# REALQUALITY
## Human Papilloma Virus (HPV) and other Sexually Transmitted Infections (STI)

**REALQUALITY kits allow the fast detection of Human Papilloma Virus (HPV) and other pathogens causing Sexually Transmitted Infections (STI).**

- *Human Papilloma Virus* (HPV)
- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Mycoplasma hominis* (MH)
- *Ureaplasma parvum* (UP)
- *Ureaplasma urealyticum* (UU)
- *Trichomonas vaginalis* (TV)

Real-Time PCR

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# REALQUALITY
## ▸ RQ-HPV **HR** Multiplex
## ▸ RQ-HPV **Screen**

**14HPV**
One-tube Multiplex PCR

**Kits for detection and identification of high-risk genotypes of the *Human Papillomavirus* by Real-Time PCR (regions E6-E7).**

REALQUALITY RQ-HPV HR Multiplex and RQ-HPV Screen have been developed according to the latest guidelines for HPV DNA assays for diagnostic screening. The assays detect the 14 high-risk HPV types and allow direct identification of the HPV genotypes 16 and 18.
The assays use single-tube multiplexed PCR including an internal control. This guarantees ease of use and makes the assays suitable for high-throughput testing.
To ensure maximum diagnostic reliability these kits target the E6 and E7 oncogenes.
One of the key events of HPV-induced oncogenesis is integration of the HPV genome into the host genome, which may lead the loss of a portion of its sequence. However, the E6 and E7 genes have been found to remain unaffected.
For this reason, the use of a diagnostic system that is based on the detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to viral integration.

**REALQUALITY RQ-HPV Screen is clinically validated according to Meijer guidelines (Iacobellis et al., 2018; Meijer C. et al., 2009).**

### PRODUCT CHARACTERISTICS:

- **Amplified region: E6 and E7 genes**.
- **Genotyping: HPV 16 and 18.**
- **Detected high-risk genotypes: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.**
- **Ready-to-use PCR mastermix**, includes **dUTP/ UNG** system to prevent carry over contamination.
- **Internal control**: Amplification of ß-globin gene in multiplex with pathogen genes.
- **Positive Controls** included.
- Easy interpretation of results with **AB Genius Report 3 software**.
- Validated instruments:

  REALQUALITY RQ-HPV HR Multiplex
  - *Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).*
  - *CFX96 Real-Time PCR Detection System (Bio-Rad).*
  - *LightCycler® 480 Real-Time PCR System version II (Roche).*
  - *Rotor-Gene Q MDx (QIAGEN).*

  REALQUALITY RQ-HPV Screen
  - *Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).*
  - *AriaDx Real-Time PCR System (Agilent Technologies).*

### SPECIMENS:

- DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples.

### SHELF LIFE:

- 18 months.

### FLUOROPHORES:

| Colour | Target |
|---|---|
| Yellow | HPV 16 |
| Red | HPV 18 |
| Green | HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 |
| Orange | ß-globin |

### ORDERING INFORMATION:

| CODE | PRODUCT | FORMAT |
|---|---|---|
| RQ-97-4M/6M | REALQUALITY RQ-HPV HR Multiplex | 50/100 test |
| RQ-97R-4M/6M | REALQUALITY RQ-HPV HR Multiplex *(for LC480 II - Roche)* | 50/100 test |
| RQ-123-4M/6M | REALQUALITY RQ-HPV Screen* | 50/100 test |

** Validated according to Meijer guidelines.*

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# REALQUALITY
## ▸ RQ-HPV **HR/LR** Multiplex

**22HPV**
Two-tubes Multiplex PCR

**Kit for detection and identification of high-risk and low-risk genotypes of the *Human Papillomavirus* by Real-Time PCR (regions E6-E7).**

REALQUALITY RQ-HPV HR/LR is an IVD that allows exhaustive diagnostic analysis. Using only two multiplexed PCRs that include internal controls, the assay detects the 14 high-risk HPV types, the 6 HPV types that are classified by the IARC as possibly high-risk and the two most common low-risk HPV genotypes. In addition, the kit allows direct identification of the main causative agents for HPV-related cancer, the HPV genotypes 16 and 18, as well as HPV 6 and HPV 11, two low-risk HPV types of particular clinical interest.
To ensure maximum diagnostic reliability these kits target the E6 and E7 oncogenes.
One of the key events of HPV-induced oncogenesis is integration of the HPV genome into the host genome, which may lead the loss of a portion of its sequence. However, the E6 and E7 genes have been found to remain unaffected.
For this reason, the use of a diagnostic system that is based on the detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to viral integration.

