In the management of HPV-driven anal cancer (ASCC) surveillance

Integrate NavDx into ASCC surveillance

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

NavDx®

Optimizing HPV+ Cancer Care

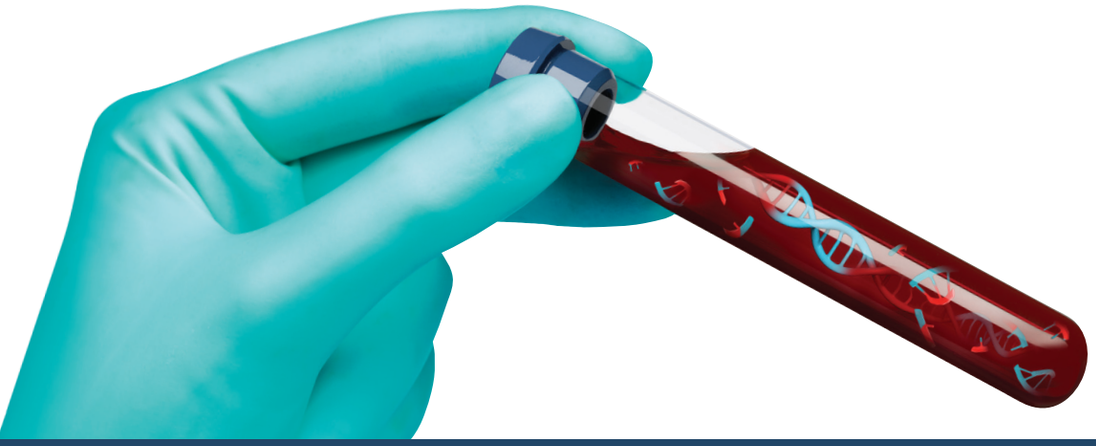
Routine NavDx testing assures early detection of patients with recurrent HPV-driven ASCC

Although physical exams, imaging and anoscopy have long been the standard of care, their ability to detect recurrence early is limited[1]

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.

NavDx® is the first and only 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 testing[1]:

- A positive post-treatment TTMV-HPV DNA Score was reported among 22 (21%) patients[1]
  - 24 recurrences (among 19 patients) were associated with a positive TTMV-HPV DNA Score[1]
  - 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 monitoring[1]



Monitoring TTMV-HPV DNA Scores with NavDx during routine ASCC surveillance visits has demonstrated clinically significant test performance metrics[1]

Timor 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 status[1]
- **92.5% NPV** (negative predictive value) with no recurrence when TTMV-HPV DNA remained undetectable[1]
- **96.0% PPV** (positive predictive value) for ASCC recurrence, when patients had 1 positive test result[1]
- **Highly effective (94.3%)** in resolving indeterminate clinical findings[1]

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]

NavDx®
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Optimize HPV+ ASCC Care with NavDx testing

NavDx lets you 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 DNA[4]
- 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 confidently considered recurrence-free, minimizing the need for unnecessary interventions[1]
- With its high specificity and high PPV, routine NavDx testing during surveillance can accurately detect HPV-driven recurrence and effectively resolve clinically indeterminate findings[1]

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]

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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.

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