QIAGEN

# Menu and flexibility with the QIAscreen HPV PCR Test

Sample to Insight

# HPV and Cervical cancer

Worldwide, HPV is one of the most common STIs

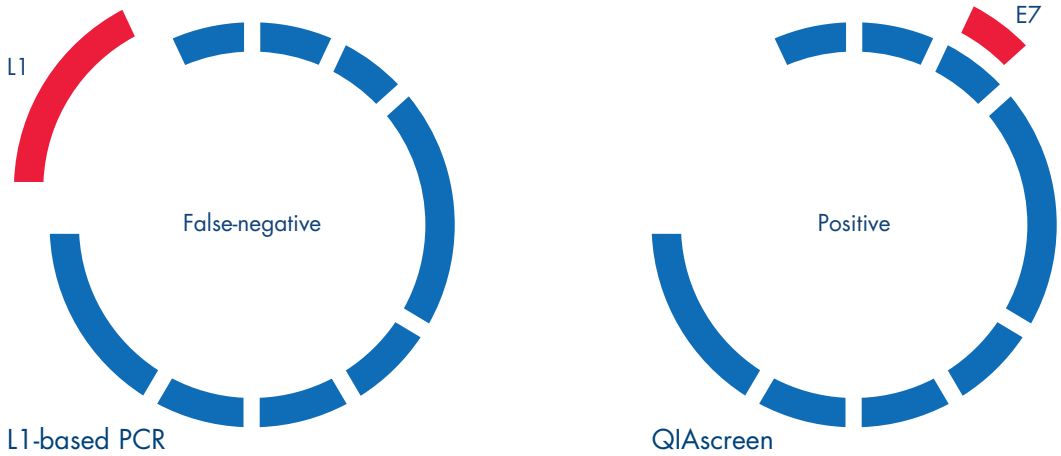
Persistent infection with high-risk HPV types is linked to virtually all cases of cervical cancer. (1)

## The World Health Organization estimated 528,000 new cases and 266,000 deaths per year (2)

The viral genome contains early (E) and late (L) genes.

The L1 gene can be deleted in cervical cancers and lead to false negatives in L1-specific PCR tests (3). The QIAscreen test circumvents this by detecting the conserved E7 gene (4).

**Figure 1: L1 deletion event seen in cancer**




## Risk of false-negatives associated with L1 deletions can be prevented with an HPV DNA test that targets conserved regions of the genome.

# Sexually Transmitted Infections

Every day >1 million sexually transmitted infections (STIs) are acquired (5).

STIs can have serious reproductive health consequences beyond the immediate impact of the infection itself.


## Detecting a menu of STIs provides timely and accurate diagnoses for patients.


# The QIAscreen HPV PCR Test

The QIAscreen HPV PCR Test is an in vitro real-time PCR-based assay for the qualitative detection of human papillomavirus (HPV) DNA of the following 15 likely (6) high-risk HPV genotypes, i.e., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 67, and 68. The assay is intended to be used for the screening of women for the risk of cervical (pre) cancer.

Validated sample types include:

- Cervical specimens collected in PreservCyt, Surepath and Pathtezt collection medium
- Self-collected vaginal brush specimens
- Self-collected cervico-vaginal lavage specimens

## Flexible workflow

Open-ended extraction that can be manual or automated

## Menu on RGQ instrument

Test with CTNG and Trich assays

## Validated for many sample types

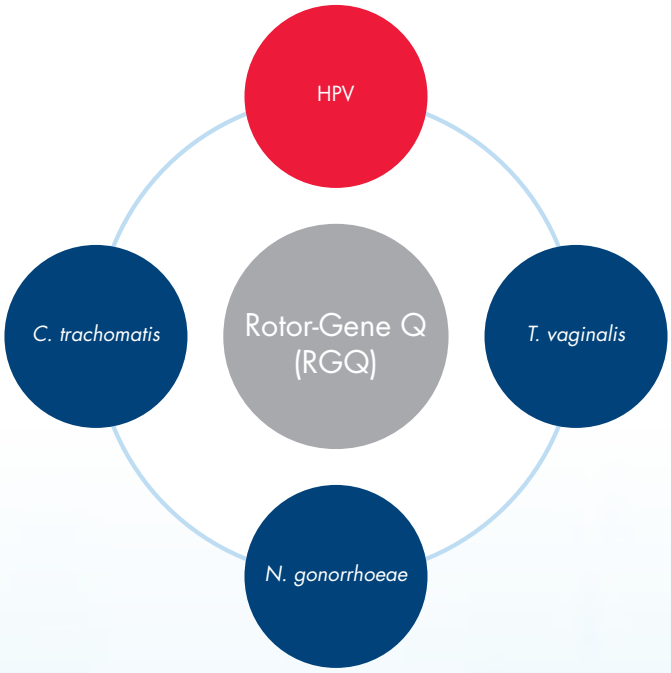
Options for self sampling

## Unique HPV targeting

Targets the viral E7 oncogene of 15 HPV types

## Meets international guidelines (4)

- 97.1% sensitivity
- 94.3% specificity
- 99.5% intra-lab reproducibility
- 99.2% inter-lab agreement





# Rotor-Gene® Q Workflow

QIAscreen can bolster your Rotor-Gene Q workflow, providing a menu of applications on one instrument. Detecting a menu of STIs provides timely and accurate diagnoses for patients.

