



# genefirst

## Papilloplex® High Risk HPV

*Accuracy and Sensitivity in Design  
Confidence and Clarity in Results*

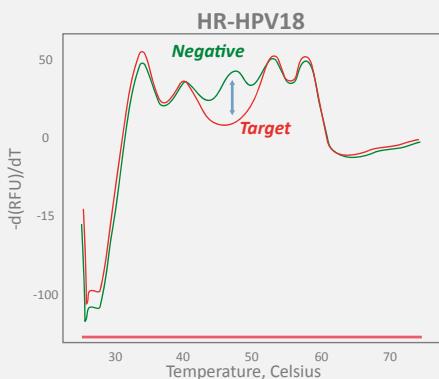
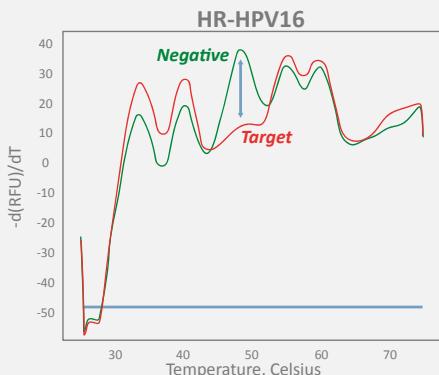
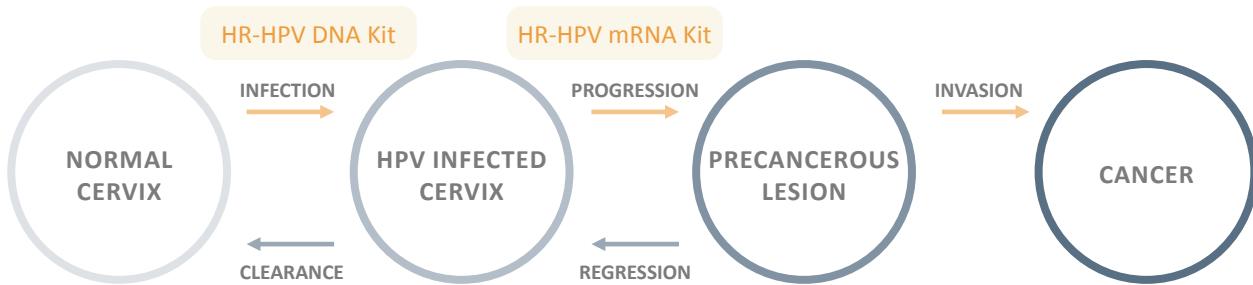


CE IVD

GeneFirst Papilloplex® HPV tests are designed for a true molecular HPV screening and triage testing strategy to support stratification of women infected with HPV

# GeneFirst Papilloplex® HPV

Infection with human papillomavirus (HPV) poses a high risk for developing cervical cancer. The progression of cervical neoplasia to invasive cervical cancer can be either due to persistent HPV infections or expression of the viral E6 and E7 oncogenes. These oncogenes are active in cervical carcinomas and their corresponding proteins are directly involved in triggering cell proliferation, inhibition of apoptosis, reprogramming of differentiation, and chromosomal instability leading to malignant transformation of host cells. The Papilloplex® HR-HPV mRNA kit (detects E6/E7 mRNA) is designed to complement the Papilloplex® HR-HPV DNA kit to identify risk of cervical cancer in HPV positive individuals without the need to monitor for persistence of infection.



## Key Features and Benefits

- Simultaneous detection and differentiation of all high-risk types including 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
- DNA test for better sensitivity and risk stratification
- Internal control for sample cellularity and PCR inhibition
- Ease-of-use in a single, multiplex, real-time PCR reaction
- Flexible, customisable throughput
- Automation compatible

## Technical Specifications

- Target sequence: E6/E7 region
- Clinical sensitivity: 100%
- Limit of detection: 100 copies for all HPV types
- Quality control: Positive and internal cellular controls of PCR amplification and sample integrity
- Validated sample type: Cervical (Thinprep)
- Recommended extraction methods: Quick DNA/RNA Viral Kit (Zymo Research); Viral-Prep Adem-Kit (Ademtech)
- Validated amplification system: Bio-Rad CFX96; SLAN96P

## Proprietary Technology

Patented multiplex real-time PCR technology (MPA) for reliable results

## Clinically Validated

Clinically validated under internationally recognised framework<sup>†</sup>

## Robust Test Design

High sensitivity and specificity for detection of HPV DNA and RNA

## Supports Clinical Decision

Comprehensive information on genotyping, co-infection and biomarker presence to better risk-stratify patients

## Innovative Approach

Dual test using the same sample (self-sample or clinic collected\*)

## Saves Time & Money

Helps reduce unnecessary colposcopies and cervical treatments

\* EU-VALHUEDS study in progress

†VALGENT-4 available and VALTRIHP study in progress

## Ordering Information

| Catalogue Number | Product Name                 | Storage | Intended Use |
|------------------|------------------------------|---------|--------------|
| MPAHPV004        | Papilloplex® HR-HPV mRNA Kit | -20° C  | CE-IVD       |
| MPAHPV006        | Papilloplex® HR-HPV DNA Kit  | -20° C  | CE-IVD       |

## GeneFirst Ltd

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