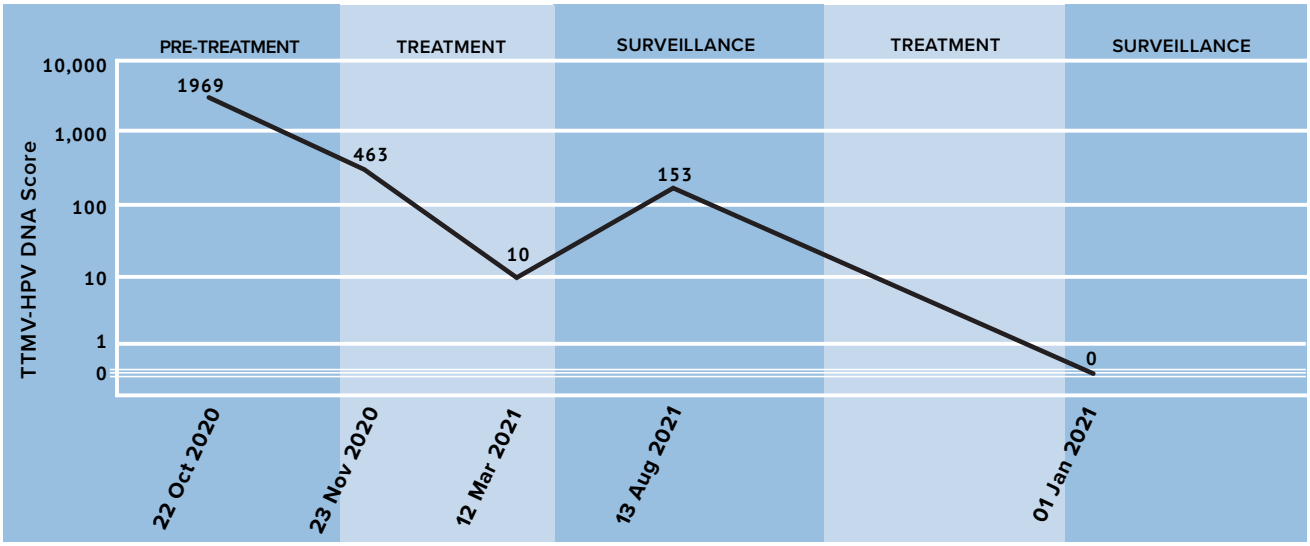
NavDx® Case Study:

Tumor tissue modified viral (TTMV®)-HPV DNA detects recurrence early during surveillance

Patient History

A 61 year-old man with no history of tobacco use presented with an abnormality in the right tonsil and a 2 cm mass in the right neck

- T2 N1 M0 p16+ squamous cell carcinoma of the tonsil was discovered with ipsilateral neck metastasis and extranodal extension.
- Pretreatment TTMV Score was 1,969
- Transoral robotic oropharyngectomy and ipsilateral modified neck dissection were performed with negative surgical margins at the primary site
- The right neck dissection specimen revealed two of 32 lymph nodes positive for metastatic tumor (2/32), with extracapsular extension by tumor noted
- Post-surgery TTMV Score decreased to 463, then the patient began adjuvant chemoradiation
- Two months after completion of adjuvant chemoradiation, PET-CT showed no evidence of disease, while NavDx testing demonstrated that TTMV Score declined to 10



Optimizing Clinical Care

- In routine follow-up, a TTMV Score of 153 was detected, leading to a PET-CT scan, which detected a contralateral neck metastasis
- The patient underwent a left selective neck dissection which revealed twenty one lymph nodes, one positive for metastatic carcinoma (1/21) with extracapsular extension identified
- Post-treatment, TTMV Score decreased to 0

Summary:

Initial testing established a baseline reference to which subsequent treatment response was compared. Detection of a rising TTMV Score during a routine follow-up visit triggered a PET-CT scan, which confirmed disease recurrence. Early detection of this recurrence allowed the patient to undergo a less extensive surgical procedure than would have been required had the recurrence been detected at a later stage.

Naveris Inc., Data on File: Case provided by Guy J. Petruzzelli, MD, PhD, FACS 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.

NavDx® Optimizing HPV+ Cancer Care

Abbreviations: CT, computed tomography; DNA, deoxyribonucleic acid; HPV, human papillomavirus; PET, positron emission tomography: TTMV, tumor tissue modifi ed viral

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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