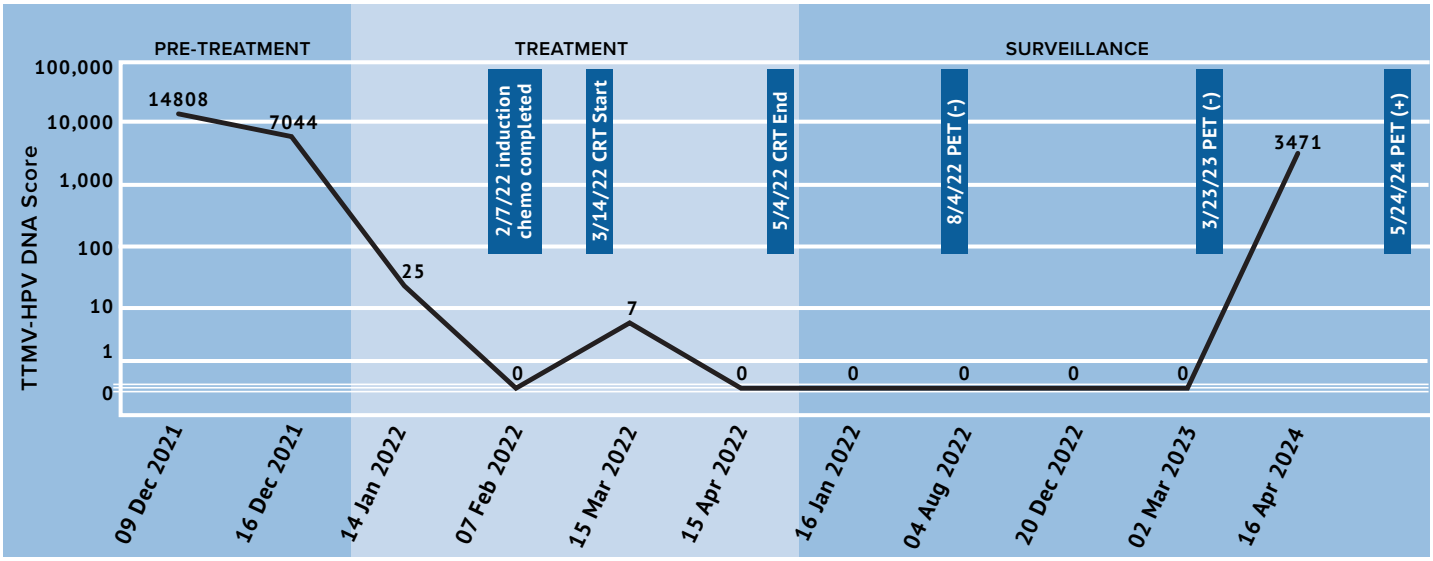
NavDx® Case Study:

TTMV®-HPV DNA monitoring detects disease recurrence in asymptomatic patients with no evidence of disease on physical examination and guides the use of imaging

Patient History

A 66-year-old male, non-smoker reported to the ED with a history of tongue swelling and complaints of edentulism, oral bleeding, dysphagia and right-neck swelling over the past six months.

- Initial right neck FNA performed outside Mt Sinai facilities: LN level 3 = SCC (+), p16 (+) and LN level 2 = SCC (+), p16 (+)
- Consultation with Mt. Sinai ENT (Dec 2021): NavDx followed by right neck FNA, LN level 2 = SCC (+), p16 (+), HPV 16 (+)
- Determined clinical stage IV T4 N2 M0 SCC of the base of tongue (BOT)
- Pretreatment TTMV Score was 14,808
- Following neoadjuvant induction chemotherapy x 3 cycles, the TTMV Score decreased to 0 at which time CRT was initiated
- Transient elevated TTMV Score (7) during CRT returned to 0; CRT ended May 2022
- Post CRT, TTMV Scores remained 0 for nearly a year (April 2022 – March 2023)



Optimizing Clinical Care

- Patient remained asymptomatic while opting for no follow-up; no additional NavDx tests were performed until April 2024 at which time the TTMV Score was positive (3471)
- The elevated TTMV Score led to a PET-CT scan which revealed multiple hypermetabolic right lung nodules

Summary:

Detection of a positive TTMV Score during surveillance eliminated patient's reluctance for having a PET-CT scan, and recurrent disease was detected. NavDx testing reliably informs disease status and guides appropriate use of imaging, such as diagnostic PET CT.

