

Unique Combination

for Precision Oncology

Dual Tumor & Liquid Biopsy Profiling



Tumor Profiling

164-gene panel



Liquid Biopsy Profiling

125-gene panel for Thoracic cancers

113-gene panel for Digestive cancers

149-gene panel for Breast and
Gynecological cancers

3 essential biomarkers

01. Actionable & resistance mutations
02. Microsatellite instability (MSI) status
03. Germline mutations (Pharmacogenomics –
DPYD and Hereditary cancer risk)

- Delivers clinically relevant mutations and biomarkers aligned with approved targeted therapies and immunotherapies.
- Uncovers additional actionable mutations that may be missed by tissue-only sampling through a dual-profiling approach.
- Enables real-time monitoring of tumor evolution and emerging resistance mutations over time.
- Optimized for low DNA input (minimum 15 ng) and variable specimen quality, ensuring reliable results in challenging cases.

High-Sensitive ctDNA-MRD Monitoring



ctDNA-MRD Monitoring

01. Tumor-informed: LOD = 0.01%

- Tumor-derived: Up to 20 personalized mutations
- Tumor-agnostic: 113 – 149 genes depending on the cancer type

02. Tumor-naïve: LOD = 0.05%

- Tumor-agnostic: 113 – 149 genes depending on the cancer type
- Genome-wide features (CNA, fragmentomics)

- One of Asia's most clinically validated ctDNA-MRD tests, supported by strong evidence, including prospective trials across 5 cancer types (800+ patients) and robust real-world data across 6 cancer types (2,000+ patients).
- Widely adopted by leading cancer centers in Asia, with 15,000+ tests performed and featured in 10+ ongoing clinical trials across 15+ hospitals in 3 countries.
- High-sensitivity ctDNA-MRD enables early recurrence risk assessment, relapse prediction well before standard imaging, and treatment assessment.

Scope of the test & Turn-around time

Panel	Cancer Type	Somatic mutations	ctDNA-MRD status	MSI status	Germline Mutations	
					Hereditary Cancer Risk	Pharmacogenomics
Thoracic Cancers	Lung	✓	✓	✓	✓	
	Mediastinal	✓	✓	✓	✓	
	Mesothelioma	✓	✓	✓	✓	
Digestive Cancers	Ampulla of Vater	✓	✓	✓	✓	✓
	Bladder	✓	⚡	✓	✓	
	Cholangiocarcinoma	✓	✓	✓	✓	
	Colorectal	✓	✓	✓	✓	✓
	Esophageal	✓	✓	✓	✓	✓
	Gallbladder	✓	✓	✓	✓	
	Gastric	✓	✓	✓	✓	✓
	GIST	✓	✓	✓	✓	
	Liver	✓	✓	✓	✓	
	Pancreatic	✓	✓	✓	✓	✓
Breast & Gynecological Cancers	Breast	✓	✓	✓	✓	✓
	Cervical	✓	✓	✓	✓	
	Endometrial	✓	✓	✓	✓	
	Fallopian Tube	✓	✓	✓	✓	
	Ovarian	✓	✓	✓	✓	
	Uterine	✓	✓	✓	✓	
Other	Prostate	✓		✓	✓	

✓ Applicable to all cancer stages

⚡ High risk of false-negative results in the early stage due to low ctDNA-shedding rate

For K-TRACK BO:

- ctDNA-MRD and somatic mutation results for bladder, cervical, endometrial, fallopian tube, and uterine cancers have a high risk of false-negative results in the early stage due to low ctDNA-shedding rates
- MSI results only apply to Colorectal cancer.



5 working days

Genomic profiling report

after receiving
FFPE samples

Result:

01. Actionable & resistance mutations
02. Microsatellite instability (MSI) status
03. Biomarkers with unknown significance



8 working days

ctDNA-MRD baseline report

after receiving both
FFPE & blood samples

Result:

01. ctDNA-MRD baseline status
02. Germline mutations (optional)
03. Actionable/resistance mutations in liquid biopsy

1st 2nd 3rd 4th 5th

8 working days

ctDNA-MRD monitoring report

after receiving
blood samples

Result:

01. ctDNA-MRD monitoring status with personalized mutations profile
02. Actionable/resistance mutations in liquid biopsy

Analytical Performance

	Tissue FFPE sample				
		Minimum tumor fraction	Sensitivity ¹	Specificity ¹	Positivity threshold
Targeted therapy (FFPE)	DNA-based somatic variant detection (at VAF = 5%) ²				
	SNVs	20%	>99%	>99%	≥5% VAF
	INDELs	20%	>99%	>99%	
	Amplification	20%	>99%	>99%	≥2 copy ratio
	Fusion (common fusions)	20%	94%	>99%	≥2 reads at breakpoint
Hereditary cancer (WBC)	Germline variants				
	SNVs		>99%	>99%	
	INDELs		>99%	>99%	
Immunotherapy ³ (FFPE)	MSI	20%	94%	>99%	≥20%

QUALITY CONTROL CRITERIA			
		Raw data	Deduplication data
FFPE	Median depth	900X	500X
	90% target regions covered at	400X	200X
WBC	Median depth	400X	300X
	90% target regions covered at	300X	200X

1. Sensitivity and specificity were determined using standard reference samples: Seraseq® gDNA TMB Mix, Seraseq® FFPE BRCA1/2 LGR Reference Material, Seraseq® Breast CNV Mix, Seraseq® Lung & Brain CNV Mix (SeraCare, USA); Oncospan gDNA, BRCA germline I gDNA, Pan-Cancer 6-Fusion Panel, Tru-Q0 DNA Reference Standards (Horizon, USA); EMQN RNA fusion reference samples.

