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

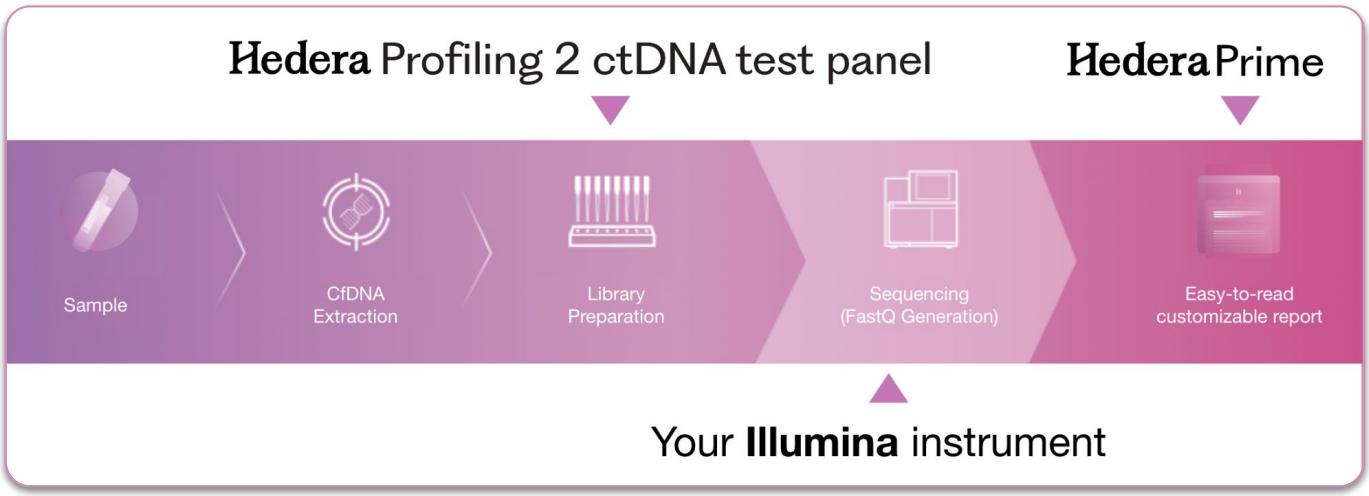
The panel detects a broad range of cfDNA variants as well as MSI

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**

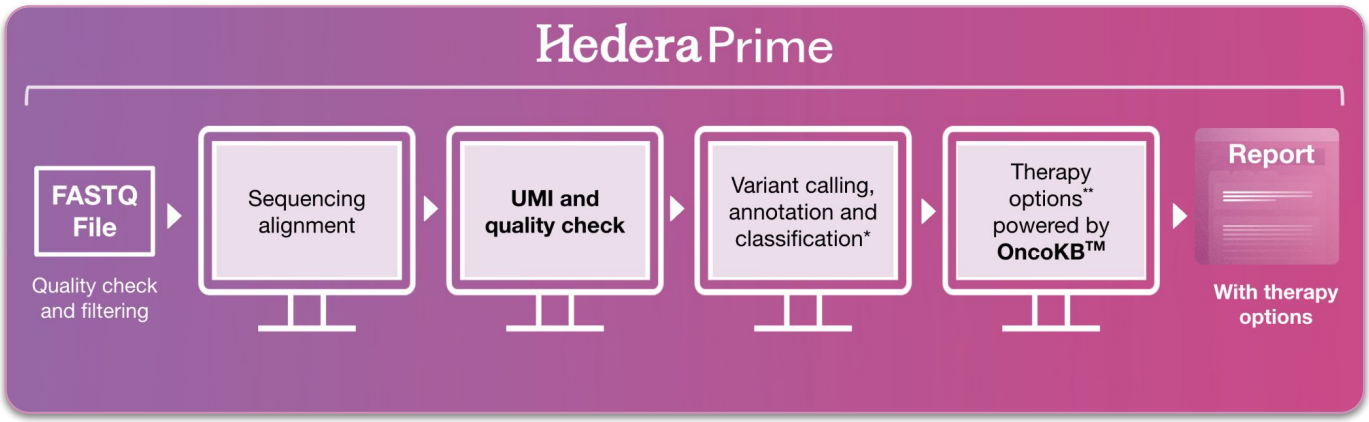
Hedera Profiling 2 ctDNA test panel swiftly integrates into your workflow

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

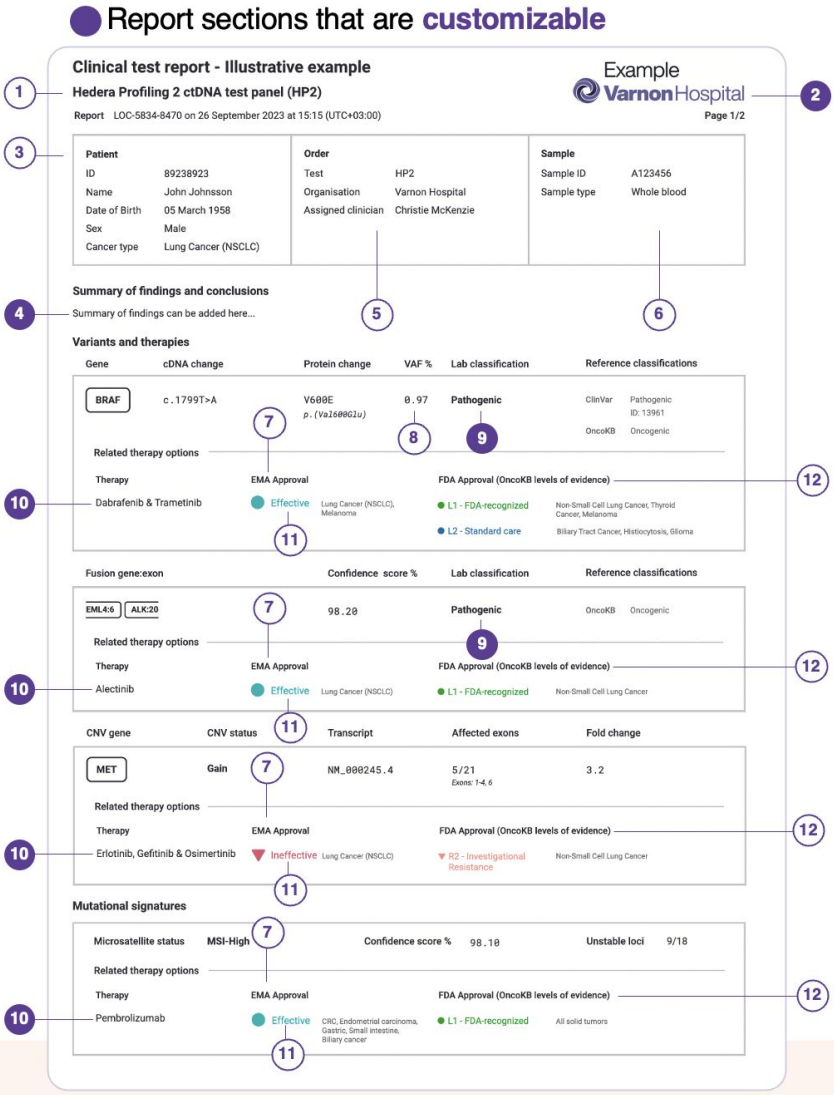


- **Hedera Prime** was developed with and for the healthcare community (**140+ experts' feedback** collected & continuously leveraged for R&D purposes)
- The report is **customizable** and can be exported as **PDF or JSON formats**

* 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



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

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

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

HP2_PSO_October 2023_v2