Naveris Inc., Data on File: Case provided by Leslie A. Worona, FNP-BC, OCN with permission

Optimizing HPV+ Cancer Surveillance

About NavDx

NavDx® is the first and only clinically validated circulating tumor tissue modified viral (TTMV®)-HPV DNA blood test that aids in the detection of HPV-driven cancer.[1] Monitoring TTMV-HPV DNA Scores with NavDx at routine surveillance visits has demonstrated unrivaled test performance metrics, assuring earlier detection of patients with residual/recurrent disease.[2-4]

- Distinguish TTMV-HPV DNA from non-cancerous sources of HPV DNA[5]
- **≥97% Specificity** and **≥89% Sensitivity** to more accurately detect true disease status[2,3]
- **≥98% NPV** with no recurrence when TTMV-HPV DNA remained undetectable[2,3]
- **≥95% PPV** for cancer recurrence, when patients had 1 positive test result[2,3]
- **Accurately detect recurrence a median of 4 months earlier** than it would present clinically via PET or CT scan to facilitate earlier initiation of salvage therapy[1]

Testing with NavDx

Clinical practice guidelines and CMS coverage policy for recurrence detection include surveillance at specified intervals:

During Surveillance

- **≥3 months - 2 years post treatment:** every 3 months
- **3-5 years post treatment:** every 6 months
- **6+ years post treatment:** 1 time per year

Pretreatment

- Test with NavDx at least 7 days after any biopsy procedure, and prior to initiating treatment

During Treatment

- During treatment, consider testing with NavDx to assess early response to treatment

Questions?

The Naveris Client Services team is available to help you via email at: contact@naveris.com or phone at (833) 628-3747.

Abbreviations: BOT, base of tongue; CRT, chemoradiation therapy; CT, computed tomography; DNA, deoxyribonucleic acid; ED, Emergency department; ENT, ears, nose throat; FNA, fine needle aspiration; HPV, human papillomavirus; LN, lymph node; NED, no evidence of disease, PE, physical exam; PET, positron emission tomography; SCC, squamous cell carcinoma; TTMV HPV DNA, tumor-tissue–modified HPV

References: 1. Chera BS, Kumar S, Shen C, et al. Plasma circulating tumor HPV DNA for the surveillance of cancer recurrence in HPV-associated oropharyngeal cancer. J Clin Oncol. 2020;38(10):1050-1058. **2.** Ferrandino RN, Chen S, Kappauf C, et al. Performance of liquid biopsy for diagnosis and surveillance of human papillomavirus-associated oropharyngeal cancer. JAMA Otolaryngol Head Neck Surg. doi: 10.1001 /jamaoto.2023.1937. **3.** Hanna GJ, Roof SA, Jabalee J, et al. Negative predictive value of circulating tumor tissue modified viral (TTMV)-HPV DNA for HPV-driven oropharyngeal cancer surveillance. Clin Cancer Res 2023. doi: 10.1158/ 1078-0432. CCR 23-1478. **4**. Berger BM, Hanna GJ et al; Clin Cancer Res 2022;28(19):4292-4301. **5.** Chera BS, Kumar S, Beaty BT, et al. Rapid clearance profile of plasma circulating tumor HPV type 16 DNA during chemoradiotherapy correlates with disease control in HPV-associated oropharyngeal cancer. Clin Cancer Res. 2019;25(15):4682-4690.

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