MOLECULAR DIAGNOSTICS TESTING SOLUTIONS

EXCELLENT PERFORMANCE OF RT-PCR TESTS
FOR ACCURATE DIAGNOSIS & TRUE SCREENING

# MOLgen

CE-IVD

## REAL-TIME PCR DIAGNOSTIC KITS

## HUMAN PAPILLOMA VIRUSES (HPV)

Human Papillomaviruses typically infect the skin and mucosal surfaces. There are more than 200 different types: approximately 100 of them are fully sequenced and 40 types are known to infect the anogenital mucosa of humans. The highest rates of newly acquired HPV infections are observed in young women, peaking at the age soon after the onset of sexual activity. HPV types detected in the anogenital tract are subdivided into low- risk and high-risk types, based on their relative risk to cause the rare complication such as neoplasia. Low-risk HPV types are typically found in low-grade squamous intraepithelial le- sions as well as anogenital warts. The high-risk HPVs are found in low- and high-grade lesions, such as cancers of cervix and other types of cancer in anogenital sites (vulva, vagina, anus).

HPV types frequently detected in the anogenital tract

| | | | |
|---|---|---|---|
| HPV types specifically to infect the anogenital mucosa of humans | >> | high-risk HPV types | 16, 18, 31, 33, 35, 45, 52, 58, 26, 39, 51, 53, 56, 59, 66, 68, 73, 82 |
| | >> | low-risk HPV types | 6, 11, 42, 43, 44 |
| | >> | unidentified-risk HPV types | other |

Collectively, HPV 16 and 18 are consistently responsible for approximately 70% of all cervical cancer cases worldwide.

## EFFECTIVE - ACCURATE - CONVENIENT

HPV testing relies on molecular methods.

- HPV testing is incorporated into cervical cancer screening in various combinations with Papanicolaou (Pap) test.
- Polymerase chain reaction an assay can be used for primary screening and genotyping
- HPV DNA detection is a negative predictor. Current research is investigating the degree of impact on unknown-risk HPV types on clinical important outcomes.

Features of MOLgen kits

- Simple nucleic acid extraction using magnetic particles
- Complex approach to PCR diagnostics encom- passing sample preparation, PCR and evaluation of results
- High sensitivity: 100 copies (genome-equivalents) per sample
- Easy-to-use: just add a sample of eluted DNA to lyophilized Ready PCR Master Mix
- Noncompetitive Internal Control (IC)
- High stability, no freezing required
- Transportation at room temperature is possible

The MOLgen assay kits for diagnostics of HPV

| | | |
|---|---|---|
| **Nucleic acids extraction kits** | >> | ■ High specificity and sensitivity<br>■ Universal and rapid amplification protocol for all infections |
| Sample type: **Urogenital swabs** | >> | ■ Multiplex detection<br>■ Validation of urogenital swabs (quantitative detection of human DNA) |

Str-format (Strip)

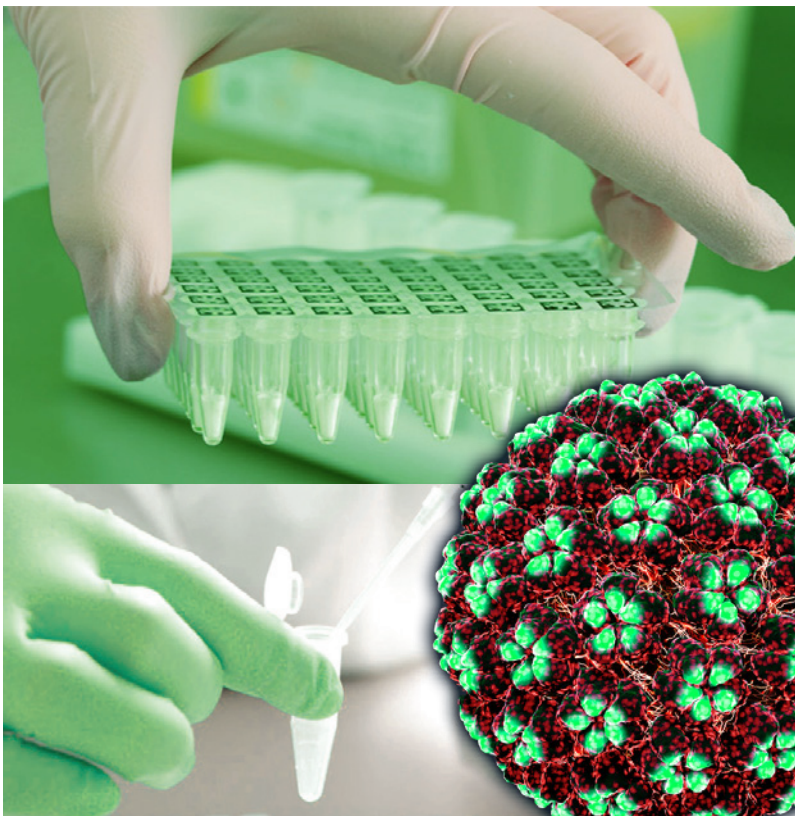
Lyophilized Ready Master Mix is in 0.2 ml white tubes of the 96-tube plate. It is the only necessary to add samples of eluted DNA into the tubes and run the test.

