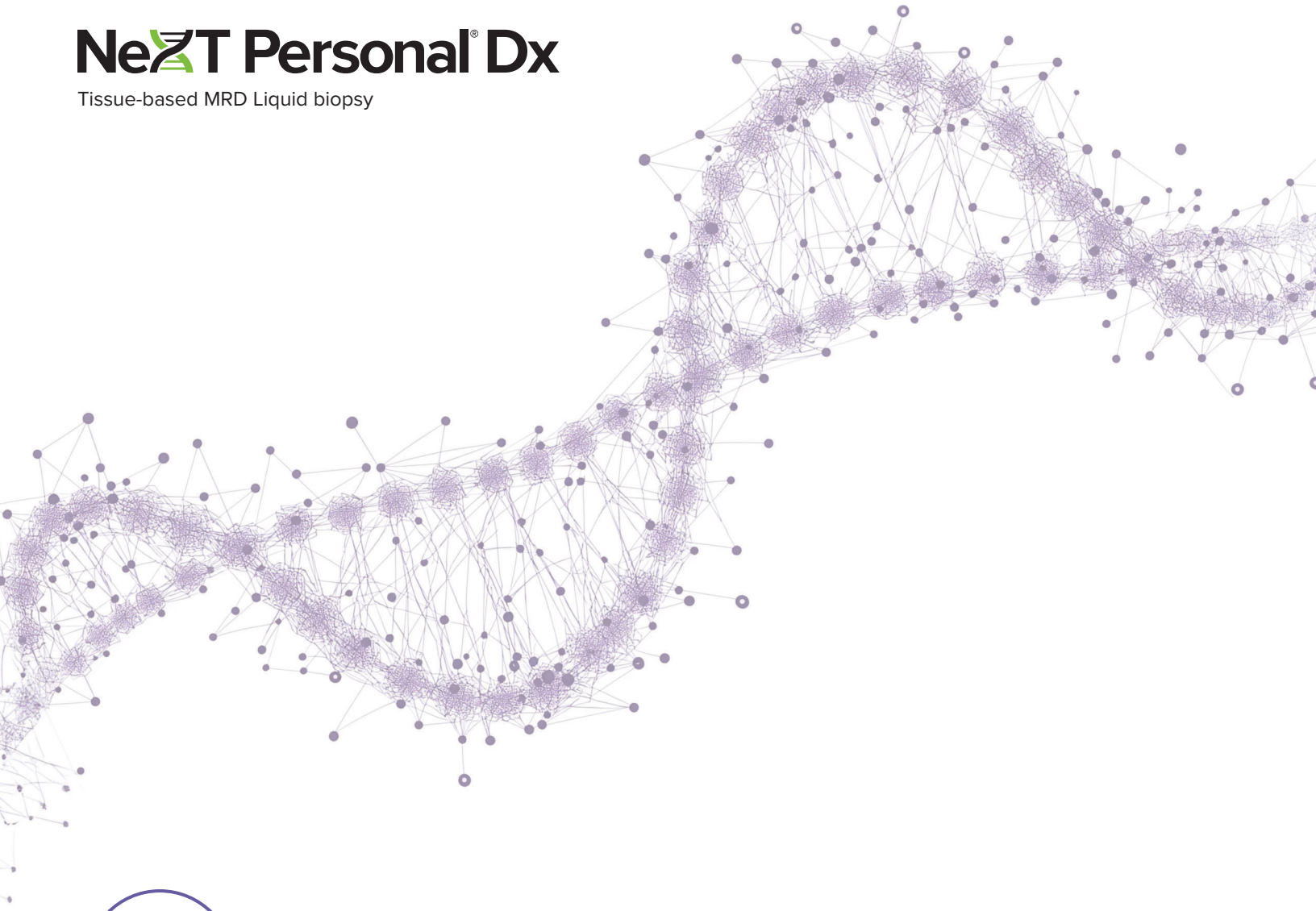
NeXT Personal® Dx

Tissue-based MRD Liquid biopsy



Track early-stage breast cancer with ultra-sensitive molecular residual disease (MRD) testing using NeXT Personal® Dx

Data presented at ASCO 2024 from study done in collaboration with Royal Marsden Hospital and Institute of Cancer Research, London.

