GENE SOLUTIONS K-TRACK™ K-TRACK™ BO

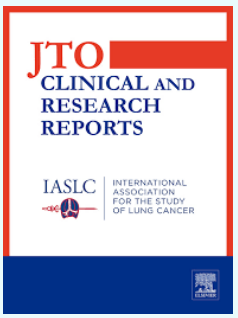
K-TRACK Portfolio in NSCLC:

A Direct Comparison of Tumor-informed and Tumor-naïve ctDNA

Newly Published Study in JTO CRR

Brief Report: Direct comparison of tumor-informed and tumor-naïve ctDNA assays for recurrence detection in early-stage non-small cell lung cancer

Scan QR code to read full-text



Minimal residual disease (MRD) detection through circulating tumor DNA (ctDNA) is transforming cancer surveillance. In early-stage NSCLC, recurrence risk is significant even after surgery. Yet, MRD testing often faces one major barrier: tissue quality.

- Tumor-informed ctDNA assays (like K-TRACK) are personalized and highly sensitive, but require tumor tissue.
- Tumor-naïve ctDNA assays (like K-TRACK BO) are tissue-independent, faster, and easier to apply - but can they match the performance?

This first-of-its-kind study in NSCLC applied both assays on the same patient samples - with the same sequencing platform - to give an unbiased, real-world comparison. It answers the pressing question:

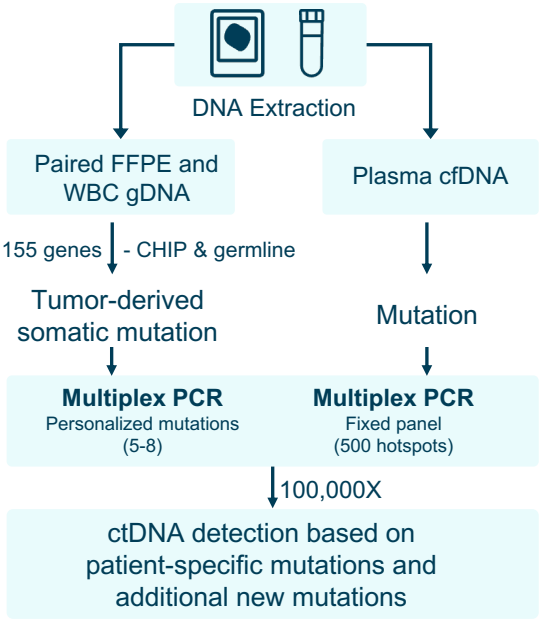
When tissue samples are limited, can blood-only tests deliver reliable results

Key takeaways

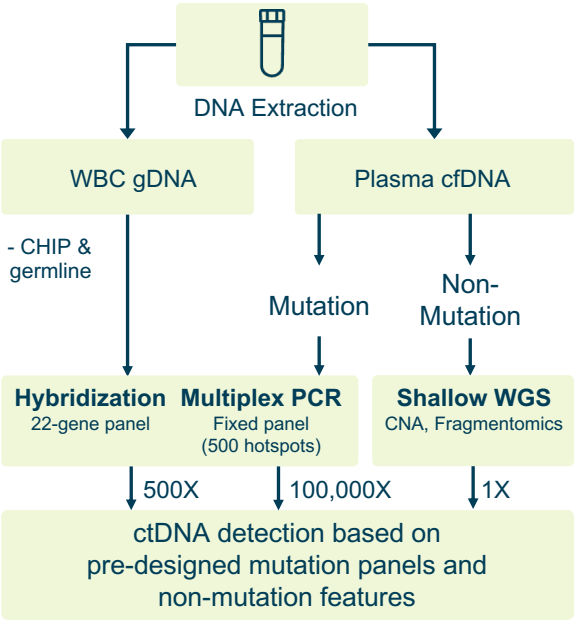
- Both approaches strongly predict recurrence: Post-operative ctDNA positivity was associated with markedly worse 24-month disease-free survival (DFS), with hazard ratios >100 ($p < 0.0001$).
- Tumor-informed K-TRACK delivers slightly higher sensitivity & specificity for detecting recurrence, while K-TRACK BO provides a reliable alternative when tissue is not available.
- ctDNA positivity preceded clinical recurrence by up to 14.4 months (median lead time: ~2–3 months), opening a window for earlier intervention or intensified follow-up.

