GynTect®

Epigenetic Markers for Cervical Cancer Diagnostics

CE-IVD-approved* diagnostic test developed by oncgnostics GmbH

*not available in the United States

GynTect® - reliable and fast diagnostics

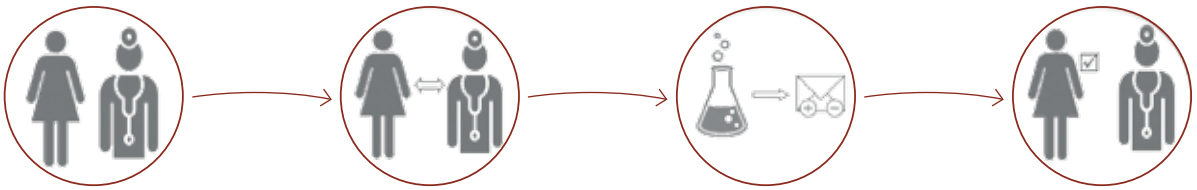
Overview:

Possible within a working day

Performed on cobas® z 480 Analyzer

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

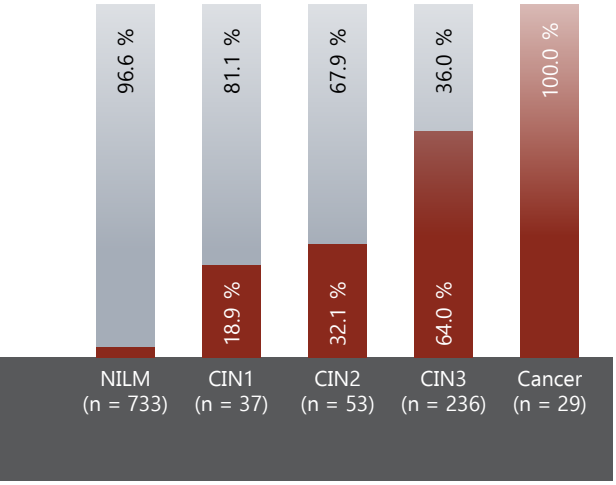
With a **negative GynTect® result**, a cancer diagnosis could be excluded at the time of testing. If there was an abnormal Pap test or HPV infection prior to the test, it is recommended to observe them further.

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 the 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 markers.

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

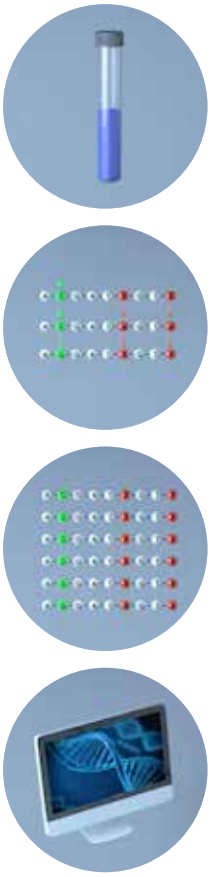
Cervical cancer is very unlikely at the time of testing. If there is a dysplasia, it is very unlikely to be malignant.

Assay principle and workflow

The GynTect® assay principle is based on the detection of DNA methylation in human gene regions 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, specific regions of the genome are analysed by PCR and an evaluation is carried out using common spreadsheet software.



1.

Patient sample:
Preparation

Hands-on time: 15 min
Sample collection:
ThinPrep PreservCyt® (Hologic).

Bisulfite treatment:
Fixation of DNA-methylation

Duration: 70 min
Hands-on time: 25 min
bisulfite conversion with the EpiTect® Fast Bisulfite Kit (Qiagen).

2.

Analytical PCR:
Detection of the DNA marker regions

Duration: 100 min
Hands-on time: 35 min
GynTect® PCR:
cobas® z 480 (Roche Diagnostics).

Data Analysis:
Evaluation of the PCR result

Hands-on time: 30 min
The algorithm if GynTect® is scored positive or negative is applied using a calculation software such as Microsoft Excel.

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 GynTect® assay includes several internal controls. Furthermore, positive and negative controls are included.

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For detailed information including videos, please scan the QR code or visit us at www.gyntect.com.

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