New Study Validates K-TRACK BO (Blood-Only) Performance for ctDNA-MRD Detection

K-TRACK BO is a tumor-naïve, multi-omics assay that provides clinicians with results covering both genomic profiling and ctDNA-MRD monitoring, supporting real-world decision-making when tumor tissue is unavailable.

In many real-world oncology settings, high-quality tumor tissue is limited or simply unavailable - yet clinicians still need reliable tools to predict recurrence risk and assess treatment response.

This retrospective study evaluates the K-TRACK BO assay, which integrates mutation detection (using both amplicon and hybridization sequencing) with the analysis of copy-number alterations (CNAs) and fragmentomics from a single blood draw to detect ctDNA-MRD (minimal residual disease) across solid tumors.

GENE SOLUTIONS
K-TRACK™ BO
THERAPEUTIC ADVANCES in Medical Oncology

Retrospective study

Tumor-naïve multimodal profiling of circulating tumor DNA to detect minimal residual disease in solid tumors

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Link to full-text
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Key Advantages of the K-TRACK BO Assay:

Only 10ml Blood Sample

Blood-only, tumor-naïve approach that does not require FFPE tissue, yet delivers performance comparable to tumor-informed assay (K-TRACK)

Multimodal Profiling

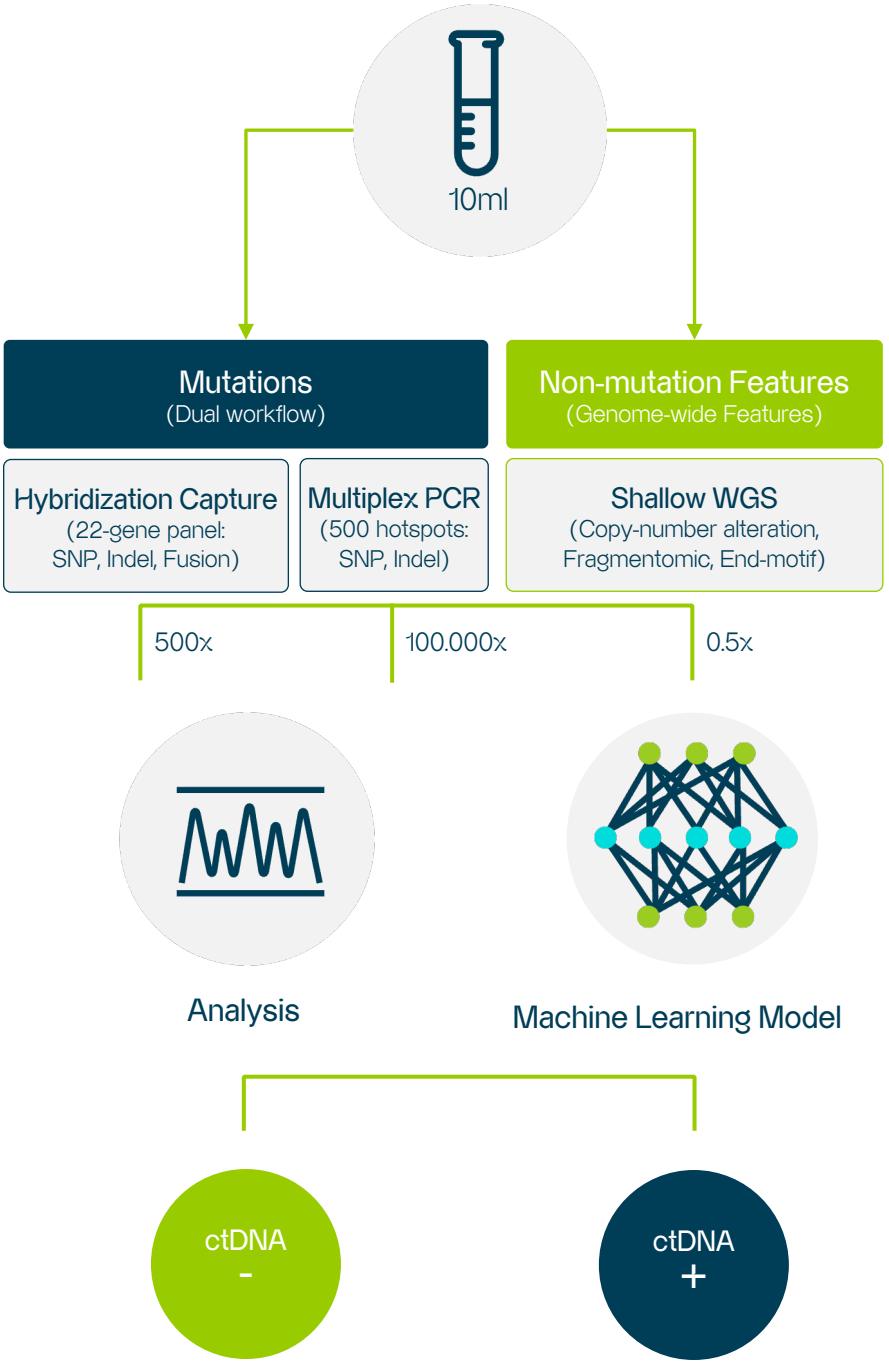
- Amplicon sequencing: ultra-deep coverage (100.000x) to detect low VAF mutations.
- Hybrid-capture sequencing: broader coverage, including fusions.

