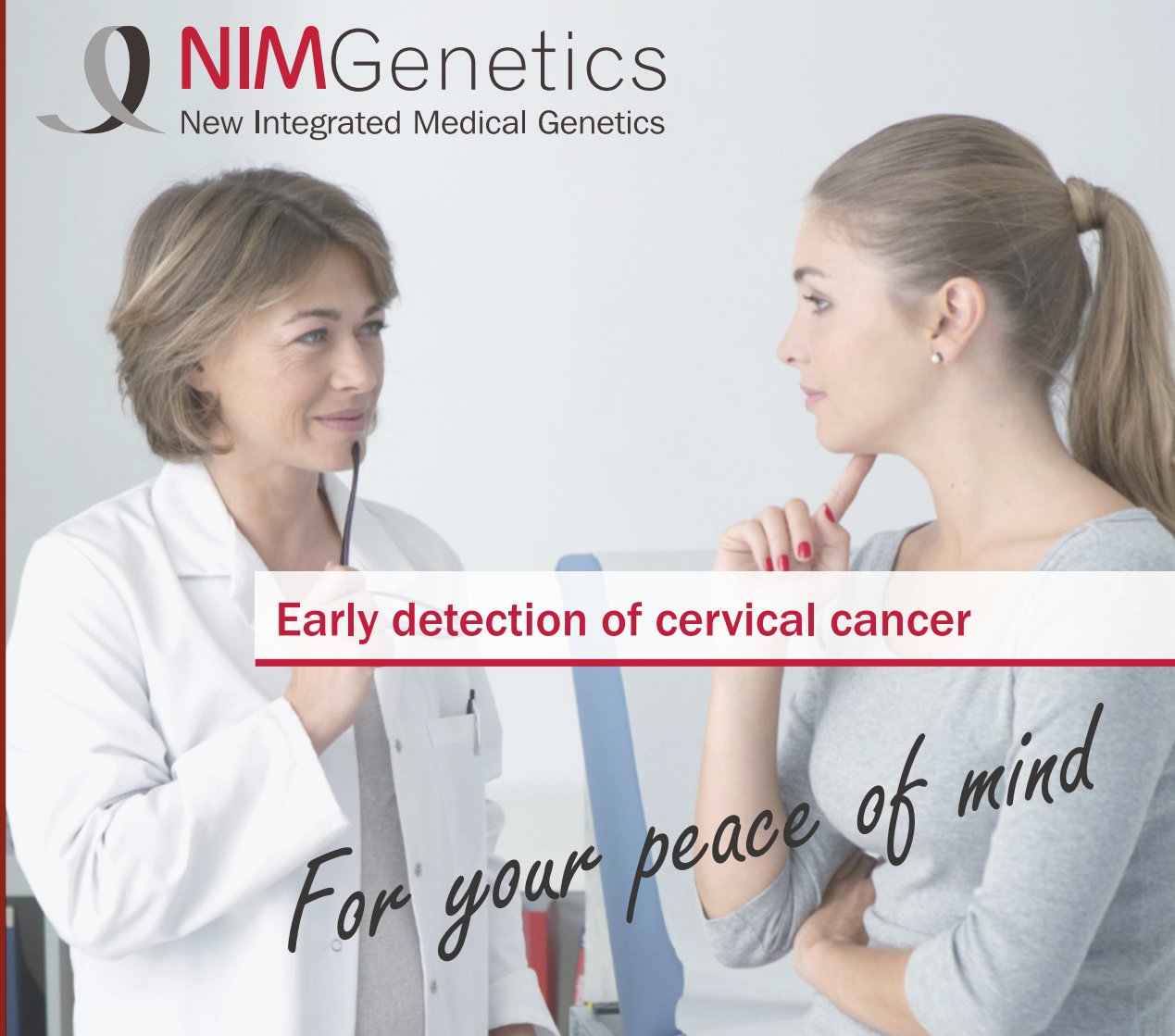
GynTect

NIMGenetics
New Integrated Medical Genetics



Early detection of cervical cancer

For your peace of mind

Diagnosing cervical cancer - the challenge

Study of epigenetic biomarkers in cervical smears is revolutionising cervical cancer screening

Cervical cancer screening currently includes:

1. Pap test, with limited sensitivity (50 - 80%) [1-2].
2. HPV (human papillomavirus) test with high sensitivity but limited specificity due to the high frequency of transient infections (SEOM 2017).

