

HUMAN PAPILOMAVIRUSES INFECTIONS

Human papillomaviruses (HPVs) are a group of more than 150 non-enveloped DNA viruses, including at least 40 HPV types, which are sexually transmitted. High-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, 82) - HCR HPV - are oncogenic, or cancerogenic and may cause cervical cancer and other types of cancer (oropharyngeal, anal). Low-risk HPV types (6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81) - LCR HPV - cause genital warts and do not appear to be oncogenic or cancerogenic. Ecoli Dx HPV portfolio provides you with an outstanding solution for HPV diagnostics including primary screening.

PRODUCT ADVANTAGES

HIGH INSTRUMENT FLEXIBILITY

- High flexibility and compatibility with a wide range of real-time PCR instruments, e.g. Ecoli eQuantia 48, Bio-Rad CFX96 Touch, QIAGEN Rotor-Gene Q, Agilent Mx3000P, ABI QuantStudio
- Most kits suitable also for 4-channel real-time PCR instruments

UNIVERSAL ASSAY WORKFLOW

- Universal PCR profiles allowing full use of the capacity of laboratory instruments

RELIABLE RESULTS

- β -globin gene internal control to monitor sample collection, storage and test stages (DNA extraction and amplification)

ELIMINATION OF POSSIBLE CONTAMINATION

- All kits contain Uracil-DNA glycosylase (UDG) and dUTPs eliminating possible contamination with amplification products

RECOMMENDED EXTRACTION KITS

- DNA-sorb-AM, cat.n. K1-12-100-CE (for manual extraction)
- DNA-sorb-D, cat.n. K8-2331-100-CE (for liquid-based cytology samples)
- E2007 ePure STD Extraction Kit (for automated extraction on ePure device)

VALIDATED TRANSPORT MEDIA FOR ALL HPV KITS

- Transport Medium with Mucolytic Agent, cat.n. 952-CE (Ecoli, Czech Republic)
- Digene Cervical Sampler and Digene transport medium (QIAGEN, Germany)
- PreservCyt (Hologic, USA)

HIGH-RISK HPV INFECTIONS

Genotyping + quantitative kits

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Storage	Fluorescent channels	Availability
H-2311-1-13-CE	AmpliSens® HPV HCR screen-titre-14 FRT PCR kit variant FRT-100 FN			110		genotyping + quantitative	12 months			
R-V67-F-CE	AmpliSens® HPV HCR genotype-titre-FRT PCR kit			110		genotyping + quantitative	12 months			
R-V12-F-CE	AmpliSens® HPV 16/18-FRT PCR kit variant FRT-100 F			110		genotyping + quantitative	12 months			

AmpliSens® HPV HCR screen-titre-14 FRT PCR kit variant FRT-100 FN

Quantitative detection:

- HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

Genotyping:

- HPV 16, 18, 45

Sample type:

- vaginal swab, cervical scrapes (ectocervix, endocervix)

Analytical sensitivity:

5x10³ copies/ml

Linear measurement range:

- 7x10³ - 1x10⁸ copies/ml

AmpliSens® HPV HCR genotype-titre-FRT PCR kit

Quantitative detection and genotyping:

- HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

Sample type:

- vaginal swab, cervical scrapes (ectocervix, endocervix), urethral scrape

Analytical sensitivity:

- 1x10³ copies/ml

Linear measurement range:

- 1x10³ - 1x10⁸ copies/ml

AmpliSens® HPV HCR genotype-titre-FRT PCR kit

Quantitative detection and genotyping:

- HPV 16 and 18

Sample type:

- vaginal swab, cervical scrapes (ectocervix, endocervix), urethral scrape

Analytical sensitivity:

1x10³ GE/ml

Linear measurement range:

- 1x10³ - 1x10⁸ GE/ml

Diagnostic characteristics were determined according to international requirements for validation of new tests for HPV detection (Meijer's criteria)

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
 on request available; RT-Room temperature 2 to 8 °C -24 to -16 °C

Genotyping + qualitative kits

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Storage	Fluorescent channels	Availability
R-V25 (RG,iQ,Mx)-CE	AmpliSens® HPV HCR genotype-FRT			108		genotyping	6 months			

Qualitative detection and genotyping:

- HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59

Sample type:

- vaginal swab, cervical scrapes (ectocervix, endocervix), urethral scrape

Analytical sensitivity:

1x10³ GE/ml

Quantitative screening kits

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Storage	Fluorescent channels	Availability
R-V31-T-2x (RG,iQ,SC)-CE	AmpliSens® HPV HCR screen-titre-FRT			108		quantitative	9 months			
R-V31-T-4x (RG,iQ,Mx)-CE	AmpliSens® HPV HCR screen-titre-FRT			108		quantitative	6 months			

AmpliSens® HPV HCR screen-titre-FRT (cat.n. R-V31-T-2x)

Quantitative detection with phylogenetic group differentiation:

- group A9 (HPV 16, 31, 33, 35, 52, 58), group A7 (HPV 18, 39, 45, 59) together with HPV 51, 56

Sample type:

- vaginal swab, cervical scrapes (ectocervix, endocervix), urethral scrape

Analytical sensitivity:

- 5x10³ GE/ml for HPV types 16, 18, 31, 35, 39, 45, 51, 52, 56 and 59

- 2,5x10⁴ GE/ml for HPV types 33 and 58

AmpliSens® HPV HCR screen-titre-FRT (cat.n. R-V31-T-4x)