Personalis®

Sensitivity matters for patients with breast cancer

In a study with early-stage breast cancer patients (n=78) in collaboration with Professor Nicholas Turner at **The Royal Marsden Hospital** and the **Institute of Cancer Research, London:** NeXT Personal® detected recurrence, on median, about **~15 months ahead of scans.**[1]

Cancer type:
early-stage breast cancer

Subtypes:
ALL (HR+ HER2-; HER2+; TNBC)

Tumor grade:
II, III, not known

Median follow up time:
~6 years

~15
month lead time to relapse[1]

100%
negative predictive value (NPV)[1]

Ultra-low detection below
<100 PPM
in the ultra-sensitive range[1]

In this study:

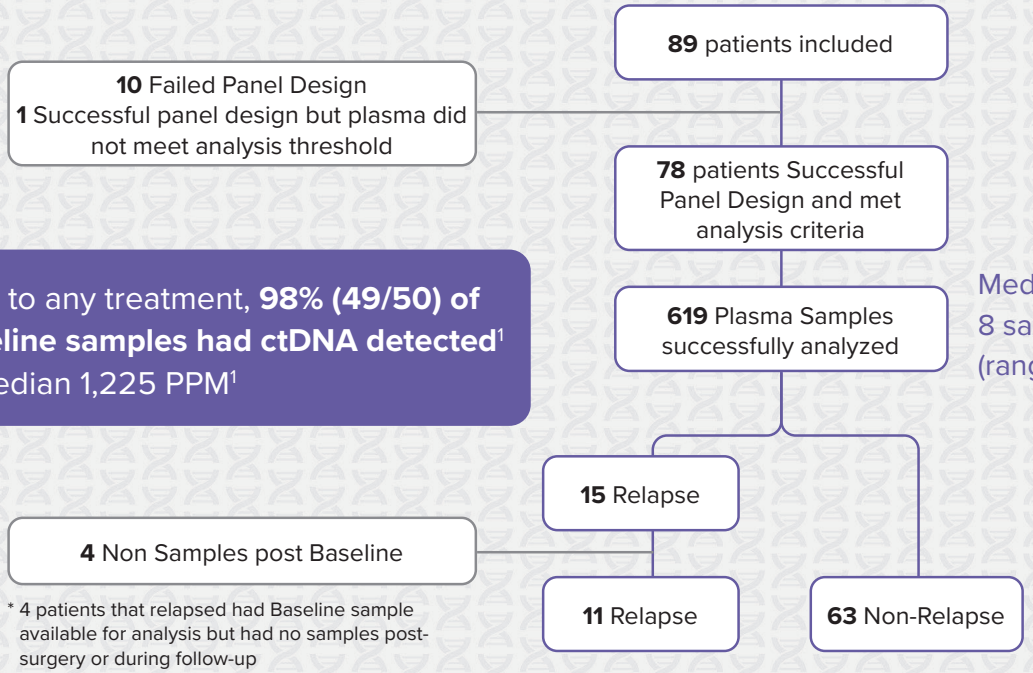
- **100% (11/11) of patients** that relapsed had detectable circulating tumor DNA (ctDNA) prior to relapse[1]
- **100% (60/60) of patients** that had undetectable ctDNA longitudinally after surgery did not relapse[1]
- Patients who started with detectable ctDNA and subsequently reached undetectable ctDNA in multiple repeat serial testing did not relapse[1]

Patient cohort

N	78 (100%)
Median Age at Diagnosis	50 (25-77)
Menopausal Status	
Pre	44 (56.4%)
Post	29 (37.2%)
Not Known	5 (6.4%)
Nodal Status	
Y	41 (52.6%)
N	34 (43.5%)
Not Known	3 (3.9%)
Histological Subtype	
IDC	65 (83.3%)
ILC	4 (5.1%)
Invasive	7 (9%)
Not Known	2 (2.6%)
Tumor Grade	
2	13 (16.7%)
3	61 (78.2%)
Not Known	4 (5.1%)

