



ScreenYu Gyn[®]

Fast and non-invasive test for cervical cancer screening

In vitro diagnostic test* by Epitype GmbH

*not available in the United States



ScreenYu Gyn®

- The clarification test for cervical cancer screening
- Single-marker test as basis for high-throughput assay
- Results possible in less than one working day

Description

Type:	Outpatient sample collection by gynaecologist
Specimen collection:	Cervical smear test in liquid-based cytology medium
Test procedure:	Quantitative Methylation-specific PCR
Marker:	ZNF671
Pre-analytics:	Bisulfite treatment required
Instrument approval:	cobas® z 480 (Roche Diagnostics), CFX96 Real-Time PCR Detection Systems (Bio-Rad)
Components:	PCR master mix, water, positive control, primer: strips of 8, lid strips
Transport:	Ambient temperature
Basic UDI-DI:	426076785SCREENYUGYNP6
Sensitivity:	CIN3+: 64.7 % (n = 608)
Specificity:	NILM: 90.7 % (n = 608)

Scope of application

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

Test principle

ScreenYu Gyn® is based on the detection of one epigenetic biomarker, i.e. methylation of a specific human DNA segment, the presence of which correlates with the existence of precancerous lesions or cervical carcinoma. The detection is carried out using the highly sensitive, methylation-specific real-time PCR method. Before performing the detection PCR, the diagnostic sample needs to be subjected to bisulfite treatment.

Distribution:

ScreenYu Gyn® 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.

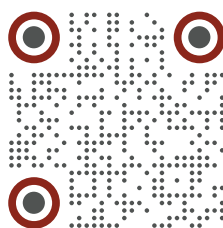
Kit	Kit size	Samples to be analysed simultaneously
SG001-46	46 samples	6-46



Epitype GmbH
Moritzburger Weg 67
01109 Dresden
Germany

Operating facility:
Löbstedter Straße 41
07749 Jena
Germany

+49 3641 55485 00
contact@epitype.de
www.epitype.de



Link to the country list and
contact to corresponding
distribution partners.

Labelling