### PRODUCT CHARACTERISTICS:

- **Amplified region: E6 and E7 genes**.
- **Genotyping: HPV 16, 18, 6 and 11.**
- **Detected high-risk genotypes: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.**
- **Detected possibly high-risk genotypes: HPV 26, 53, 67, 70, 73, 82.**
- **Ready-to-use PCR mastermixe**s, include **dUTP/ UNG** system to prevent carry over contamination.
- **Internal control**: Amplification of ß-globin gene in multiplex with pathogen genes.
- **Positive Controls** included.
- Easy interpretation of results with **AB Genius Report 3 software**.
- Validated instruments:

  *- Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).*

  *- CFX96 Real-Time PCR Detection System (Bio-Rad).*

  *- LightCycler® 480 Real-Time PCR System version II (Roche).*

  *- Rotor-Gene Q MDx (QIAGEN).*

### SPECIMENS:

- DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples.

### SHELF LIFE:

- 18 months.

### FLUOROPHORES:

**Reaction 1 (RX-1)**

| Colour | Target |
|---|---|
| Yellow | HPV 16 |
| Red | HPV 18 |
| Green | HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 |
| Orange | ß-globin |

**Reaction 2 (RX-2)**

| Colour | Target |
|---|---|
| Yellow | HPV 6 |
| Red | HPV 11 |
| Green | HPV 26, 53, 67, 70, 73, 82 |
| Orange | ß-globin |

### ORDERING INFORMATION:

| CODE | PRODUCT | FORMAT |
|---|---|---|
| RQ-99-4M/6M | REALQUALITY RQ-HPV HR/LR Multiplex | 50/100 test |
| RQ-99R-4M/6M | REALQUALITY RQ-HPV HR/LR Multiplex *(for LC480 II - Roche)* | 50/100 test |

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# REALQUALITY
## ▸ RQ-**Multi** HPV Detection

**28HPV**
Two-tubes Multiplex PCR

**Kit for detection of 28 high-risk and low-risk genotypes of the *Human Papillomavirus* by Real-Time PCR (regions E6-E7).**

REALQUALITY RQ-Multi HPV Detection is an IVD that allows exhaustive diagnostic analysis. Using only two multiplexed PCRs that include internal controls the assay detects 14 high-risk, 6 possibly high-risk and 8 low-risk HPV genotypes. In addition, the kit allows direct identification of the main causative agents for HPV-related cancer, the HPV genotypes 16 and 18.
To ensure maximum diagnostic reliability these kits target the E6 and E7 oncogenes.
One of the key events of HPV-induced oncogenesis is integration of the HPV genome into the host genome, which may lead the loss of a portion of its sequence. However, the E6 and E7 genes have been found to remain unaffected.
For this reason, the use of a diagnostic system that is based on the detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to viral integration.

### PRODUCT CHARACTERISTICS:

- **Amplified region: E6 and E7 genes**.
- **Genotyping: HPV 16 and 18.**
- **Detected high-risk genotypes: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.**
- **Detected possibly high-risk genotypes: HPV 26, 53, 67, 70, 73, 82.**
- **Detected low-risk genotypes: HPV 6, 11, 40, 42, 43, 44, 55, 83.**
- **Ready-to-use PCR mastermixes**, include **dUTP/ UNG** system to prevent carry over contamination.
- **Internal control**: Amplification of ß-globin gene in multiplex with pathogen genes.
- **Positive Controls** included.
- Easy interpretation of results with **AB Genius Report 3 software**.
- Validated instruments:

  *- Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).*
  *- CFX96 Real-Time PCR Detection System (Bio-Rad).*
  *- LightCycler® 480 Real-Time PCR System version II (Roche).*

### SPECIMENS:

- DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples.

### SHELF LIFE:

- 18 months.

### FLUOROPHORES:

**Reaction 1 (RX-1)**

| Colour | Target |
|---|---|
| Yellow | HPV 16 |
| Red | HPV 18 |
| Green | HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 |
| Orange | ß-globin |

**Reaction 2 (RX-2)**

| Colour | Target |
|---|---|
| Yellow | HPV 40,42,43, 44, 55, 83 |
| Red | HPV 6, 11 |
| Green | HPV 26, 53, 67, 70, 73, 82 |
| Orange | ß-globin |

### ORDERING INFORMATION:

| CODE | PRODUCT | FORMAT |
|---|---|---|
| RQ-103-4M/6M | REALQUALITY RQ-Multi HPV Detection | 50/100 test |
| RQ-103R-4M/6M | REALQUALITY RQ-Multi HPV Detection *(for LC480 II - Roche)* | 50/100 test |

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# REALQUALITY
# ▸ RQ-**STI CT/NG/MG**

**3STI**
One-tube Multiplex PCR

**Kit for detection of *Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium* by Real-Time PCR.**

| Pathogen | Target Region |
|---|---|
| **STI CT/NG/MG Real time mix** | |
| ***Chlamydia trachomatis*** | • *MOMP gene*<br>• *Cryptic plasmid* |
| ***Neisseria gonorrhoeae*** | • *porA pseudo gene*<br>• *multi-copy opa gene* |
| ***Mycoplasma genitalium*** | • *MgPa gene* |

The kit includes the use of a double amplification target for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. This approach guarantees the maximum diagnostic reliability for the identification of variants and a high analytical sensitivity, since the cryptic plasmid of CT and the opa gene of NG are present in multiple copies (respectively from 7 to 10 copies per CT organism and up to 11 copies per NG organism).