Receptor Subtype	
HR+ HER2-	18 (23.1%)
HER2+	35 (44.8%)
TNBC	23 (29.5%)
Not Known	2 (2.6%)
pCR	
Y	30 (38.4%)
N	46 (59%)
Biopsy NA	2 (2.6%)
Neoadjuvant	
Y	76 (97.4%)
N	2 (2.6%)
Adjuvant	
Y	36 (46.1%)
N	41 (52.6%)
Not Known	1 (1.3%)
Adjuvant Endocrine	
Y	40 (51.3%)
N	38 (48.7%)

High pre-treatment detection with ultra-sensitive **NeXT Personal assay**[1]



Prior to any treatment, **98% (49/50) of baseline samples had ctDNA detected**[1]
- Median 1,225 PPM[1]

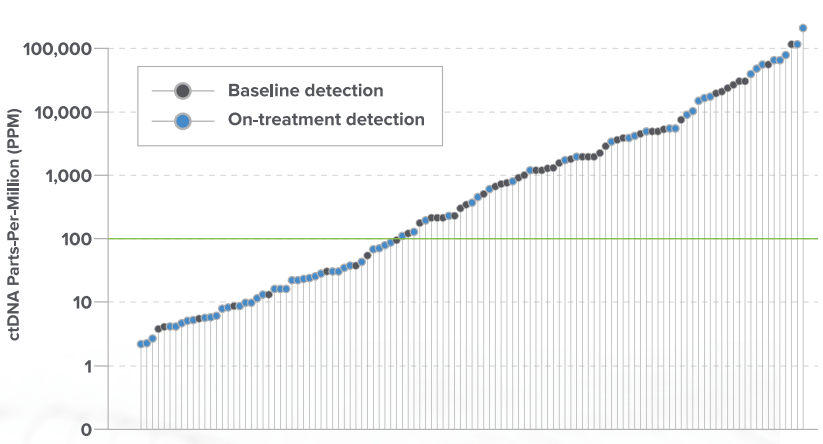
* 4 patients that relapsed had Baseline sample available for analysis but had no samples post-surgery or during follow-up

39% of detections could have been missed with a less sensitive assay[1]

39% (45/115) of ctDNA detections were in the ultra-sensitive range below **100 Parts Per Million (PPM)**.[1]

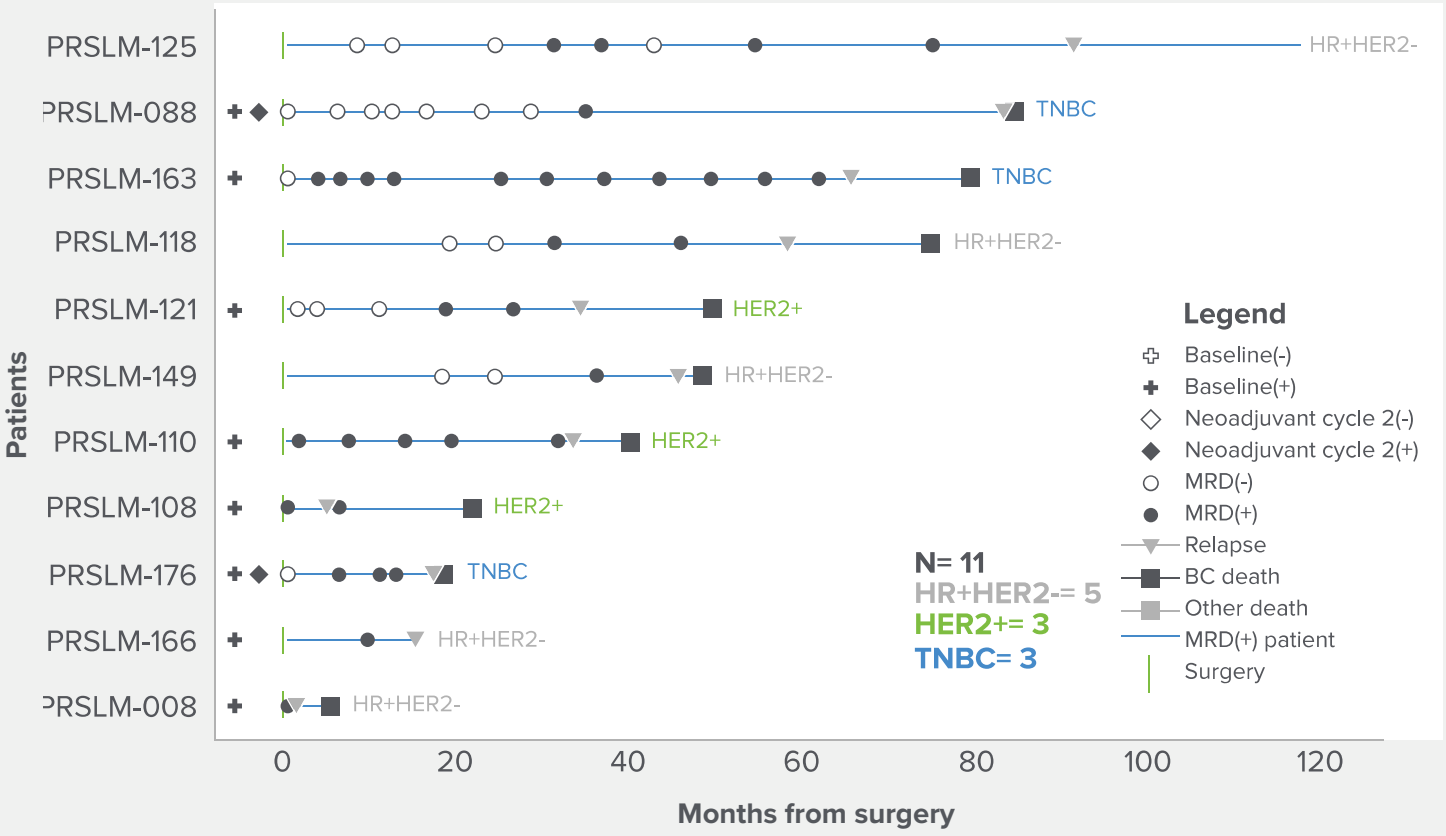
Median detection was 366 PPM (range 3.73-112,011)[1]