The low sensitivity and specificity of these tests makes it necessary to include molecular studies that increase their reliability and facilitate therapeutic decisions.

The analysis of the state of methylation of selected gene assemblies (*epigenetic biomarkers*) provides molecular information on the risk of malignancy of pre-tumour lesions, and therefore the study of epigenetic biomarkers:

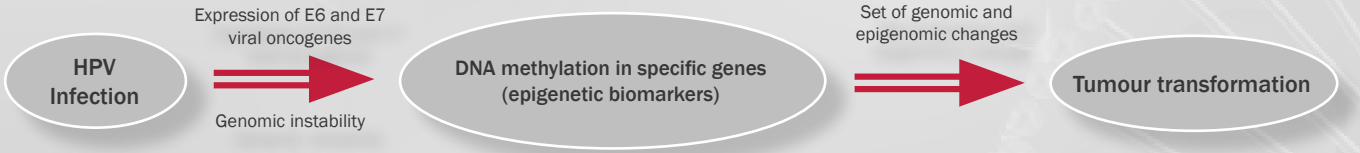
- **Helps with therapeutic decisions and early diagnosis.**
- **Complements colposcopy and cervical biopsy results in HR-HPV (high-risk HPV) positive patients.**

(*): A gene itself can constitute an epigenetic biomarker. When the biomarker is composed of multiple genes, it is also called a *fingerprint or epigenetic signature*

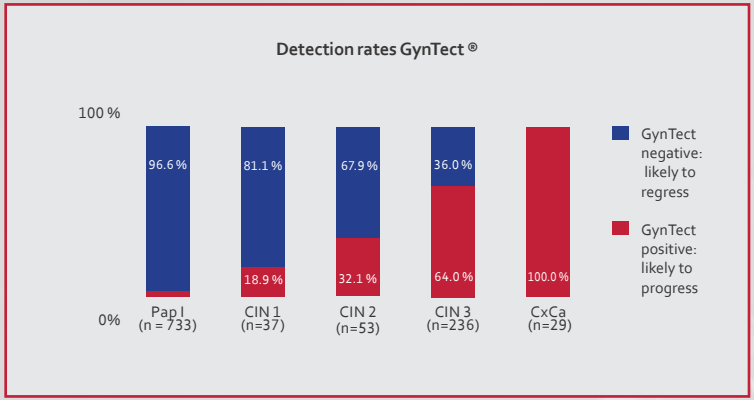
(1): Int. J. Cancer 119, 1095-1101 (2006)
(2): J Obstet Gynaecol. 2019 Jul 25:1-7

Non-invasive, fast, and reliable triage that complements HPV typing for early detection of cervical cancer

GynTect® is based on the epigenetic signature composed by six hypermethylation markers, making it possible to rule out the presence of the tumour in patients with a positive HPV test as early as the cervical smear



Sensitivity > 99.9 % for cervical cancer caused by HPV infection



GynTect® detection capability based on clinical status.
Data of 1,088 cervical smears from various clinical trials:
(https://www.oncgnostics.com/gyntect-cervical-cancer/information-for-physicians/trial-data/?lang=en)

GynTect® detects tumour transformation, not infection

Using specific methylation PCR (MSP), it studies six epigenetic markers (ASTN1, ZNF671, DLX1, ITGA4, RXFP3, SOX17) for cervical tumorigenesis.