Compatible thermal cyclers

Recommended for: AMPLilab (Adaltis, ITA), CFX96™, iCycler iQ5™, iCycler iQ™ (Bio-Rad, USA), DT-96, DT-Lite (DNA-Technology Research and Production Company ZAO, Russia) and their analogues.

*It is possible to use other thermal cyclers with similar technical characteristics, but their application requires additional validation.*

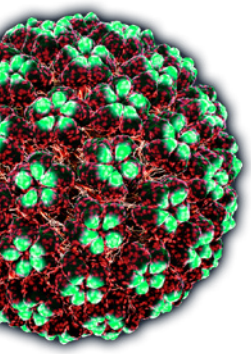


## HUMAN PAPILLOMA VIRUSES (HPV)

| Code | Kit Name | Format | Detection Channels | Number of Tests |
|---|---|---|---|---|
| ME184470 | ■ **MOLgen DNA HPV 44 S1**<br>Detection of Human papilloma virus (HPV) type 44 DNA | STR | FAM, ROX | 96 |
| ME184480 | ■ **MOLgen DNA HPV 66 S1**<br>Detection of Human papilloma virus (HPV) type 66 DNA | STR | FAM, ROX | 96 |
| ME184880 | ■ **MOLgen DNA HPV 68 S1**<br>Detection of Human papilloma virus (HPV) type 68 DNA | STR | FAM, ROX | 96 |
| ME184750 | ■ **MOLgen DNA HPV 6/11 S1**<br>Detection of Human papilloma virus (HPV) types 6 and 11 DNA | STR | FAM, ROX, HEX | 96 |
| ME184730 | ■ **MOLgen DNA HPV 16/18 S1**<br>Detection of Human papilloma virus (HPV) types 16 and 18 DNA | STR | FAM, ROX, HEX | 96 |
| ME184710 | ■ **MOLgen DNA HPV 31/33 S1**<br>Ddetection of Human papilloma virus (HPV) types 31 and 33 DNA | STR | FAM, ROX, HEX | 96 |
| ME184690 | ■ **MOLgen DNA HPV 35/45 S1**<br>Detection of Human papilloma virus (HPV) types 35 and 45 DNA | STR | FAM, ROX, HEX | 96 |
| ME184590 | ■ **MOLgen DNA HPV 26/51 S1**<br>Detection of Human papilloma virus (HPV) types 26 and 51 DNA | STR | FAM, ROX, HEX | 96 |
| ME184460 | ■ **MOLgen DNA HPV 6/11/44 S1**<br>Detection of Human papilloma virus (HPV) types 6, 11 and 44 DNA | STR | FAM, ROX, HEX, Cy5 | 96 |
| ME184490 | ■ **MOLgen DNA HPV 26/53/66 S1**<br>Detection of Human papilloma virus (HPV) types 26, 53 and 66 DNA | STR | FAM, ROX, HEX, Cy5 | 96 |
| ME184510 | ■ **MOLgen DNA HPV 68/73/82 S1**<br>Detection of Human papilloma virus (HPV) types 68, 73 and 82 DNA | STR | FAM, ROX, HEX, Cy5 | 96 |
| ME184780 | ■ **MOLgen DNA HPV HCR genotype S1 (quantitative)**<br>Reagent kit is intended for differential determination and the quantitation of Human papilloma virus (HPV) types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 DNA | STR | FAM, ROX, HEX, Cy5 | 96 |
| ME184790 | ■ **MOLgen DNA HPV HCR genotype S1**<br>Reagent kit is intended for differential determination of Human papilloma virus (HPV) types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 DNA | STR | FAM, ROX, HEX, Cy5 | 96 |
| ME184440 | ■ **MOLgen DNA HPV HCR screen S1**<br>Reagent kit is intended for detection of Human papilloma virus (HPV) types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 DNA | STR | FAM, ROX, HEX | 96 |

Reagent kit is intended for detection of Human papilloma viruses in clinical specimens by real-time PCR.
The kit contains reagents for realtime PCR only.



ADALTIS
MOLECULAR DIAGNOSTICS

For more information

# WWW.ADALTIS.NET


Customer Care Center:
e-mail: **info@adaltis.net**

Technical Assistance:
e-mail: **service@adaltis.net**

**Legal Registered Office**
Via Durini, 27
20122 Milano, Italy

Tel: + 39 0774 5791
Fax. + 39 0774 353085

Sales and Marketing Office
e-mail: **sales@adaltis.net**

Order handling and Logistics
e-mail: **order@adaltis.net**

**Adaltis S.r.l. Headquarter**
**Production and**
**Development Plant**

Via Luigi Einaudi 7
Guidonia di Montecelio
00012 Rome, Italy


ADALTIS is certified in compliance with ISO9001 and ISO 13485.
Our products are CE-IVD.


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