2. Somatic SNVs and INDELs at 1%≤ VAF <5% were detected with 82% sensitivity and >99% specificity.

3. MSI performance for matched tumor-normal analysis. For FFPE-only testing, accuracy of MSI analysis was reduced by 5-10%.

	Liquid biopsy sample				
		Minimum tumor fraction	Sensitivity ⁴	Specificity ⁴	Positivity threshold
Targeted therapy (Plasma)	Somatic variants (at VAF = 0.1%) ⁵ – Tumor-informed				
	SNVs		95.6%	>99%	≥2 reads
	INDELs (<20 bp)				
	Fusion (common fusions)	0.1%	90.5%	>99%	≥2 reads at breakpoint
	Amplification	2%	81.3%	>99%	≥2 copy ratio (2.2 copies)
ctDNA-MRD (sample-level)	Tumor-informed mutations	0.01%	95.3%	>98%	≥1 positive mutation
QUALITY CONTROL CRITERIA					
		Raw data	Deduplication data		
ctDNA	Median depth	20,000X	5,000X		
	90% target regions covered at	10,000X	2,500-5,000X		

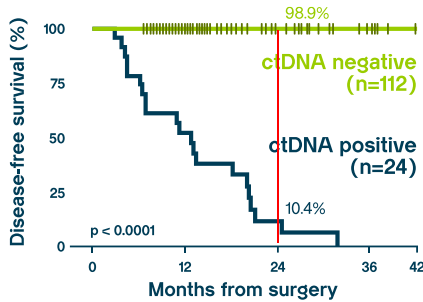
4. Sensitivity and specificity were determined using clinical sample and standard reference samples: Seraseq® ctDNA MRD Panel Mix (SeraCare, USA); Non-small cell lung cancer ctDNA panel (Horizon, USA).

5. Somatic SNVs and INDELs at 0.01%≤ VAF <0.1% were detected with 63.8% sensitivity and >99% specificity.

Clinically Validated Performance of ctDNA-MRD Monitoring

Colorectal cancer

Clinical trial + Real-world data^{1,3,4,6}



91.7% sensitivity to relapse

Specificity = 98.2%

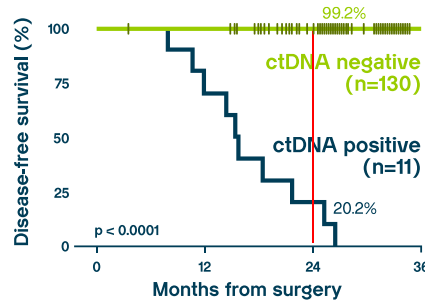
PPV = 91.7%; NPV = 98.2%

24-month Disease-free survival: 10.7%

Lead time: up to 19.5 (months)

Breast cancer (All subtypes)

Clinical trial^{2,3,4,5}



90.9% sensitivity to relapse

Specificity = 98.8%

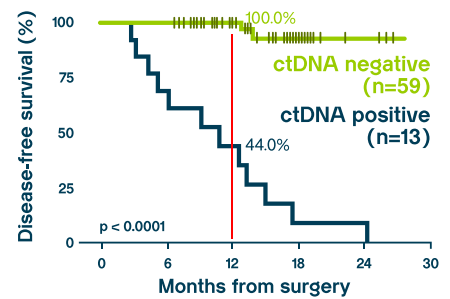
PPV = 90.9%; NPV = 98.8%

24-month Disease-free survival: 20.2%

Lead time: up to 13.2 (months)

Lung cancer

Real-world Data^{3,4}



85.7% sensitivity to relapse

Specificity = 98.3%

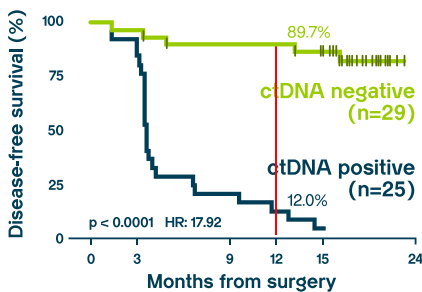
PPV = 92.3%; NPV = 96.6%

12-month Disease-free survival: 44.0%

Lead time: up to 14.4 (months)

Hepatocellular carcinoma

Clinical trials^{3,4}



82.8% sensitivity to relapse

Specificity = 96.0%

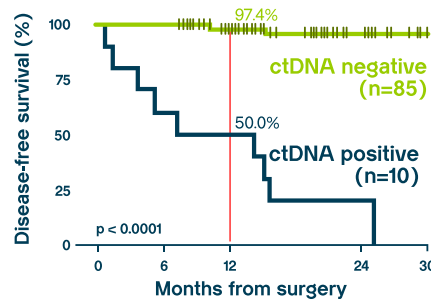
PPV = 96.0%; NPV = 82.8%

12-month Disease-free survival: 12.0%

Lead time: up to 7.3 (months)

Gastric cancer

Ongoing clinical trial + Real-world data^{3,4}



75.0% sensitivity to relapse

Specificity = 98.8%

PPV = 90.0%; NPV = 96.5%

12-month Disease-free survival: 50.0%

Lead time: up to 6.1 (months)

1. Front Oncol vol. 12 1069296. 12 Dec. 2022
2. Mol Oncol vol. 17,4 (2023): 598–610
3. CO Glob Oncol vol.9, Supp_1 (2023): 110–110
4. Annals of Oncology 34 (2023): S1624
5. APBCS 2024
6. ESMO Real World Data and Digital Oncology 6 (2024): 100076.



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