

# Hedera Profiling 2 ctDNA test panel (for cfDNA samples run with NGS)

**Hedera Profiling 2 ctDNA test panel : 32-gene assay optimized to run cfDNA samples with NGS**

## 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.

## Specifications

- **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.

# Hedera Profiling 2 ctDNA test panel includes SNVs, Indels, CNVs, Fusions & MSI

The panel detects a broad range of cfDNA variants as well as MSI

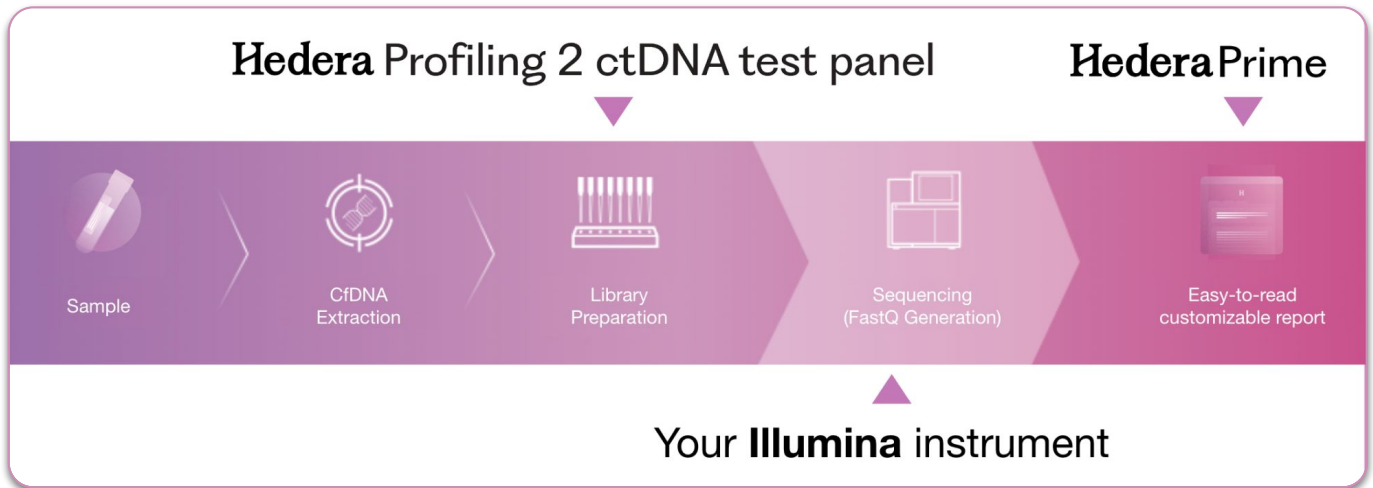
Gene	SNVs	Indels	CNVs	Fusions
AKT1	•	•		
ALK	•	•	•	•
BRAF	•	•	•	
EGFR	•	•	•	•
ERBB2	•	•	•	
ESR1	•	•		
FGFR1	•	•	•	•
FGFR2	•	•	•	•
FGFR3	•	•	•	•
FGFR4	•	•		
GNA11	•	•		
GNAQ	•	•		
GNAS	•	•		
HRAS	•	•	•	
IDH1	•	•		
IDH2	•	•		
KEAP1	•	•		
KIT	•	•		
KRAS	•	•	•	
MAP2K1	•	•		
MET	•	•	•	•
NRAS	•	•	•	
NTRK1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

⇒ For **in-house genomic profiling** of cfDNA samples (total panel size: **90 kb**)

⇒ The panel also integrates **METex14 skipping** and **EGFR variant VIII**

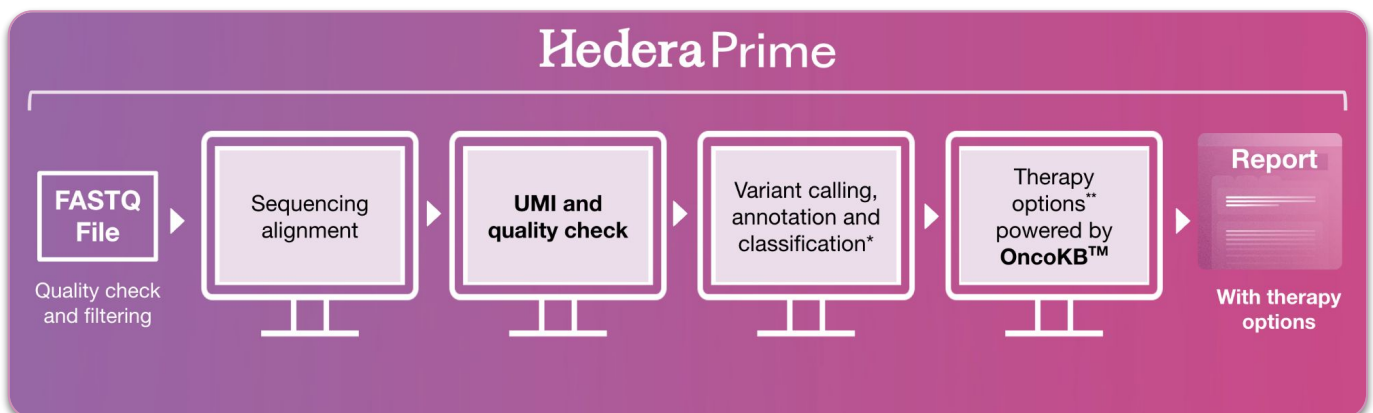
# Hedera Profiling 2 ctDNA test panel swiftly integrates into your workflow

