



infos for
physicians

ScreenYu Gyn[®] Epigenetic Cervical Cancer Diagnostics

CE-IVD approved* diagnostic test developed by oncnostics GmbH

*not available in the USA

ScreenYu Gyn® - safe and fast diagnostics

Advantage for doctors

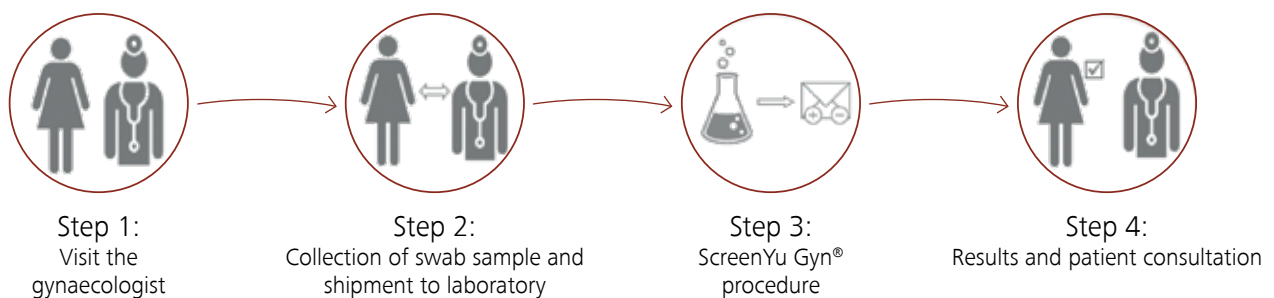
Reliable clarification of abnormalities with only one swab

Fast laboratory results

Negative test result: watchful waiting in gynecological practice

Since the introduction of the new S3 guideline on the prevention of cervical cancer in 2020, gynaecological practices have received an increasing number of inquiries from women who are worried about their abnormal Pap test or positive HPV test results. With ScreenYu Gyn®, many of these stressful results can be further clarified by private consultation with the gynaecologist.

ScreenYu Gyn® is a quick and non-invasive test for clarifying abnormalities found in the standard cervical cancer screening. The test can provide a reliable result with one additional smear sample and within just a few days.



An existent infection with HPV can lead to genetic instability of the infected cells and eventually to the formation of cervical cancer. During cancer development, epigenetic changes occur in the DNA.

ScreenYu Gyn® recognizes epigenetic changes in human genetic material, which only occurs during the development of cancer. Therefore, ScreenYu Gyn® identifies patients with malignant cellular changes.



A reliable result

A **negative ScreenYu Gyn® result** means that cancer can be ruled out at the time of testing. If there was an abnormal Pap or HPV test beforehand, then it is advisable to continue monitoring.

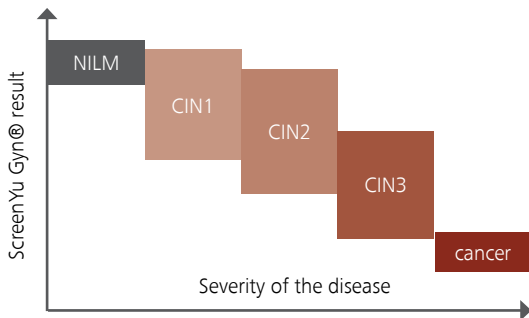
A **positive ScreenYu Gyn® result** could indicate a malignant precursor or even cancer. Further measures, such as colposcopy-assisted diagnostics or surgical therapies, are recommended.

Based on the study data, ScreenYu Gyn® is suitable for determining the malignancy status of patients with an abnormal Pap smear. In the study conducted for approval, ScreenYu Gyn® detected all cases of cervical carcinoma (sensitivity= 100 %).

ScreenYu Gyn® is rarely positive in normal patients (specificity in healthy individuals = 90.7%). Cancer develops from the histopathological-defined dysplasias CIN1, CIN2 and CIN3. For each of these categories, the detection rate of ScreenYu Gyn® progressively increases.

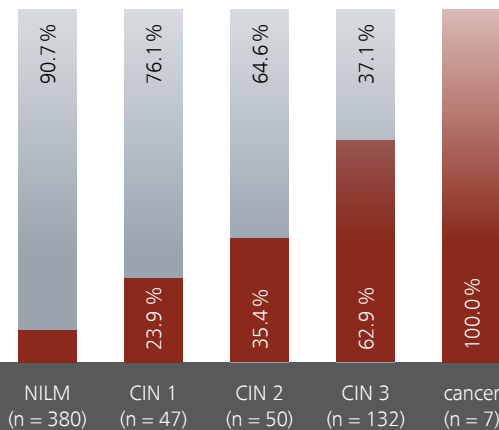
The quantitative ScreenYu Gyn® PCR value correlates with the severity of the dysplasia: the more severe the tissue change, the lower the value. The ScreenYu Gyn® result could give an indication of the severity of the disease.

Correlation ScreenYu Gyn®-malignancy



The ScreenYu Gyn® PCR value correlates with the severity of the disease: the lower the value, the more serious the disease.

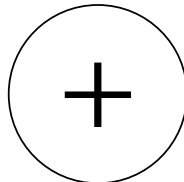
Study data ScreenYu Gyn®



Detection rate of ScreenYu Gyn® (red bar) depending on the clinical status of the patient.

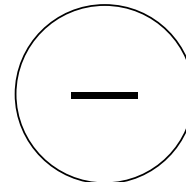
Confidence interval for confidence level = 95%:
NILM: 6.6 – 12.7%; CIN 1: 12.6 – 38.8%;
CIN 2: 22.2 – 50.5%; CIN 3: 54.0 – 71.1%;
Cancer: 59.0 – 100%

Positive ScreenYu Gyn® results



Malignant tissue changes, or even a carcinoma, could be present. Invasive diagnostic and therapeutic actions are advisable.

Negative ScreenYu Gyn® results



Cervical cancer is very unlikely at the time of the test. If a dysplasia is present, there is a high probability it is not malignant.



Clinical performance characteristics

ScreenYu Gyn® detects the DNA methylation marker ZNF671. The clinical performance characteristics of ScreenYu Gyn® were determined in a study with over 600 patient samples. A positive ScreenYu Gyn® result was obtained from more than 62% of histologically confirmed CIN3 (n = 132) and all carcinoma (n = 7) samples. Less than 10% of samples with cytologically unremarkable findings (NILM; n = 380) were ScreenYu Gyn® positive.

ScreenYu Gyn® shows a 64.7% sensitivity for the detection of CIN3+. The specificity for inconspicuous patients is >90% (illustrated in the table below).

➔ **This shows that unnecessary conizations can be avoided.**

ScreenYu Gyn® was less sensitive in the detection of CIN1 and CIN2. However, these results could stem from the fact that CIN lesions can heal spontaneously, especially in younger women. Studies indicate that lesions with a negative ScreenYu Gyn® result do not progress to cancer.

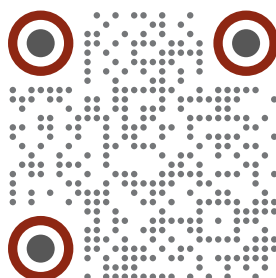
	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Performance CIN3+/NILM	64.7 %	90.7 %	72.0 %	87.4 %



To summarize: Based on the available data, ScreenYu Gyn® is very well suited for clarifying abnormal Pap findings and/or positive HPV test results.

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For more information please scan the QR Code or visit us at www.gyntec.com/screenyu-gyn/