Ultra-low ctDNA detection levels



Ultra-sensitive ctDNA detection with NeXT Personal during post-surgical serial monitoring was strongly predictive of clinical outcomes[1]

Swimmer plot depicting patients who clinically relapsed

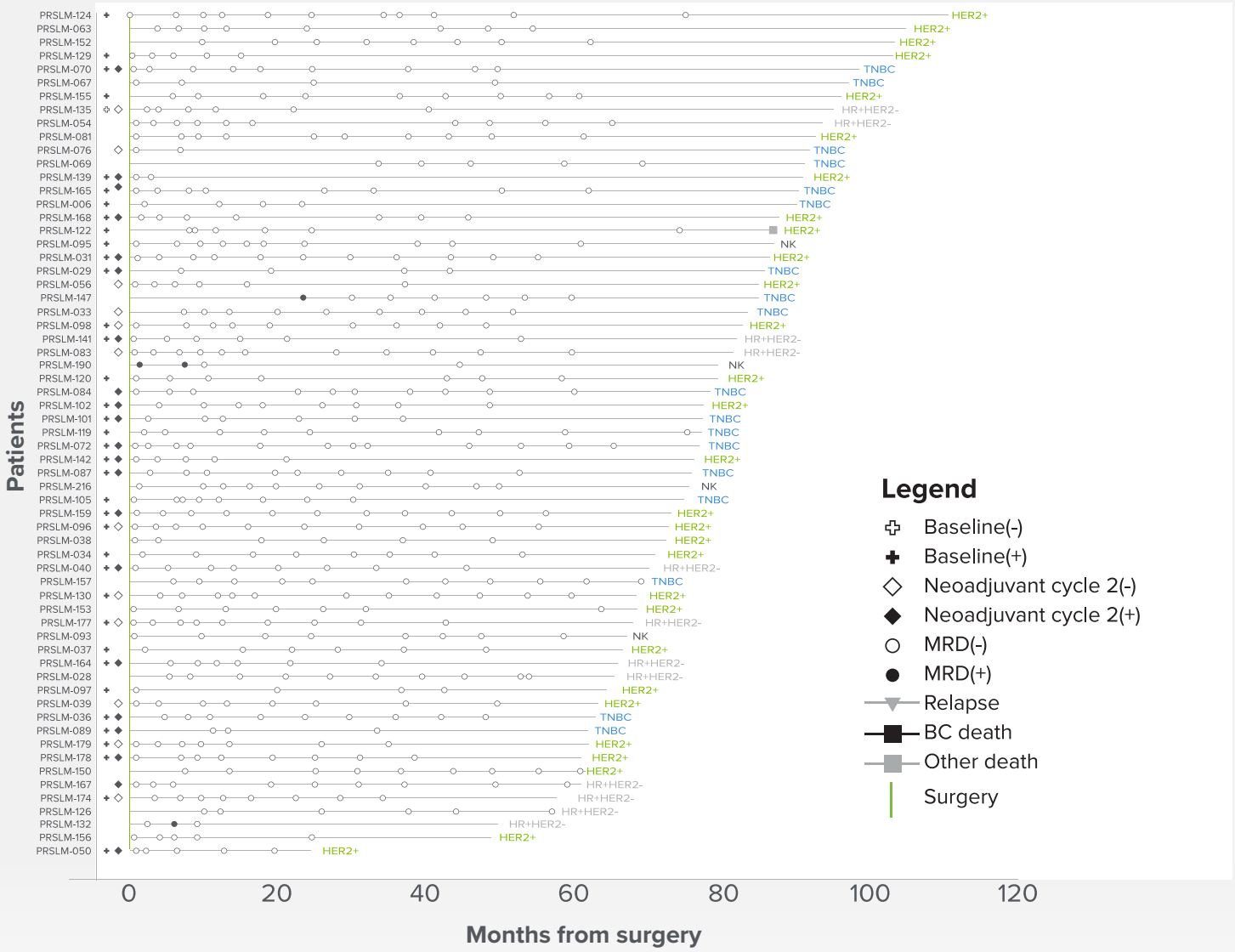


100% (11/11) of patients who relapsed had detectable ctDNA prior to relapse[1]

- Median ctDNA level of first detection = 13.1 PPM[1]
- Median lead time ~15 months (range 4-41 months) over clinical relapse[1]

Ultra-sensitive NeXT Personal testing demonstrated the **importance of a negative result** for patients with early-stage breast cancer[1]

Swimmer plot depicting patients who did not clinically relapse



100% (60/60) of patients that had repeat undetectable ctDNA longitudinally after surgery did not relapse (NPV)[1]

