



GynTest®

Fast and non-invasive test for cervical cancer screening

In vitro diagnostic test* by EpiType GmbH

*not available in the United States



GynTect®

- The clarification test for cervical cancer screening
- Results in less than one working day
- Non-invasive: smear test instead of surgery

Description

Type:	Outpatient sample collection by gynaecologist
Specimen collection:	Cervical smear test
Test procedure:	Methylation-specific PCR (MSP)
Marker:	ASTN1, DLX1, ITGA4, RFXP3, SOX17, ZNF671
Pre-analytics:	Bisulfite treatment required
Instrument approval:	cobas® z 480 (Roche Diagnostics), CFX96 Real-Time PCR Detection Systems (Bio-Rad)
Content:	PCR master mix, water, positive control, primer in qPCR tube strips, caps
Transport:	Ambient temperature
Basic UDI-DI:	426076785GYNTECTYM
Sensitivity:	CIN3+: 58.3 % (n=611)
Specificity:	NILM: 95.8 % (n=611)

Scope of application

GynTect® is used as a clarification test in cervical cancer screening. The sample is taken exclusively by qualified medical staff. The test is suitable for women of all age groups (> 18 y).

Test principle

GynTect® is based on the detection of 6 epigenetic biomarkers, i.e. methylations of specific human DNA segments, the presence of which correlates with the existence of precancerous lesions or cervical carcinoma. The detection is carried out using the highly sensitive, methyl-specific real-time PCR method. Before performing the detection PCR, the diagnostic sample needs to be subjected to bisulfite treatment.

Distribution:

GynTect® is offered in two kit sizes:

Kit	Kit size	Samples to be analysed simultaneously
GT003-10	10 samples	10
GT003-06	6 samples	1-6

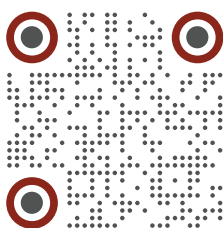
GynTect® is distributed directly by Epitype GmbH or distribution partners. Contacts to distribution partners for the respective countries can be found under www.gyntect.com or QR code below.



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Link to the country list and
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Labelling