Fast sample-to-report workflow combining your existing instrument with Hedera Dx offering



- **3 hours** hands on time
- **5 calendar** days from sample to report
- **< 5 min** tertiary analysis and reporting

Consolidate biomarker testing and save time on each report with Hedera Prime



- **Hedera Prime** was developed with and for the healthcare community (**140+ experts' feedback** collected & continuously leveraged for R&D purposes)
- The report is **customizable** and can be exported as **PDF or JSON** formats

\* via multiple databases including ClinVar, OncoKB, OMIM, gnomAD, dbSNP, Mastermind, BRCA Exchange  
\*\* EMA (European Medicines Agency) therapy options is currently also available for NSCLC samples

# Hedera Prime facilitates the creation of an easy-to-interpret customizable report

## Annotated sample report

**Report sections that are customizable**

**Clinical test report - Illustrative example**  
**Hedera Profiling 2 ctDNA test panel (HP2)**  
 Report LOC-5834-8470 on 26 September 2023 at 15:15 (UTC+03:00) Example Varnon Hospital Page 1/2

Patient	Order	Sample
ID: 89238923	Test: HP2	Sample ID: A123456
Name: John Johnsson	Organisation: Varnon Hospital	Sample type: Whole blood
Date of Birth: 05 March 1958	Assigned clinician: Christie McKenzie	
Sex: Male		
Cancer type: Lung Cancer (NSCLC)		

**Summary of findings and conclusions**  
 Summary of findings can be added here...

**Variants and therapies**

Gene	cDNA change	Protein change	VAF %	Lab classification	Reference classifications
<b>BRAF</b>	c. 1799T>A	V686E p. (Va2486G2u)	0.97	<b>Pathogenic</b>	ClinVar: Pathogenic ID: 13961 OncoKB: Oncogenic
<b>Related therapy options</b>					
Therapy: Dabrafenib & Trametinib	EMA Approval: <b>Effective</b>	Lung Cancer (NSCLC), Melanoma	FDA Approval (OncoKB levels of evidence): <b>L1 - FDA-recognized</b>	Non-Small Cell Lung Cancer, Thyroid Cancer, Melanoma Biliary Tract Cancer, Histocytosis, Glioma	
<b>Fusion gene:exon</b>					
<b>EML4-5</b>   <b>ALK20</b>		98.20	<b>Pathogenic</b>	OncoKB: Oncogenic	
<b>Related therapy options</b>					
Therapy: Alectinib	EMA Approval: <b>Effective</b>	Lung Cancer (NSCLC)	FDA Approval (OncoKB levels of evidence): <b>L1 - FDA-recognized</b>	Non-Small Cell Lung Cancer	
<b>CNV gene</b>					
<b>MET</b>	Gain	Transcript: NM_009245.4	Affected exons: 5/21 (Exons: 1-4,6)	Fold change: 3.2	
<b>Related therapy options</b>					
Therapy: Erlotinib, Gefitinib & Osimertinib	EMA Approval: <b>Ineffective</b>	Lung Cancer (NSCLC)	FDA Approval (OncoKB levels of evidence): <b>R2 - Investigational Resistance</b>	Non-Small Cell Lung Cancer	
<b>Mutational signatures</b>					
Microsatellite status: <b>MSI-High</b>	Confidence score %: 98.10	Unstable loci: 9/18			
<b>Related therapy options</b>					
Therapy: Pembrolizumab	EMA Approval: <b>Effective</b>	CRC, Endometrial carcinoma, Gastric, Small intestine, Biliary cancer	FDA Approval (OncoKB levels of evidence): <b>L1 - FDA-recognized</b>	All solid tumors	

The report can be exported as a **PDF** or **JSON** formats.

- 1 Assay Name
- 5 Assigned Clinician
- 9 Reference Classification based on Multiple Databases\* (final classification curated by the lab)
- 2 Customizable Logo
- 6 Sample Details
- 10 Therapy Options with a Match to Gene Alteration / MSI (displayed drug(s) selection done by the lab)
- 3 Patient Information
- 7 EMA Approved Therapies
- 11 Effective (green) or Resistance (red) Status of the Therapy Linked to Gene Alteration
- 4 Lab's Own Conclusions
- 8 Variant Allele Frequency (VAF)
- 12 OncoKB™ Level of Evidence (incl. FDA approval status, if applicable)

\*ClinVar, OncoKB, OMIM, gnomAD, dbSNP, Mastermind