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THESSALONIKI
Laboratories - Offices
65, Georgikis Scholis Avenue,
57001 Thessaloniki
ZEDA building
T: 0030 2310.474.282,
2310.474.284
F: 0030 2310.474.285
Mobile: 0030 6944.677.746
E-mail: info@biohellenika.gr

ATHENS
Offices
2 Mesogion Str,
Athens Tower, Building A'
T: 0030 210.77.08.882,
210.77.08.218
F: 0030 210.77.90.788
M: 0030 6973.346.704
email: info@biollenikasa.gr

Laboratories
NATIONAL HELLENIC RESEARCH FOUNDATION (NHRF)
48 Vasileos Konstantinou Str.
11635 Athens
T: 0030 210.72.73.700
F: 0030 210.72.46.618

TAK.EIE
28A Archelaou Str.,
11635 Athens
T: 0030 210 7299140
F: 0030 210.72.99.140

LARISSA
Offices
3 Megalou Alexandrou Str.
6th floor, 41222
T: 0030 2410.535.603
F; 0030 2410.535.664
M: 0030 6973.984.260

PATRA
Offices
Kos 18 & Panepistimiou 3
T: 0030 2610.437.436
F: 0030 2610.431.339
M: 0030 6978.483.170

IOANNINA
Offices
Technological Park, Pedini
T: 0030 26510.97.667
F: 0030 26510.97.673
M: 0030 6970.267.540

IRAKLION - CRETE
Offices
17 Amaltheias
& Katechaki Str., 71201
T: 0030 2810.229.351
M: 0030 6970.803.497

CHANIA - CRETE
Offices
40-42 Tzanakaki Str.
T: 0030 2821058758
M: 0030 6976.977.384

Scientific Consultants:
K. Kouzi, MD PhD Associate Professor Histology - Embryology, AUTh, Cell phone: +306944677746
G. Koliakos, MD PhD Associate Professor of Biochemistry, AUTh

www.biohellenika.gr
OPEN LINE ___ 801.11. 99299
(Calls only from line phone)

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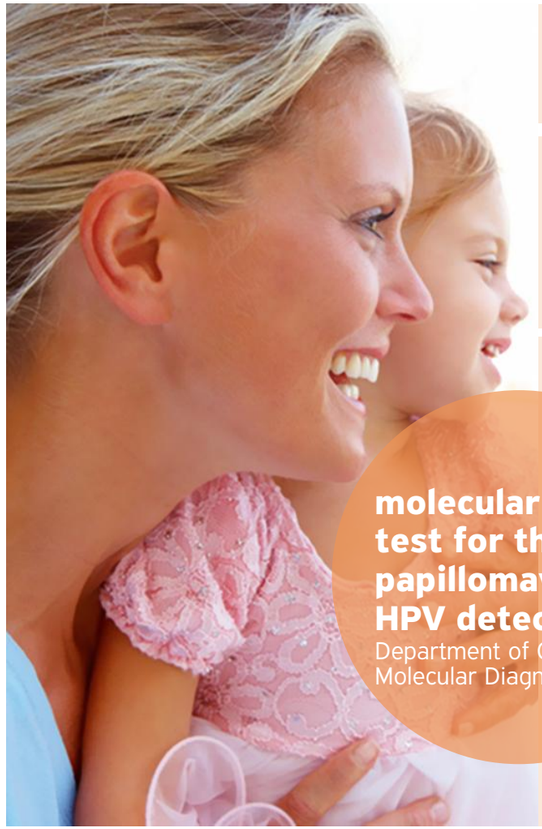
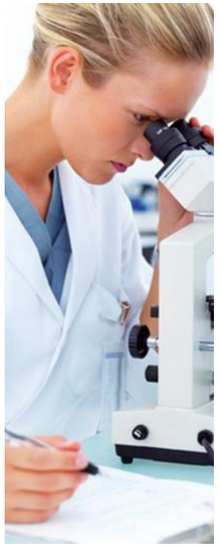


molecular test for the human papillomavirus HPV detection

Department of Genetics and Molecular Diagnostics



Molecular test for the Human papillomavirus – HPV

(Human papillomavirus – HPV)

Why is the virus dangerous?

- 0 Cervical carcinoma is the second most common type of cancer in women genital system, after ovary cancer.
- HPV infections is the main cause of cervical cancer.
- Nearly 471,000 new cases are reported annually, and 233,000 deaths [1,2]. In Europe approximately 60,000 new cases and nearly 30,000 deaths are recorded annually, while in Greece 8,0000 new cases are reported annually [3].

How is the virus transmitted?

- HPV infection is one of the most common sexually transmitted diseases.
- Approximately 75-80% of women and men are infected with HPV at some time over the course of their lives.
- The frequency peak for detectable HPV infections lies in the age group between 20 and 25 years.
- An HPV infection is in most cases eliminated by the body's immune system over a time period of about 8 to 14 months.
- In most cases the infection is asymptomatic and the carrier does not know that she/he has been infected by the virus.
- Exposure to HPV does not necessarily mean malignancy occurrence [5-9].

Which viral types are known today?

- Well over 100 HPV types are known thus far, divided in high and low risk. The classification is made according to their propensity to trigger cancer growth [10].
- High-risk types cause precancerous stages (dysplasias, cervical intraepithelial neoplasias, CIN) and cancer. These are 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73 and 82. They are identified in 99.7% of all cases of cervical carcinoma. A majority of cervical carcinoma cases (approx. 70%) are triggered by just two hr-HPV types: HPV type 16 (53.5%) and HPV type 18 (17.2%)
- The ability of the virus to create tumor is increased, when multiple infections are present, with different HPV types.
- The most common low risk HPV types are 6, 11, 40, 42, 43 και 44 [11].

Molecular testing advantages

Molecular test, detection and genotyping of the virus is the most modern and reliable diagnosis method. It should be applied in combination with annual PAP-test in women of over of 30 years of age. Molecular testing is necessary, since PAP-test can detect only cervical damages and not the cause of the cancer.

Therefore, a molecular test that can quickly and reliably detect multiple HPV genotypes in cervical smear becomes a necessity. Early detection of the virus and monitoring of the infection is important, in order to avoid cancer. Negative result deriving from a molecular test offers the possibility of vaccinations against high risk HPV in women of all age.

Biohellenika S.A. offers the service of molecular detection and genotyping of HPV with the method of DNA microarrays (PapilloCheck – CE-IVD).

PapilloCheck is considered the most indicated way of detection and genotyping of HPV because:

- **PapilloCheck is based on the most advanced diagnostic technologies of Molecular Biology. In specific, it is based on HPV-DNA hybridization on DNA-chips (Biochips). It is the only system based on DNA-MicroArrays.**
- **This technology allows for fast, reliable and highly sensitive (98%) detection of multiple HPV infections. In contrast, other methods fail to detect accurately multiple (over two) infections.**
- **Papillocheck is suitable for detection and genotyping of 24 viral types, 18 of which are classified as high risk and six as low risk, as already mentioned.**
- **Papillocheck is one of the few methods for HPV genotyping that is certified in the European Union (CE) as an in vitro diagnostic (IVD) for the qualitative type-specific identification of 24 human papillomavirus types from a cervical smear [12].**

Sampling

HPV test is applied in cervical smear, collected with a special sterilized swab, offered for free by Biohellenika (after communication). The swab must be sent in our labs within 48 hours, while, until then, it is stored at 4°C.