NEO GENOMICS

NEO | RaDaR® ST
Head and Neck

ctDNA detection of residual disease and recurrence in HPV-negative head and neck cancer

The two questions current methods can't answer

In HPV-negative head and neck cancer, current adjuvant therapy and surveillance methods cannot definitively answer two critical questions that determine patient outcomes.

Question 1: Did surgery remove all the cancer?

Even with pathologically negative margins, microscopic residual disease may remain undetected.

Question 2: Is the disease returning before symptoms appear?

Imaging often detects recurrence only after disease burden has grown significantly, limiting detection options.

What this means for your patients

Detecting ctDNA in HPV-negative HNSCC can mean the difference for the success of surgery and chemotherapy/radiation, a fundamental shift in how cancer treatment and recurrence is detected and managed.

	Imaging-based detection (current standard)	**Molecular detection** (with MRD testing)
Post-surgical	Uncertainty despite negative margins	Molecular assessment of resection
Recurrence detection timing	Detected when visible on imaging	Detected up to a median of 119 days before imaging changes[3]
Treatment opportunity	Limited by disease burden and extent	Optimized when disease burden is minimal

The solution: Ultra-sensitive molecular detection

RaDaR ST detects circulating tumor DNA (ctDNA) at ultra-low levels — as low as 1 ppm[1]—providing post–surgical and molecular surveillance evidence of disease long before imaging changes appear. This unprecedented sensitivity ensures no patient with recurrent disease goes undetected during the critical surveillance window.

Clinical performance in HPV-negative HNSCC (LIONESS Clinical Study[2,3])

Metric	Result
Sensitivity for recurrence	**91.3%**
Detection threshold	**As low as 2.6 ppm**
Median lead time ahead of imaging	**Nearly 4 months**

"We caught this early — let's intervene while salvage is most effective"

1. Sensitivity demonstrated across four independent analytical and clinical validation studies, with detection down to 1 part per million (ppm) under study-specific conditions. LOD95 is 11 ppm. Data on file.
2. Flach, S., Howarth, K., Hackinger, S. et al. Liquid BIOpsy for MiNimal RESidual DiSease Detection in Head and Neck Squamous Cell Carcinoma (LIONESS)—a personalised circulating tumour DNA analysis in head and neck squamous cell carcinoma. *Br J Cancer 126*, 1186–1195 (2022)
3. Flach, S., Pipinikas, C., Huberty, T. et al. Personalized ctDNA analysis for detection of residual disease and recurrence in surgically treated HNSCC patients. *npj Precis.* Onc. 10, 103 (2026)

Clinical scenarios: When to use MRD testing

Scenario 1
Adjuvant landmark

- **Patient:** HPV-negative oral cavity cancer, post-surgical resection with negative margins
- **Clinical question:** Did we achieve complete resection at the molecular level?

Action

1st blood draw before surgery

2nd blood draw 12 weeks post surgery

Negative ctDNA post-surgery:
Molecular assessment of resection, supporting standard surveillance

Positive ctDNA post-surgery:
Consider the high-risk of relapse associated with ctDNA positivity during adjuvant therapy or surveillance planning discussions

Scenario 2
Surveillance monitoring

- **Patient:** HPV-negative laryngeal cancer, 12 months post-treatment, NED on imaging
- **Clinical question:** Is molecular residual disease (MRD) detected?

Action

1st blood draw post adjuvant therapy

Serial testing cadence every 3 months

ctDNA detected, imaging negative:
Consider shorter intervals between imaging, intensified or alternative imaging options, and discuss preparation for relapse

Serial negative ctDNA:
Continue standard surveillance with confidence

RaDaR ST workflow

Step 1	Analyze tissue by whole exome sequencing (WES) to develop a customized panel used for subsequent blood monitoring
Step 2	Simple blood draw (standard phlebotomy) at surveillance visit
Step 3	Results delivered in 7-10 business days
Step 4	Serial RaDaR ST monitoring, frequency based on clinical scenario

Comprehensive support:

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

Ideal patient population

HPV-negative head and neck cancer patients at highest risk

- Stage II-IV disease
- Close or positive margins (even if re-resected)

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