Integrated Multi-omics, AI model

- Combining mutation detection with genome-wide features (CNA and fragmentomics) increased ctDNA detection sensitivity by >10% in metastatic-stage patients ($p < 0.05$).
- Repurposed hybrid-capture cfDNA libraries for shallow WGS - simplifying workflow and reducing cost compared to other assays.

CHIP Filtering Improves Specificity

- CHIP filtering via WBC sequencing minimized false positives (e.g., common TP53 variants at VAF <1%).



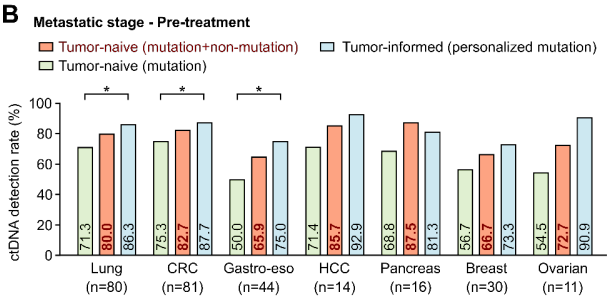
ctDNA, circulating tumor DNA; PCR, polymerase chain reaction; WGS, whole genome sequencing; SNP, single nucleotide polymorphism; AI, artificial intelligence; CNA, copy number alteration; VAF, variant allele frequency; CHIP, clonal hematopoiesis of indeterminate potential; WBC, white blood cells

Swipe right for detailed results

The addition of non-mutation features (CNAs and fragmentomics) in the metastatic stage significantly

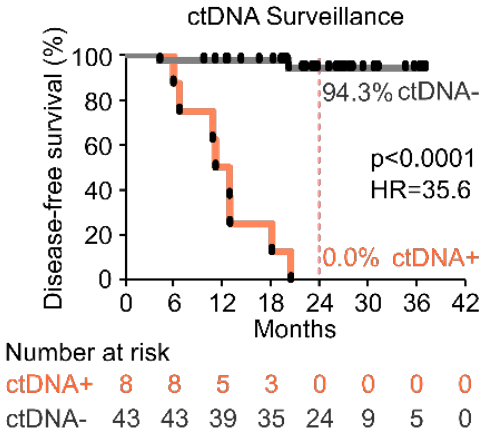
Improved the sensitivity of ctDNA detection compared with mutation-only methods, with performance comparable to the standard tumor-informed assay (K-TRACK).

ctDNA detection increased by up to **19%**



Surveillance ctDNA status during post-surgical serial monitoring was strongly predictive of clinical relapse

Colorectal cancer



80.0%
Sensitivity to relapse

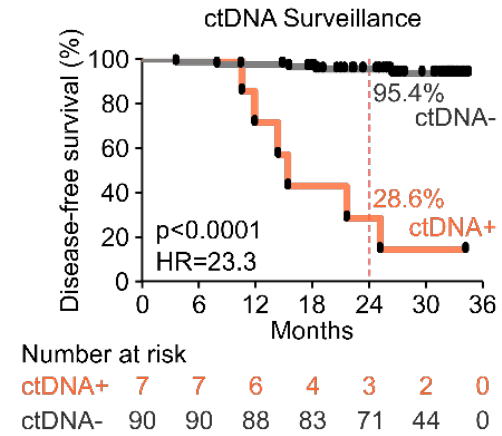
100.0%
Specificity

The 24-month DFS of patients:
ctDNA (+) = 0.0%
ctDNA (-) = 94.3%

Median lead time before clinical relapse

5.7
Months

Breast cancer



54.5%
Sensitivity to relapse

98.8%
Specificity

The 24-month DFS of patients:
ctDNA (+) = 28.6%
ctDNA (-) = 95.4%

Median lead time before clinical relapse

5.5
Months

ctDNA, circulating tumor DNA; CNA, copy number alteration; CRC, colorectal cancer; HCC, hepatocellular carcinoma; VAF, variant allele frequency; HR; hazard ratio

