

In the management of HPV-driven
anal cancer surveillance

Anal Squamous
Cell Carcinoma
(ASCC)

Let their
blood TTMV® help
achieve a new
standard of care



NavDx®
Optimizing HPV+ Cancer Care

Routine NavDx testing assures early detection of patients with recurrent HPV-driven ASCC

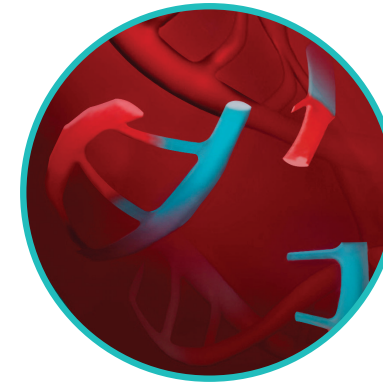
Although physical exams, imaging and anoscopy have long been the standard of care, their ability to detect recurrence early is limited¹

Post-treatment ASCC surveillance can be challenging as it relies on the presentation of physical symptoms, imaging or the limited availability of high-resolution anoscopy, all of which can delay detection of recurrence.

The NavDx[®] test is the first and most clinically validated circulating tumor tissue modified viral (TTMV[®])-HPV DNA blood test that can aid in the detection of HPV-driven cancers, including ASCC.^{1,2} In a recent retrospective clinical study, among the 89% of ASCC patients (104/117) who had routine TTMV-HPV DNA surveillance testing¹:

- ◆ A positive post-treatment TTMV-HPV DNA Score was reported among 22 (21%) patients¹
 - 24 recurrences (among 19 patients) were associated with a positive TTMV-HPV DNA Score¹
 - A single positive TTMV-HPV DNA Score was the first indication of recurrence, in 58.3% (14) instances, preceding clinical confirmation by a median of 59 days (range 10-536 days)¹
- ◆ NavDx testing provided a more sensitive and accessible, procedure-independent, approach to routine surveillance monitoring¹

Monitoring TTMV-HPV DNA Scores with the NavDx test during routine ASCC surveillance visits has demonstrated clinically significant test performance metrics¹

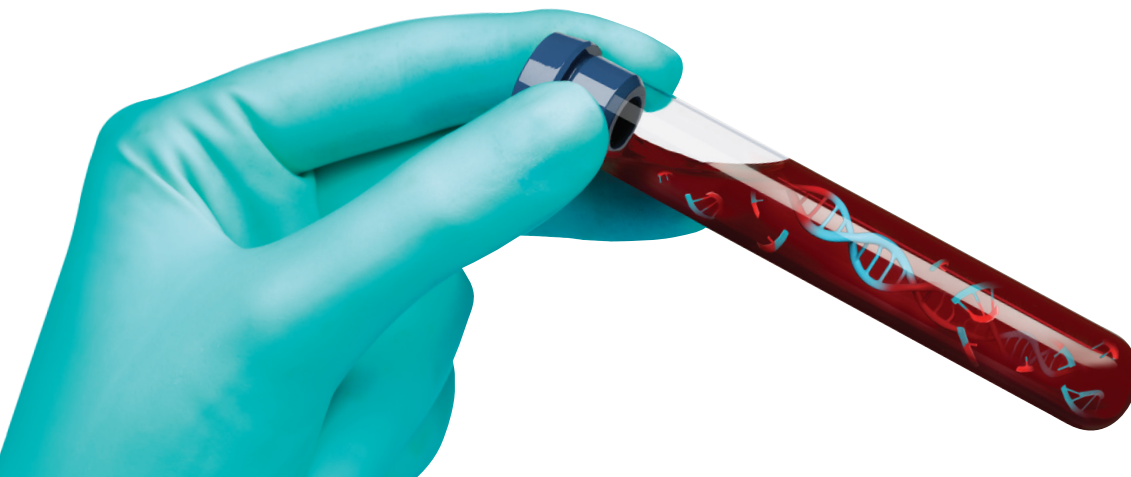


Tumor tissue modified viral (TTMV)-HPV DNA is a unique biomarker released into the blood from tumors driven by human papillomavirus (HPV)²

- ◆ **98.4% Specificity** and **82.8% Sensitivity** to accurately detect true disease status¹
- ◆ **92.5% NPV** (negative predictive value) with no recurrence when TTMV-HPV DNA remained undetectable¹
- ◆ **96.0% PPV** (positive predictive value) for ASCC recurrence, when patients had one positive test result¹
- ◆ **Highly effective (94.3%)** in resolving indeterminate clinical findings¹

Clinical practice guidelines for HPV-driven ASCC recurrence detection include surveillance every 3-6 months for 5 years following treatment

Patients whose TTMV-HPV DNA Scores remained negative experienced significantly better recurrence-free survival than those with one or more positive Scores ($p < 0.0001$)¹



Optimizing Care of HPV+ ASCC with NavDx testing

The NavDx test allows you to optimize the clinical management of HPV-driven ASCC by assessing treatment response, identifying the presence of molecular residual disease, and assuring earlier detection of recurrence, with a more sensitive, procedure-independent and easily accessible blood test.¹⁻³ The easy to interpret, actionable NavDx test report informs clinical decisions, enabling you to intervene earlier, which may result in improved outcomes:

- ◆ Distinguish tumor tissue modified viral (TTMV)-HPV DNA from non-cancerous sources of HPV DNA⁴
- ◆ Rapidly assess treatment response and predict patient prognosis ahead of radiographic assessment of disease^{1,3}
- ◆ The high NPV ensures that most patients with negative TTMV-HPV DNA Scores can be considered recurrence-free, minimizing the need for unnecessary interventions¹
- ◆ With its high specificity and high PPV, routine NavDx testing during surveillance can accurately detect HPV-driven recurrence and effectively resolve clinically indeterminate findings¹

Integrating NavDx testing into routine post-treatment surveillance could represent a paradigm shift, as it is readily accessible and supports patients in maintaining guideline-specified surveillance intervals.¹

www.navdx.com

References: **1.** Kabarriti R, Lloyd S, Jabalee J, et al. Evaluating Tumor Tissue Modified Viral (TTMV)-HPV DNA for the Early Detection of Anal Squamous Cell Carcinoma Recurrence. *Cancers*. 2025; 17(2):174. <https://doi.org/10.3390/cancers17020174>. **2.** 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*. Apr 1 2020;38(10):1050-1058. doi:10.1200/JCO.19.02444. **3.** Huffman B, Singh H, Horick N, et al. Circulating Tumor Tissue Modified Viral-Human Papillomavirus DNA (TTMV-HPV DNA) is a Biomarker of Response to Pembrolizumab in Anal Cancer. *EUROGIN*. March 2024. **4.** 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*. Aug 1 2019;25(15):4682-4690. doi:10.1158/1078-0432.CCR-19-0211.



Naveris Inc., 21 Hickory Drive, Suite 600, Waltham, MA 02451
www.naveris.com | support@naveris.com

© 2025 Naveris Inc. | US Patent 11,168,373 and 11,254,989 | NavDx-1025-166/R2

NavDx[®]
Optimizing HPV+ Cancer Care