## PRODUCT CHARACTERISTICS:

- Detection and identification of **3 STI** causing pathogens by one-tube multiplex PCR.
- **Two target regions for both C. trachomatis and N. gonorrohoeae** increase the clinical specificity and sensitivity of the test.
- **Ready-to-use PCR mastermix**, includes **dUTP/ UNG** system to prevent carry over contamination.
- **Internal control**: amplification of ß-globin gene in multiplex with pathogens genes.
- **Positive controls** included.
- Easy interpretation of results with **AB Genius Report 3 software**.
- Validated instruments:

*- AriaDx Real-Time PCR System (Agilent Technologies).*
*- Applied Biosystems 7500 Fast Dx Real-Time PCR System (Applied Biosystems).*
*- CFX96 Real-Time PCR Detection System (Bio-Rad).*
*- Rotor-Gene Q MDx (QIAGEN).*

## FLUOROPHORES:

| Colour | Target |
|---|---|
| Green | Chlamydia trachomatis (CT) |
| Yellow | Neisseria gonorrhoeae (NG) |
| Red | Mycoplasma genitalium (MG) |
| Orange | ß-globin |

## SPECIMENS:

- DNA extracted from cervico-vaginal, urogenital, urethral swabs and urine. It has also been tested on DNA extracted from prostatic secretion, rectal swab, seminal fluid and urethral biopsy.

## SHELF LIFE:

- 18 months.

## ORDERING INFORMATION:

| CODE | PRODUCT | FORMAT |
|---|---|---|
| RQ-107-4M/6M | REALQUALITY RQ-STI CT/NG/MG | 50/100 test |

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# REALQUALITY
## ▸ RQ-**SevenSTI**

**7STI**
Two-tubes Multiplex PCR

**Kit for detection of *Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium, Mycoplasma hominis, Trichomonas vaginalis, Ureaplasma urealyticum* and *Ureaplasma parvum* by Real-Time PCR.**

| Pathogen | Target Region |
|---|---|
| **STI CT/NG/MG Real time mix** | |
| ***Chlamydia trachomatis*** | • *MOMP gene*<br>• *Cryptic plasmid* |
| ***Neisseria gonorrhoeae*** | • *porA pseudo gene*<br>• *multi-copy opa gene* |
| ***Mycoplasma genitalium*** | • *MgPa gene* |

| Pathogen | Target Region |
|---|---|
| **STI TV/MH/UU/UP Real time mix** | |
| ***Trichomonas vaginalis*** | • *Repeated sequence* |
| ***Mycoplasma hominis*** | • *16s rRNA* |
| ***Ureaplasma urealyticum*** | • *Urease gene* |
| ***Ureaplasma parvum*** | • *Urease gene* |

The kit includes the use of a double amplification target for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. This approach guarantees the maximum diagnostic reliability for the identification of variants and a high analytical sensitivity, since the cryptic plasmid of CT and the opa gene of NG are present in multiple copies (respectively from 7 to 10 copies per CT organism and up to 11 copies per NG organism).

## PRODUCT CHARACTERISTICS:

- Detection and identification of **7 STI** causing pathogens by two-tube multiplex PCR.
- **Two target regions for both C. trachomatis and N. gonorrohoeae** increase the clinical specificity and sensitivity of the test.
- **Ready-to-use PCR mastermix**, includes **dUTP/UNG** system to prevent carry over contamination.
- **Internal control**: amplification of ß-globin gene in multiplex with pathogens genes.
- **Positive controls** included.
- Easy interpretation of results with **AB Genius Report 3 software**.
- Validated instruments:

  *- AriaDx Real-Time PCR System (Agilent Technologies).*
  *- CFX96 Real-Time PCR Detection System (Bio-Rad).*
  *- Rotor-Gene Q 6plex (QIAGEN).*

## SPECIMENS:

- DNA extracted from urogenital, cervical-vaginal and urethral swabs and urine.

## SHELF LIFE:

- 18 months.

## FLUOROPHORES:

**Reaction 1 (RX-1)**

| Colour | Target |
|---|---|
| Green | *Chlamydia trachomatis* (CT) |
| Yellow | *Neisseria gonorrhoeae* (NG) |
| Red | *Mycoplasma genitalium* (MG) |
| Orange | ß-globin |

**Reaction 2 (RX-2)**

| Colour | Target |
|---|---|
| Green | *Trichomonas vaginalis* (TV) |
| Yellow | *Ureaplasma urealyticum* (UU) |
| Red | *Mycoplasma hominis* (MH) |
| Orange | *Ureaplasma parvum* (UP) |

## ORDERING INFORMATION:

| CODE | PRODUCT | FORMAT |
|---|---|---|
| RQ-127-4M/6M | REALQUALITY RQ-SevenSTI | 50/100 test |

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