- 3 additional patients were initially positive post-surgically but subsequently cleared ctDNA longitudinally and did not relapse[1]

Powered to see MRD that previously avoided detection[1-6]

NeXT Personal® Dx is a tumor-informed molecular residual disease (MRD) liquid biopsy with ultra-high sensitivity and specificity. Leveraging whole-genome sequencing (WGS), advanced bioinformatics, and comprehensive personalized signatures based on up to 1800 variants, NeXT Personal® Dx achieves industry-leading performance to empower earlier insights that can shape the trajectory of cancer care.[2-3]

Guide patient management with ultra-high analytical sensitivity and specificity

Whole-genome sequencing

Leverage WGS-based personalized signatures that target up to 1800 variants

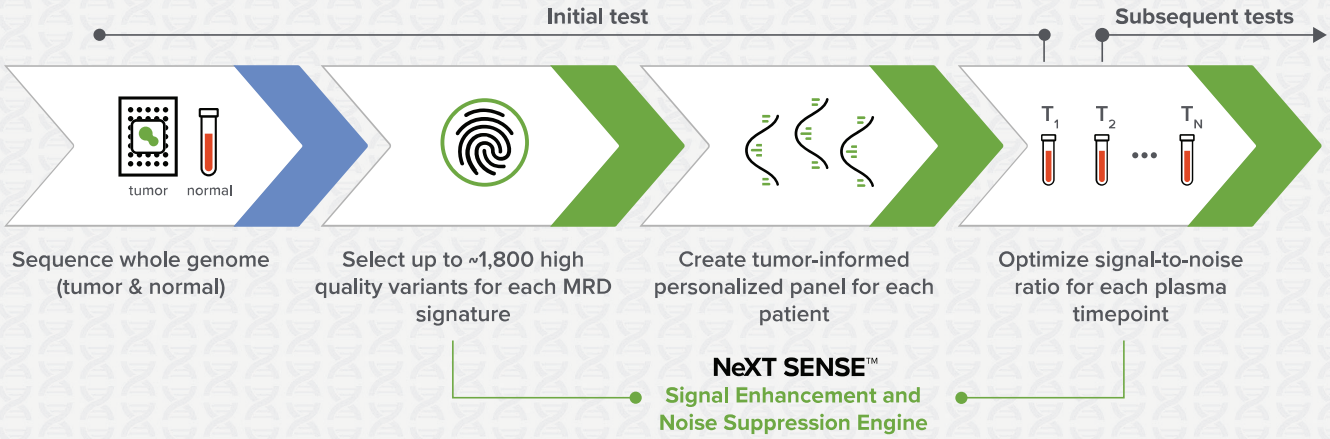
100% analytical sensitivity[2]

