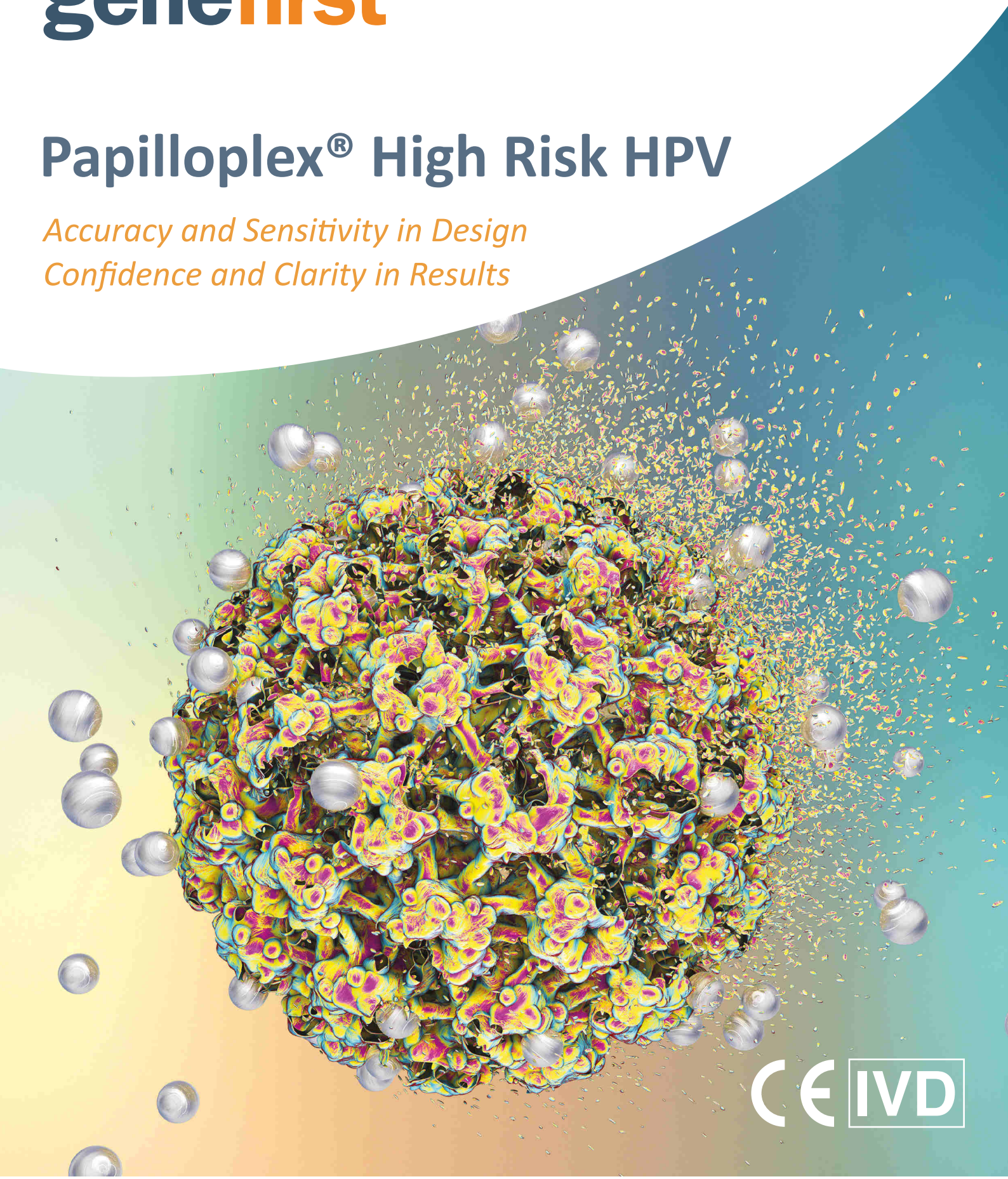
genefirst

Papilloplex® High Risk HPV

Accuracy and Sensitivity in Design
Confidence and Clarity in Results

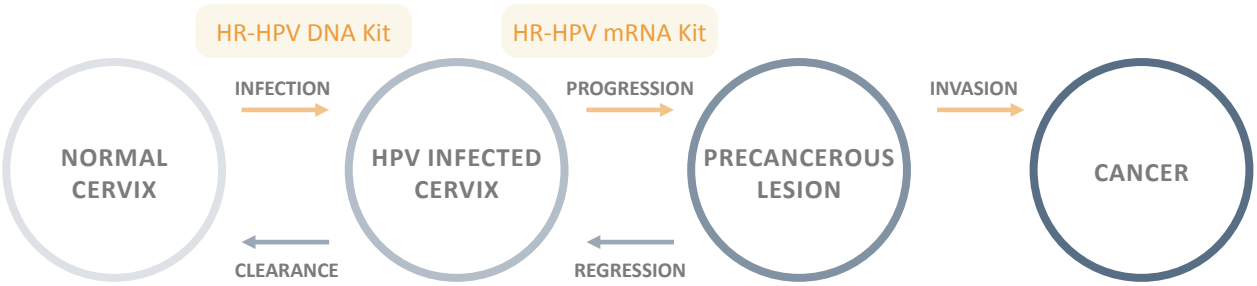


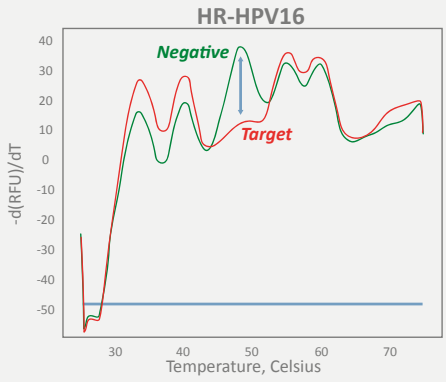
CE IVD

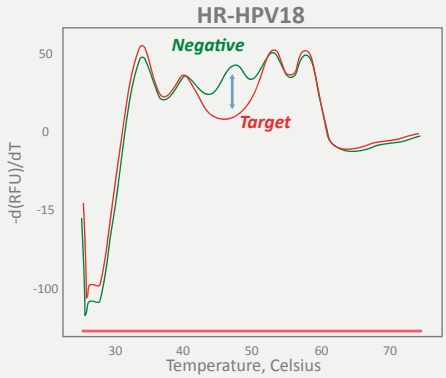
GeneFirst Papilloplex® HPV tests are designed for a true molecular HPV screening and triage testing strategy to support stratification of women infected with HPV

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

Robust Test Design

High sensitivity and specificity for detection of HPV DNA and RNA

Innovative Approach

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

Clinically Validated

Clinically validated under internationally recognised framework†

Supports Clinical Decision

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

Saves Time & Money

Helps reduce unnecessary colposcopies and cervical treatments

* EU-VALHUDES 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

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