QIAscreen rounds out QIAGEN's family of PCR-based women's health tests on the Rotor-Gene Q instrument, which include tests for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis*. Labs can conduct a panel of women's health tests in a more streamlined and resourceful manner to provide comprehensive insights for clinicians and patients.

## QIAscreen is validated by the Meijer criteria (4)

| | Reference assay GP5+/6+ PCR | QIAscreen* | Meets Meijer guidelines |
|---|---|---|---|
| **Sensitivity CIN2+** | 97.1% (67/69) | 97.1% (67/69) | **Yes** |
| **Specificity CIN2+** | 93.7% (772/824) | 94.3% (777/824) | **Yes** |
| **Intra-lab reproducibility** | – | 99.5% (544/547) | **Yes** |
| **Inter-lab agreement** | – | 99.2% (527/531) | **Yes** |

*Performance characteristics are indicated for the HPV-Risk assay, now available as QIAscreen.

## Performance comparison of QIAscreen and HC2® tests (7)

For women ≥ 30 years old:

| | CIN3+ | | CIN2+ | |
|---|---|---|---|---|
| **Test** | **Sensitivity** | **Specificity** | **Sensitivity** | **Specificity** |
| QIAscreen | 97.0% (95% CI: 89.5 - 99.6%) | 91.8% (95% CI: 89.9 - 93.4%) | 92.9% (95% CI: 85.8 - 97.1%) | 94.2% (95% CI: 92.6 - 95.6%) |
| HC2 | 97.0% (95% CI: 89.5 - 99.6%) | 89.8% (95% CI: 87.8 - 91.6%) | 95.9% (95% CI: 89.9 - 98.9%) | 92.5% (95% CI: 90.7 - 94.1%) |

The QIAscreen test performs comparably with the HC2 test.

# QIAscreen joins QIAGEN's comprehensive cervical cancer screening portfolio.

## Ordering Information

| Product | Contents | Cat. No. |
|---|---|---|
| QIAscreen HPV PCR Test | For 72 reactions, includes: Master Mix, Positive Control, Negative Control, Instructions for Use | 617005 |
| **Rotor-Gene Q MDx** | | |
| Rotor-Gene Q MDx HRM System | Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training | 9002035 |
| | Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training not included | 9002032 |
| **Rotor-Gene Q MDx Accessories** | | |
| Loading Block 72 x 0.1 ml Tubes | Aluminum block for manual reaction set up with a single-channel pipet in 72 x 0.1 ml tubes | 9018901 |
| Strip Tubes and Caps, 0.1 ml (250) | 250 strips of 4 tubes and caps for 1000 reactions | 981103 |
| Strip Tubes and Caps, 0.1 ml (2500) | 10 x 250 strips of 4 tubes and caps for 10,000 reactions | 981106 |

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

Self-screen B.V. is the legal manufacturer of the QIAscreen HPV PCR Test.


**References:**

1. Bosch, F.X. et al. (2002) The causal relation between human papillomavirus and cervical cancer. J Clin Pathol **55**, 244-265.
2. World Health Organization. (2017) Human papillomavirus vaccines: WHO position paper. WER **92**, 241–68.
3. Capone, R. et al. (2000) Detection and Quantitation of Human Papillomavirus (HPV) DNA in the Sera of Patients with HPV-associated Head and Neck Squamous Cell Carcinoma. Clin Canc Res **6**, 4171–75.
4. Hesselink, A. et al. (2014) Clinical Validation of the HPV-Risk Assay, a Novel Real-Time PCR Assay for Detection of High-Risk Human Papillomavirus DNA by Targeting the E7 Region. J Clin Microbiol **52**, 890-96.
5. World Health Organization. Sexually Transmitted Infections Fact Sheet. 3 August 2016
6. International Agency for Research on Cancer. (2009). A review of human carcinogens. Part B: Biological Agents. Monographs 100B.
7. Polman N. et al. (2017) Evaluation of the clinical performance of the HPV-Risk assay using the VALGENT-3 panel. J Clin Microbiol **55**, 3544-51.
8. QIAscreen HPV PCR Test Kit Handbook. Version 1. August 2018.