

ScreenYu Gyn® Epigenetic Cervical Cancer Diagnostics

CE-IVD approved* diagnostic test developed by oncgnostics GmbH *not available in the USA

A reliable result

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 %).

increases.

disease.

Positive ScreenYu Gyn® results

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

ScreenYu Gyn®- safe and fast diagnostics

Advantage for doctors

Reliable clarification of abnormalities with only one swab

Fast laboratory results

Negative test result: monitoring in a gynaecologist 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.

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®



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%

Step 2: Collection of swab sample and shipment to laboratory



ScreenYu Gyn® procedure



Step 4: Results and patient consultation

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.

Step 1: Visit the gynaecologist



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.

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

The guantitative 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



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.







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Assay principle and workflow

The ScreenYu Gyn® assay is based on the detection of DNA methylation in one human gene region that occurs specifically during carcinogenesis. In the process of DNA methylation, methyl groups are added to the DNA. These are always cytosines located next to guanines ('CpG dinucleotides').

The analysis of a patient sample comprises two steps:

- 1. First, methylation is fixed by bisulfite treatment.
- 2. Subsequently, a specific region of the genome is analysed by PCR and an evaluation is carried out using common spreadsheet software.



Only originally methylated DNA regions are amplified in the PCR. Therefore, this procedure is also called Methylation-specific PCR (MSP).

For a reliable workflow, the ScreenYu Gyn® assay includes one internal control. Positive and negative controls are also included.



For more information please scan the QR Code or visit us at www.gyntect.com/en/screen-yu-gyn/