HIGH-RISK HPV

REALQUALITY
RQ-HPV **HR** Multiplex

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

REALQUALITY RQ-HPV HR Multiplex has been developed according to the latest guidelines for HPV DNA assays for diagnostic screening. The assay detects the 14 high-risk HPV types and allows direct identification of the HPV genotypes 16 and 18.
The assay uses single-tube multiplexed PCR including an internal control. This guarantees ease of use and renders the assay suitable for high-throughput testing.

To ensure maximum diagnostic reliability this kit utilizes the regions of 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 to loss of a portion of the HPV genome as well as abnormal gene expression. However, expression of the E6 and E7 genes has been found to remain unaffected.
For this reason, use of a diagnostic system that is based on detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to aberrant viral integration.

REALQUALITY
RQ-HPV HR Multiplex

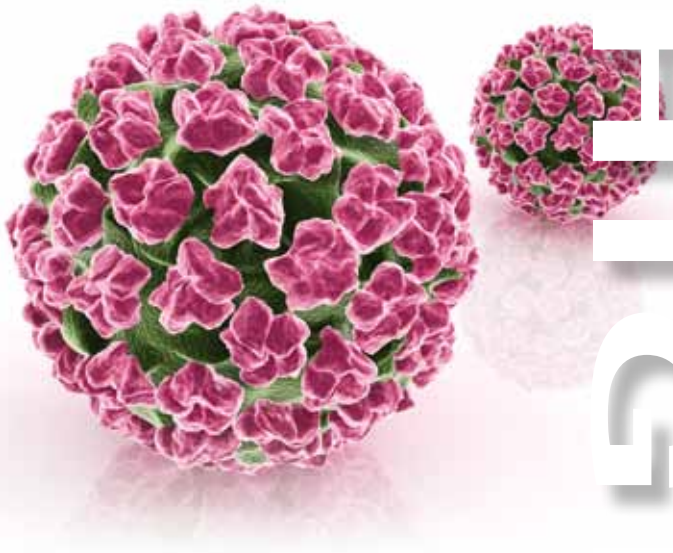
One-tube Multiplex PCR

14HPV

CE IVD

AB ANALITICA®
ADVANCED BIOMEDICINE

AB-BRO_RQ-HPV_HR_e20151211



HIGH-RISK HPV

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
- Suitable sample types: DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples
- Internal control: Amplification of ß-globin gene (BG) in multiplex with pathogen genes
- Validated instruments:
  - Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System *(Applied Biosystems)*
  - Dx Real-Time System and CFX96 Real-Time PCR Detection System *(Bio-Rad)*
  - LightCycler® 480 Real-Time PCR System version II *(LC 480 II - Roche)*

SPECIFICATIONS:

- Analytical specificity: No non-specific binding of primers and probes, no cross-reaction
- Analytical sensitivity (detection limit):
  - 155.25 virus genome copies/mL* for HPV 16
  - 182.25 virus genome copies/mL* for HPV 18
- Diagnostic specificity: 99.1%
- Diagnostic sensitivity: 99.5%
- Accuracy: 99.3%

* The values refer to an extraction system using 400 µL of starting sample and an elution volume of 90 µL

REPRODUCIBILITY:

- Mean intra-assay variability: 0.63%
- Mean inter-assay variability: 0.71%

SHELF LIFE:

- 12 months

FLUOROPHORES

Fluorophore	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

CE IVD

CODE	PRODUCT	FORMAT
RQ-97-48/96	REALQUALITY RQ-HPV HR Multiplex	48/96 test
RQ-97R-48/96	REALQUALITY RQ-HPV HR Multiplex (for LC 480 II - *Roche*)	48/96 test

This product uses technology patented by Biosearch Technologies, licensed for use in Human Molecular Diagnostic applications

AB ANALITICA® ADVANCED BIOMEDICINE

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