

Assessment of DNA methylation markers for the detection of VIN, VAIN and vulva or vagina carcinoma\*

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## Objectives

The majority of vaginal cancers and a lesser proportion of vulvar cancers are associated with HPV. Rising incidence rates of vulvar cancer seem to be mainly attributable to high-risk HPV-positive cases. Currently, no organized screening is performed in any country, so early detection is often an incidental finding during routine visit at the gynecologist.

#### Methods

Scrapes from patients with vulvar and vaginal carcinoma as well as vulvar (VIN) and vaginal intraepithelial neoplasias (VAIN) were analyzed for methylation of the six marker regions ASTN1, DLX1, ITGA4, RXFP3, SOX17 and ZNF671 comprising the cervical cancer diagnostic test GynTect.

Histopa- thology	samples	HPV- positive	HPV- negative
VIN	25	21	4
Vulva Ca	37	16	21
VAIN	8	8	0
Vaginal Ca	6	6	0

Table 1: Samples included in the study

#### Results

Among 37 Vulva cancers 16 were HPV-positive, 21 HPV-negative

- 15 of 16 HPV-positive vulva cancers were DNA methylation-positive
- 13 of the 21 HPV-negative vulva cancers were DNA methylation-positive

All 6 Vagina cancers were HPV-positive

• All 6 samples were GynTect-positive

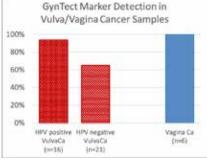


Figure 1

Absolute GynTect results on all 28 VIN/VAIN samples with valid tests 19 samples were GynTect-positive

- All GynTect-positive samples were HPV-positive
- The four HPV-negative VINs were also GynTect-negative
- Of the 16 VINs with valid GynTect result,
  15 were GynTect-positive; two of the four "invalid" samples were positive each for 5 markers
- Of the 8 VAINs all HPV-positive 4 were GynTect-positive

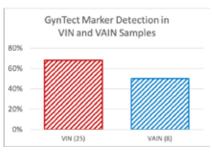


Figure 2

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### Conclusion

The six DNA methylation markers comprising the cervical cancer diagnostic GynTect, may be useful in diagnostics of vulvovaginal diseases as well, as a high proportion of the samples were positive for GynTect, partially irrespective of the HPV status. Thus, in combination with HPV diagnostics, DNA methylation testing with these markers might be a promising tool for early detection of malignant vulvar or vaginal disease.

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