensitivity	Analytical specificity	VAF range observed
SNVs + Indels ≥ 0.5% VAF	ESCAT Level I *NSCLC only*	5/36	280/287	**> 97%**	**> 99%**	0.11-1.25%
	ESCAT Level I *All tumor types*	5/36	409/422	**> 96%**	**> 99%**	0.11-1.95%
	All variants	5/36	1947/2150	**> 90%**	**> 99%**	0.1-1.95%
Fusions ≥ 0.5% VAF	All variants	7/64	54/54	**100%**	**100%**	0.21-1.0%

- **High sensitivity and specificity for key genomic alterations**
- **Results based on 30 ng of input cfDNA** (commercial reference control DNA) for all SNVs, Indels and Fusions with samples run on a NextSeq 2000 instrument

Learn more about Hedera Comply

Tailored expert IVDR implementation program for local compliance, facilitating routine liquid biopsy testing with in-house validation support.

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HederaDx

Hedera Profiling 2 ctDNA test panel: robustly pre-validated and eases your local verification step

78 validation samples were run covering 2150 variants for SNVs/Indels and 54 for Fusions in 27 genes across > 6 cancer types

Performance characteristics for ESCAT Level I variants

Clinically relevant variants	Alteration type	Tumor type(s)	Number positive / Number expected	VAF range observed	Analytical sensitivity
ALK (Acquired resistance kinase domain mutations)	SNV	NSCLC	50/50	0.12-0.67%	**100%**
BRAF V600E	SNV	NSCLC,CRC, Melanoma	16/16	0.12-0.97%	**100%**
EGFR Ex 19 Deletions	Indel	NSCLC	23/23	0.14-0.8%	**100%**
EGFR Exon 20 insertions	Indel	NSCLC	12/13	0.13-0.72%	**> 92%**
EGFR L858R	SNV	NSCLC	19/19	0.13-0.8%	**100%**
EGFR T790M	SNV	NSCLC	19/19	0.11-0.59%	**100%**
ESR1 D538G	SNV	Breast	10/10	0.13-0.46%	**100%**
IDH1 R132C	SNV	CHOL	10/10	0.12-0.77%	**100%**
KIT SNVs	SNV	GIST	78/80	0.12-0.88%	**> 97%**
KIT insertions/deletions	Indel	GIST	84/90	0.11-1.28%	**> 93%**
KRAS G12C/D/V	SNV	NSCLC, CRC	15/15	0.3-1.23%	**100%**
KRAS Q61K/H	SNV	NSCLC, CRC	16/16	0.13-0.77%	**100%**
MET Exon 14 Skipping	-	NSCLC	10/10	0.35-0.8%	**100%**
PDGFRA D842V	SNV	GIST	10/10	0.22-0.79%	**100%**
PIK3CA E545K	SNV	Breast	27/29	0.12-0.73%	**93%**
PIK3CA H1047R	SNV	Breast	16/16	0.13-1.95%	**100%**
RET mutations	SNV	Thyroid, NSCLC	19/20	0.18-0.58%	**95%**
RET mutations	Indel	Thyroid	16/20	0.15-0.73%	**80%**
ALK Fusions	Fusion	NSCLC	18/18	0.1-0.28%	**100%**
ROS1 Fusions	Fusion	NSCLC	10/10	0.5-1%	**100%**
RET Fusions	Fusion	NSCLC	16/16	0.12-0.43%	**100%**

- **High sensitivity for key ESCAT Level I genomic alterations including NSCLC ones**

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Contact us for more information about Hedera Profiling 2 ctDNA test panel and our services offering:
info@hederadx.com | +41 21 588 16 54 I www.hederadx.com (contact form)

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