Key aspects of early cervical cancer detection

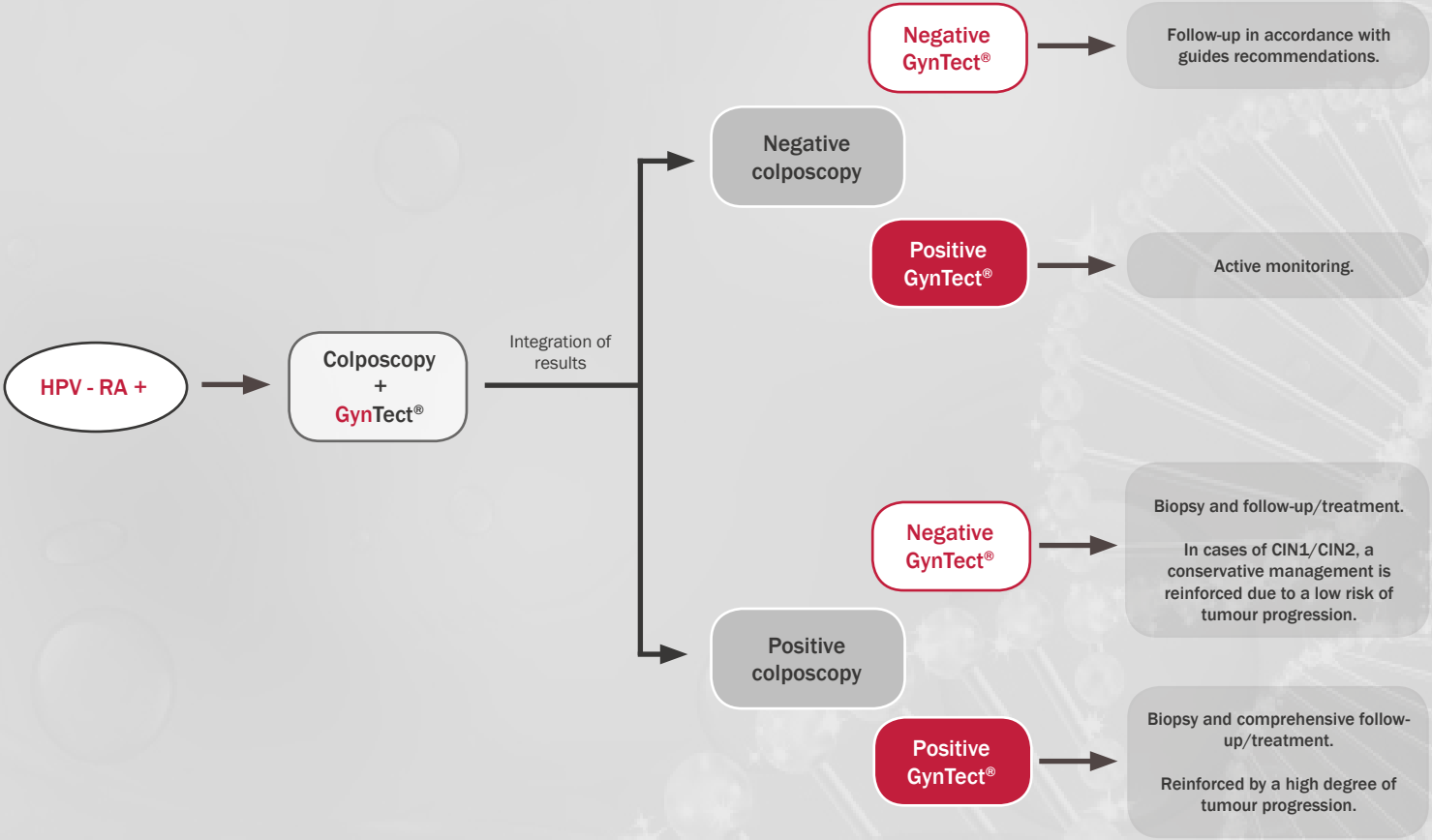
Risk of tumour progression is a key factor in preventing cervical cancer

