

ctDNA detection of recurrence in HR+/HER2- breast cancer

The surveillance gap in HR+/HER2- breast cancer

For survivors of HR+/HER2- breast cancer beyond 5 years, current surveillance relies primarily on clinical assessment and symptom reporting—often meaning recurrence is detected late, when disease burden may be high, and treatment options may be limited.

The clinical challenge:

- Guidelines do not recommend routine imaging or tumor markers after 5 years post-diagnosis
- Over half of all metastatic recurrences occur 5 years or later after diagnosis.
- Most recurrences are detected symptomatically, when disease burden is advanced



The solution: Ultra-sensitive molecular surveillance

RaDaR ST detects circulating tumor DNA (ctDNA) at ultra-low levels, as low as 1 ppm³, identifying molecular evidence of recurrence before imaging changes appear—providing an unprecedented window to identify clinical recurrence when disease burden is minimal.

RaDaR ST Clinical Performance

Metric	Result
Sensitivity for distant recurrence	100% ^{1,2}
Median lead time before clinical detection	16.7 months ^{1,2}
Detection threshold	As low as 1ppm ³

The 16.7-month window: what it means clinically

A median lead time of 16.7 months isn't just a statistic—it represents a fundamental shift in how recurrence is detected and managed.

	Symptomatic Detection (Current Standard)	Molecular Detection (With MRD Testing)
Patient Status	Symptomatic (pain, dyspnea, etc.)	Asymptomatic, monitored
Treatment	Systemic therapy	Potential for disease control/ intervention and clinical trials
Opportunity	Limited by disease burden and extent	Potentially optimized when disease burden is minimal



"We detected recurrence early — let's discuss additional monitoring or intervention options"

1 Lipsyc-Sharf M, de Bruin EC, Santos K, McEwen R, Stetson D, Patel A, Kirkner GJ, Hughes ME, Tolane SM, Partridge AH, Krop IE, Knape C, Feger U, Marsico G, Howarth K, Winer EP, Lin NU, Parsons HA. Circulating Tumor DNA and Late Recurrence in High-Risk Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Breast Cancer. *J Clin Oncol*. 2022 Aug 1;40(22):2408-2419.

2 Tae-Kyung Robyn Yoo et al. Circulating tumor DNA and late recurrence in high-risk, hormone receptor-positive, HER2-negative breast cancer: An updated analysis of the CHIRP study. *J Clin Oncol* 43, 3055-3055 (2025)

3 Sensitivity demonstrated across four independent analytical and clinical validation studies, with detection down to 1 part per million (ppm) under study-specific conditions. LOD95 of 11 ppm. Data on file.

Ideal Patient Population for MRD Surveillance

Target high-risk HR+/HER2- survivors beyond 5 years with these features:

- Stage II-III at initial diagnosis

Clinical Utility:

- **Negative ctDNA:** Continue standard surveillance
- **Positive ctDNA:** Consider intensified or alternative imaging options and potential for relapse
- **Serial monitoring:** Consider standard surveillance with reassurance, and serial ctDNA testing for long-term recurrence monitoring

Getting started

Start with 5-10 of your highest-risk HR+/HER2- survivors beyond 5 years:

- Offer initial ctDNA testing at next surveillance visit
- Serial monitoring every 6 months
- Evaluate integration into your practice workflow

RaDaR ST workflow

Step 1

Analyze tissue by whole exome sequencing (WES) to develop a customized panel used for initial test and subsequent monitoring

Step 2

Simple blood draw (standard phlebotomy) at surveillance visit

Step 3

Results delivered in 7-10 business days with clinical interpretation

Step 4

Serial RaDaR ST monitoring, frequency based on clinical scenario

Comprehensive Support:

- Test kits and requisition materials
- Dedicated team to support follow-up (serial) testing
- Dedicated billing and financial assistance support team
- Medical consultation available
- Clear and concise test report
- Optional mobile phlebotomy services



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