Innovative Integrations Powering K-TRACK Methods

K-TRACK
Tumor-informed approach



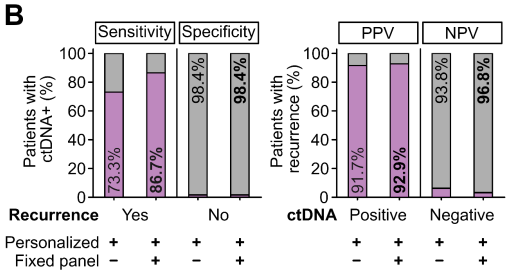
K-TRACK BO
Tumor-naïve approach

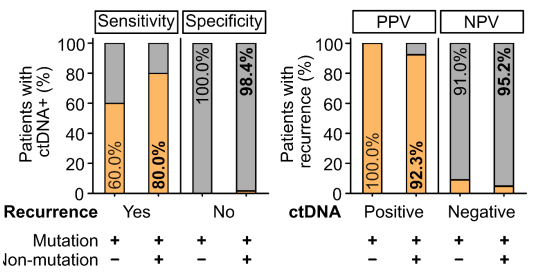


Recurrence Detection
Clinical Performance

98.4% Specificity
86.7% Sensitivity
PPV: 92.9%
NPV: 96.8%
Lead time: up to 14.4 months

Specificity **98.4%**
Sensitivity **80.0%**
PPV: 92.3%
NPV: 95.2%
Lead time: up to 14.4 months





The **500-hotspot lung panel** increased sensitivity by **13.4%**

Adding **non-mutation features** increased sensitivity by **20.0%**

Translating Into Real-world Clinical Practice

Post-operative

Risk Stratification

Risk stratify patients after surgery to help identify those with residual disease who may benefit from adjuvant treatment for high-risk individuals

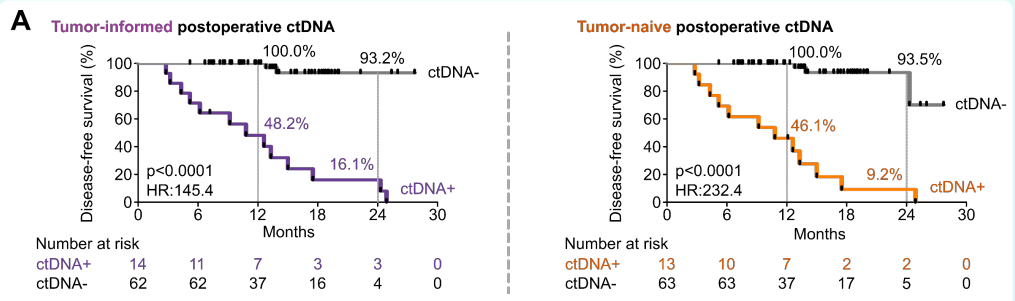
Monitoring

Monitor and help detect recurrence ahead of conventional tools with serial ctDNA testing.

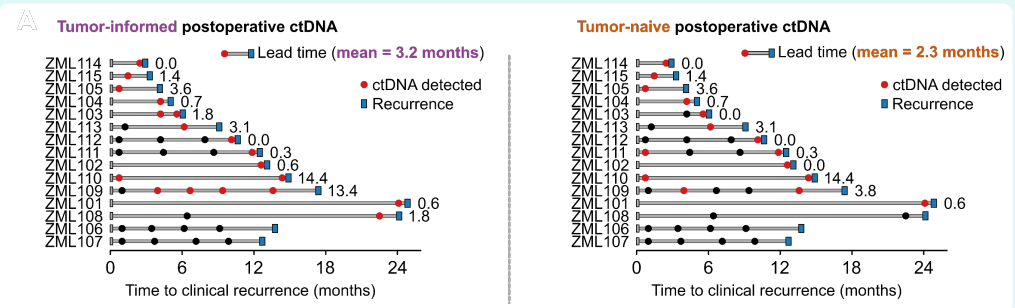
Identify new resistance mutation.

Postoperative **ctDNA positivity strongly predicts** lower 24-month DFS rates

At 24 months, ctDNA-positive patients have very high-risk of early relapse and extremely poor DFS (HR >100). ctDNA-negative ≈ 93% DFS vs ctDNA-positive 16.1% (informed) / 9.2% (naïve).