Quantitative detection with phylogenetic group differentiation:

- group A9 (HPV 16, 31, 33, 35, 52, 58), group A7 (HPV 18, 39, 45, 59), and HPV 51, 56

Sample type:

- vaginal swab, cervical scrapes (ectocervix, endocervix), urethral scrape

Analytical sensitivity:







- 5x10³ GE/ml for HPV types 16, 18, 31, 35, 39, 45, 51, 52, 56 and 59

- 2,5x10⁴ GE/ml for HPV types 33 and 58

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
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LOW-RISK HPV INFECTIONS

Genotyping + qualitative kit

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Storage	Fluorescent channels	Availability
R-V11-Mod(RG,iQ,Mx)-CE	AmpliSens® HPV 6/11-FRT PCR kit variant FRT-100F			110		genotyping	12 months			

Qualitative detection and genotyping:

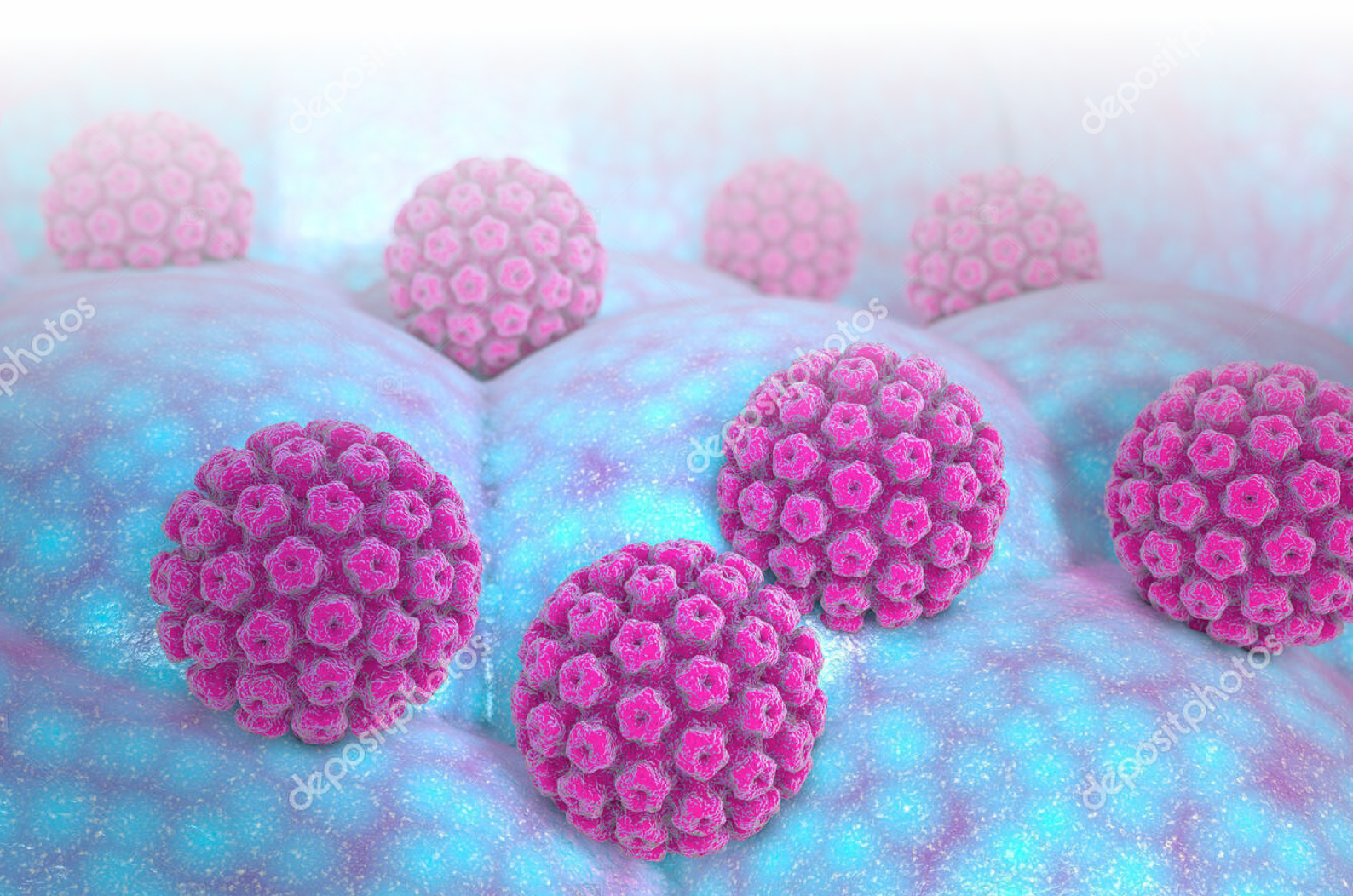
- HPV 6, 11










Sample type:

- samples of epithelial cells, vaginal swab, cervical scrapes (ectocervix, endocervix), urethral scrape

Analytical sensitivity:

- 1×10^3 GE/ml



 Real-Time
  Reverse transcription
  Fluorescent End-Point
  Reagents in stock tubes
  Ready-to-use PCR tubes
 on request
  available; RT-Room temperature
  2 to 8 °C
  -24 to -16 °C