GynTect®
Epigenetic Marker for Cervical Cancer Diagnostics

CE-IVD-approved diagnostic test developed by oncgnostics GmbH

GynTect® - reliable and fast diagnostics

Overview:

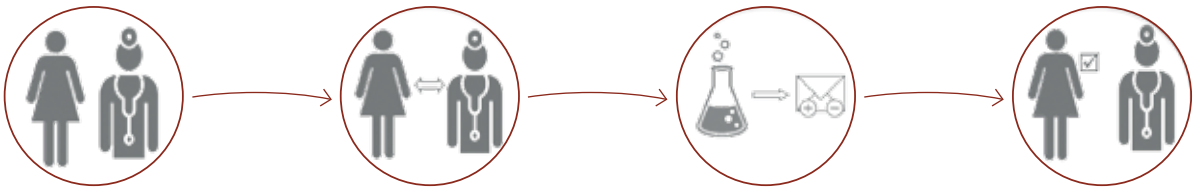
It detects malignant changes in patients

Reliable results with only one smear

Laboratory results possible within one working day

If the cervical cancer screening test is abnormal with the Pap test or positive with the HPV test, the patient is suddenly in an exceptional situation. Although both tests indicate a possible cancer, in many cases there is no malignant disease and the positive test result was a false alarm. Further examinations are necessary for reliable clarification, such as a colposcopy, with biopsy if necessary. In case of abnormalities, the allegedly affected tissue is often removed.

GynTect® is a fast and non-invasive test for clarification of abnormalities in cervical cancer screening, as only one further smear makes a reliable result possible in a few days.



Step 1:
Visit at gynaecologist

Step 2:
Cervical smear is sent to the lab

Step 3:
Performance of GynTect®

Step 4:
Result: Discussion with patient

An existing infection with HPV may lead to genetic instability of the infected cells and eventually cervical cancer. In the course of carcinogenesis, changes (methylations) occur in the DNA.

GynTect® recognizes six areas of the human genome, which only exist methylated during cancer cells' development. GynTect® thus identifies patients with malignant changes.

Decision thanks to reliable results

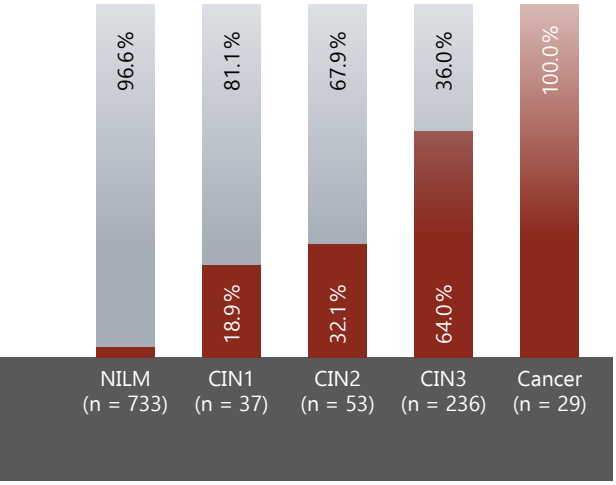
With a **negative GynTect® result**, a cancer diagnosis could be excluded at the time of testing. If there was an abnormal Pap test or HPV infection prior to the test, it is recommended to observe them further.

If there is a **positive GynTect® result**, a malignant precursor or even cancer is very likely. Further steps such as diagnostics assisted by colposcopy and surgical therapies are recommended.

Based on available study data, GynTect® provides a clear indication of malignancy status in patients with abnormal Pap smear: In all previous studies, GynTect® was able to detect all cancer cases of the cervix (Sensitivity = 100%).

GynTect® is rarely positive in cytological normal patients (Specificity = 96.6%). Cancer occurs via the histopathology defined dysplasia CIN1, CIN2 and CIN3. GynTect® detection rates for this dysplasia increase continuously. This indicates a prognostic value of the GynTect® cancer marker.

Study data GynTect®



Detection rate GynTect® (red bar) depending upon clinical status of the patient

Confidence interval for confidence level = 95%: NILM: 2.22-4.99%; CIN1: 7.96-34.16%; CIN2: 19.92%-46.32%; CIN3: 57.5-70.11%; Cancer: 88.06-100%

Positive GynTect® result

Cervical cancer or a malignant precursor is very likely. Therapeutic action is recommended!

Negative GynTect® result

Cervical cancer is very unlikely at the time of testing. If there is a dysplasia, it is very unlikely to be malignant.

Clinical Performance

GynTect® clinical performance was determined in studies involving more than 3500 patient samples. The table below summarizes 1088 patient data samples in liquid-based cytology medium: Histopathology results were present for 32.6% of the patients: in 37 cases CIN1, in 53 cases CIN2, in 236 cases CIN3 and in 29 cases a cervical cancer was diagnosed. 67.4% of the women had a cytological normal finding (PAP I/NILM). For this group no histopathology finding has been made.

GynTect® indicates a high sensitivity and specificity in the detection of CIN3+ findings, as shown in the table below. GynTect® detected all cervical cancer cases. Only 3.4% of the samples with normal cytological finding (PAP I) were GynTect® positive.

➔ **This shows that unnecessary cervical conisation may be avoided.**

GynTect® was less sensitive to the detection of CIN1 and CIN2. These results must be considered in the context that many CIN lesions heal spontaneously, especially in younger women. Future studies should show that GynTect® negative lesions will regress and not result in cancer.

In summary: GynTect® reliably detected all cervical cancer in previous studies. Based on the available data, GynTect® can clarify abnormal Pap findings and/or positive HPV test results.

	Sensitivity	Specificity	positive predict value	negative predict value	Prevalence
Performance CIN3+	67.9%	94.0%	78.6%	90.1%	24.4%
Performance CIN2+	61.9%	95.8%	86.0%	85.9%	29.2%

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