- The progression rate of a cancerous lesion increases in proportion to the severity of the lesion. While the likelihood of CIN1 (Cervical Intraepithelial Neoplasia) progression is very low, women with CIN3 are at high risk of developing cervical cancer in the absence of treatment [1-5].
- A negative colposcopy can mask an incipient lesion.
- The treatment decision depends, among other factors, on:
  - The degree of lesion
  - The patient's age
  - The affected woman's child-bearing desires
- The risk of lesion progression is a key piece of information in clinical management.

Alterations in the pattern of DNA methylation correlate with a high risk of malignancy [6-8]

(1): Bansal N et al. Anticancer Res 2008;28(3B):1763–6
(2): Trimble CL et al. Clin Cancer Res 2005;11(13)
(3): Loopik DL. J Low Genit Tract Dis. 2016 Jul;20(3):213-7
(4): Gynecol Obstet Invest. 2019 May 3:1-6
(5): McCredie MR et al. Lancet Oncology 2008, 9(5), 425–434
(6): Gomih A et al. Int J Cancer. 2018 Aug 1;143(3):552-560
(7): Esteller M. N Eng J Med 2008 Mar 13;358(11):1148-59
(8): Baylin, SB & Jones PA. Nature Reviews Cancer 2011, 11(10), 726–734

Interpretation of GynTect® results



GynTect®

GynTect® step by step

Gynaecological consultation

The specialist requests a GynTect® test to be performed on their patient by following these steps:

1. **Patient orientation who, together with her physician,** must sign the informed consent.
2. **Sampling:** GynTect® is performed from the conventional cervical smear, which must be transferred to the specific transport medium (ThinPrep PreserveCyt® (Hologic)).
3. **Sample collection:** NIMGenetics will collect the sample for analysis.

GynTect® analysis and report issue

After the sample has been analysed using GynTect®, the results report will be issued, which will be received by the specialist within an average of 5 business days by means of an encrypted e-mail.

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Interpretation of results

A negative GynTect® test result

- Reinforces the result for absence of lesions in the context of a negative colposcopy.
- Supports a conservative attitude in cases of CIN1/CIN2 (biopsy).

A positive GynTect® test result

- In the absence of lesions, a positive result justifies an intensified follow-up of the patient.
- In the presence of lesions, this result indicates an increased risk of progression, and therefore supports interventional therapy.

The GynTect® result can be modified over time, depending on the evolution of the lesion.

- **Provides peace of mind and confidence for the specialist and the patient**

  A positive hrHPV result may cause concern for the patient, despite a low-risk cytology. In this situation, a negative GynTect® result may rule out the presence of cervical cancer. Likewise, it indicates a low risk of tumour progression, without the need for special therapeutic or follow-up measures.

- **Facilitates therapeutic decisions**

  The risk of tumour progression is a factor that complements the biopsy result and helps the specialist decide between monitoring and treatment.

- **High reliability of results**

  Studies have shown a sensitivity of over 99.9% in cervical carcinoma.

- **NIMGenetics and Oncgnostics, working together in oncological genetic diagnosis**

  Oncgnostics has its origin in the public-private partnership at Jena, where the work of Prof. Dr. Matthias Dürst, co-founder of this company, contributed greatly to the discovery of the human papillomavirus as the cause of cervical cancer. For this finding, Dr. Harald zur Hausen was awarded the Nobel prize in Medicine (2008).

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oncgnostics
MOLECULAR CANCER DIAGNOSTICS

La Suma de Todos
Comunidad de Madrid

NIMGenetics is a Genetic Diagnosis centre authorised by the Department of Health and Consumption of the Community of Madrid, registered in the corresponding Register under number CS 10673

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www.nimgenetics.com

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