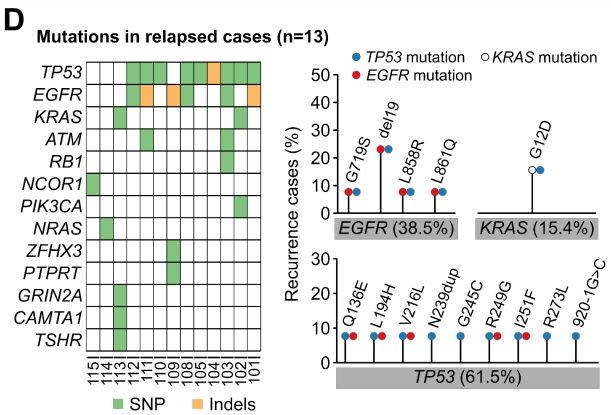
ctDNA positivity precedes **early clinical recurrence** by up to 14.4 months



The **fixed 500-hotspot** panel can reveal **resistance mutations**

Early plasma mutations most often *TP53* (61.5%), *EGFR* (38.5%), *KRAS* (15.4%); frequent TP53+EGFR co-mutations.

In addition to recurrence detection, the fixed hotspot panel can also help reveal resistance mutations at relapse - information that may support downstream therapy planning in appropriate contexts



Choosing the Right Approach: Tumor-Informed K-TRACK vs Tumor-Naïve K-TRACK BO

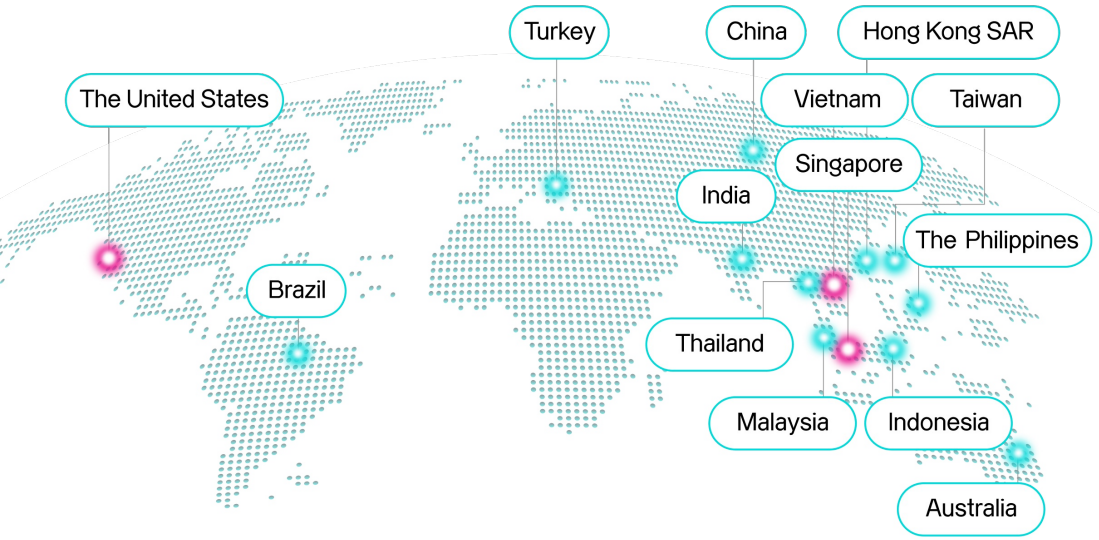
K-TRACK

- When tissue is available and adequate
- Best for centers where high-quality FFPE is routinely available.
- Offers slightly higher sensitivity and specificity for both analytical ctDNA detection and recurrence prediction.
- The 500-hotspot lung panel can:
  - ✓ Improve ctDNA detection when FFPE quality is suboptimal.
  - ✓ Reveal new resistance mutations at relapse, potentially informing targeted therapy choices.

K-TRACK BO (blood-only)

- Designed for scenarios where:
  - ✓ Tissue is not available,
  - ✓ Tissue quantity/quality is insufficient for NGS, or
  - ✓ Turnaround time for tissue testing would be too long.
- Combines targeted mutations (22-gene panel + 500-hotspot) with non-mutation features (fragmentomics and CNA) to improve sensitivity.
- Comparable prognostic power vs tumor-informed.

Together, the K-TRACK portfolio offers a flexible, real-world ctDNA-MRD solution for diverse clinical settings



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