Swipe right for case studies

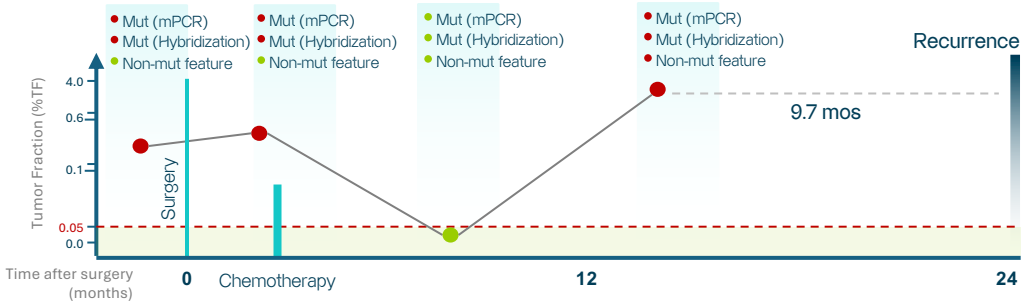
Clinical applications: Case studies

Positive Negative

Breast cancer | Stage III, luminal B

41-year-old | Female

Recurrence | Lead time: 9.7 months

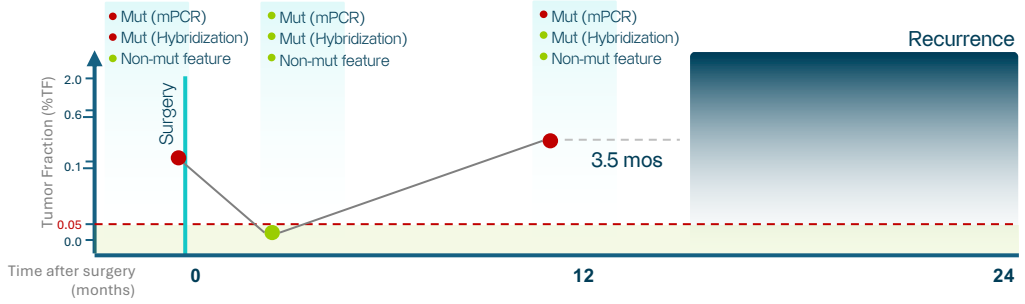


ctDNA detected 9.7 months before clinical recurrence, with strong correlation across all 3 components: mutations (amplicon + hybridization) and non-mutation features.

Colon cancer | Stage IIA

65-year-old | Male

Recurrence | Lead time: 3.5 months

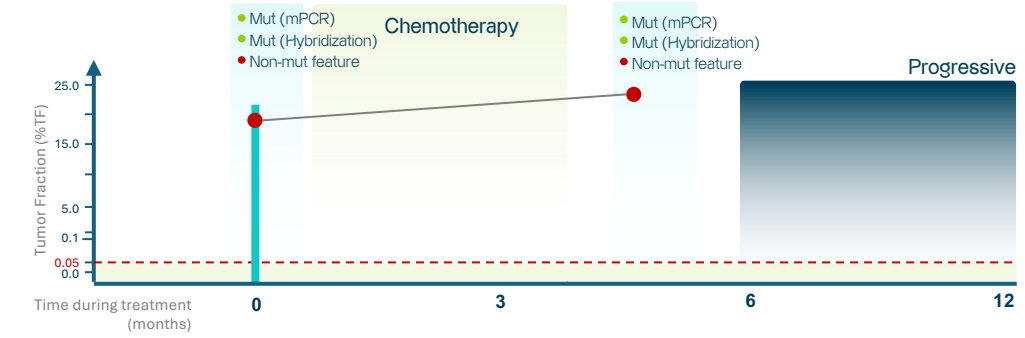


ctDNA detected 3.5 months earlier than recurrence, highlighting the sensitivity of amplicon sequencing for low-level ctDNA.

Breast cancer | Metastatic

36-year-old | Female

Progressive disease

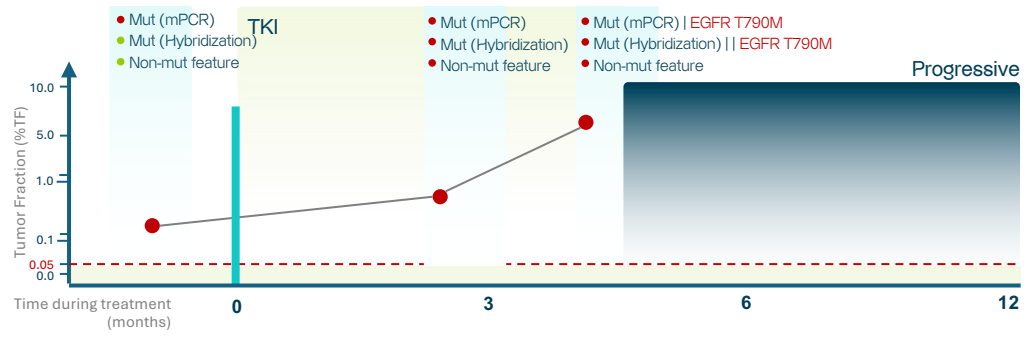


ctDNA persistence after chemotherapy predicted progression; only non-mutation features were positive, underscoring their role in advanced disease.

Lung cancer | Stage IIIB

68-year-old | Female

Progressive disease



ctDNA monitoring revealed EGFR T790M resistance mutation, help guiding therapy adjustment.

mut, mutation; mPCR, multiplex polymerase chain reaction; ctDNA, circulating tumor DNA