Detect MRD earlier at lower levels with an assay that can detect circulating tumor DNA (ctDNA) down to ~1 Parts Per Million (PPM)

100% analytical specificity[2]

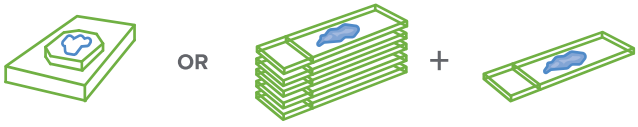
Minimize false-positives while maximizing the tumor signature with our proprietary technology

Our unique technology enables **ultra-high sensitivity and specificity**



Get insights from **less tissue and blood**

Samples needed for initial test

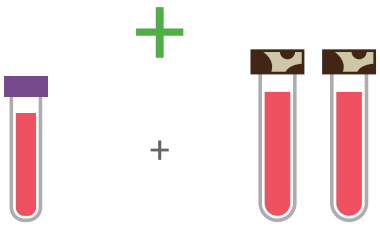


FFPE Block

Minimum 5 (10 micron thick) unstained slides

1 unstained slide or H&E slides

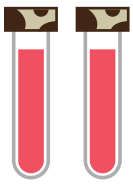
FFPE Tumor Tissue: Each initial test requires a minimum of 5, 10-micron slides (or comparable amount of tissue) OR a tissue block. BOTH require an H&E slide or additional unstained slide.



1 EDTA tube | Whole blood (6mL K2)

2 Streck tubes | Plasma (10mL Tiger Top)

Samples needed for follow-up tests



2 Streck tubes | Plasma (10mL Tiger Top)

NeXT Personal® Dx delivers exceptional performance even with small samples. Tissue and blood samples are required for the initial test to design the tumor-informed panel. Subsequent tests only require blood samples.

Take the first step toward partnership with **Personalis to shape the future of cancer care.**

LEARN MORE

personalis.com

Email:
clientservices@personalis.com

Call:
855-373-7978 (M-F 6am-5pm PST)

REFERENCES

1. Garcia-Murillas I., et al. (2024, June 2). Ultra-sensitive ctDNA mutation tracking to identify molecular residual disease and predict relapse in early breast cancer patients. ASCO Annual Meeting, Chicago, IL, United States. **2.** Northcott, Josette, et al. (2024). Analytical validation of NeXT Personal®, an ultra-sensitive personalized circulating tumor DNA assay. Oncotarget, 15, 200–218. www.oncotarget.com/article/28565/text/, https://doi.org/10.18632/oncotarget.28565. **3.** Black, JRM, et al. An ultra-sensitive and specific ctDNA assay provides novel pre-operative disease stratification in early stage lung cancer. ESMO annual meeting. 2023. **4.** Abbosh, C., et al. Phylogenetic ctDNA analysis depicts early-stage lung cancer evolution. Nature 545, 446–451 (2017). **5.** Abbosh, C. et al. Tracking early lung cancer metastatic dissemination in TRACERx using ctDNA. Nature 616, 553–562 (2023). **6.** For evaluations across Abbosh '17, Abbosh '23, and this study, while the patients were drawn from the TRACERx cohort, the specific patients analyzed may be different, which may lead to potential differences in study results.

This test is a laboratory developed test (LDT) and is performed in the CAP accredited, CLIA-certified Personalis Clinical Laboratory. The test was developed, and its performance characteristics determined by the Personalis Clinical Laboratory. It has not been cleared or approved by the United States Food and Drug Administration (FDA).

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