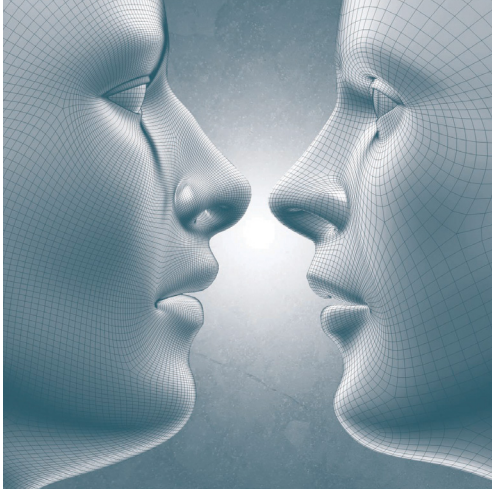
Fast Track DIAGNOSTICS

A Siemens Healthineers Company



Reliable

Simple

Sensitive

Syndromic real-time PCR multiplexing kits

FTD HPV High Risk

FTD completes its comprehensive Sexually Transmitted Infections panel by offering a multiplex real-time PCR for detection and differentiation of human papillomavirus 16, human papillomavirus 18, and for detection of a pool of 12 other High Risk human papillomavirus genotypes, including a human endogenous control.

HPV overview

The human papillomavirus (HPV) is a double-stranded circular DNA virus that can be easily transmitted through sexual contact. HPV infection is one of the most common viral infections of the reproductive tract and is the major risk factor for the development of cervical carcinoma. From over 150 genotypes of HPV being identified, 14 High Risk genotypes are responsible for nearly all cervical cancers, with HPV type 16 and 18 alone accounting for over 70% of cases.[1]

Although over 90% of HPV infections are resolved within 2 years, a small proportion of infections from any of the 14 High Risk HPV subtypes can persist and progress into neoplastic lesions. Cytology and real-time PCR co-testing is considered as the regular screening test for an early and accurate detection of HPV infection.[2]

References:

[1] Cuzick, J. *et al.* (2006) *Journal of Cancer,* 119(5), pp. 1095-1101

[2] Groves, I.J. *et al.* (2015) *Journal of Pathology,* 235, pp. 527-538

Features of the kit

- **Quality assured:** CE-IVD (*in vitro* diagnostic), external quality assessments and clinical studies
- **Accuracy:** high sensitivity, high specificity
- **Reliability:** consistent results with excellent repeatability and reproducibility
- **Fast:** real-time PCR multiplexing kit detecting simultaneously all the High Risk genotypes of human papillomavirus
- **Shelf life:** 12 months from manufacture
- **Compatibility:** can be used with most extraction and PCR platforms on the market
- **Cost-effective:** competitive prices, value for money offer

Assay information

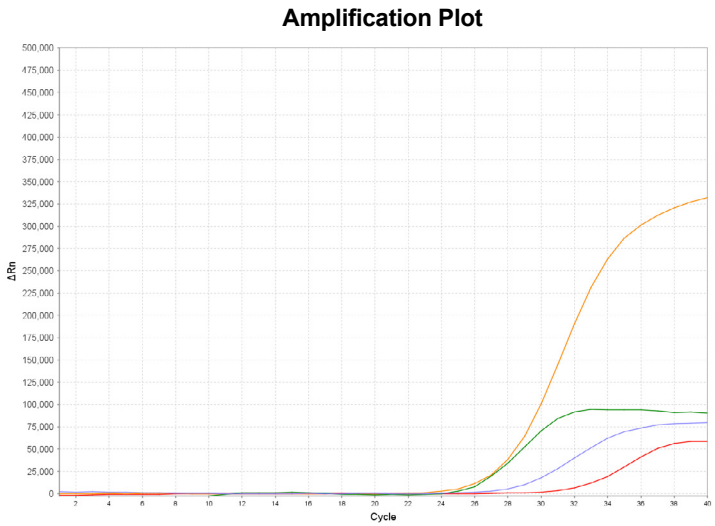


Figure 1. Amplification curves representing all targets
A positive sample for all targets was extracted and tested by qPCR. HPV 16 is detected in the yellow channel (yellow curve), HPV 18 in the orange channel (orange curve) and the pool of 12 other High Risk HPV genotypes in the green channel (green curve). The internal control is a housekeeping gene detected in the red channel (red curve).

Kit description	
Principle	Multiplex real-time PCR for detection of pathogen genes by TaqMan® technology
Packaging	All qRT-PCR reagents included Flexible 32 or 64 reactions kit size
Genotypes	HPV16, HPV18, HPV31, HPV33, HPV35, HPV39, HPV45, HPV51, HPV52, HPV56, HPV58, HPV59, HPV66, HPV68
Gene target	E6-E7 genes, responsible for HPV-mediated oncogenesis
Specimen	Extracted nucleic acid from cervical swabs
Endogenous control	Housekeeping gene targeted to ensure the quality of the extraction

Quality assured

All FTD kits are regularly controlled by Quality Control for Molecular Diagnostics (QCMD) panels and other external quality assessment programs. In addition, FTD kits undergo pre- and post-market clinical performance evaluation studies. See example below:

	EQA samples		Clinical samples	
	Number of tests performed on samples	Accuracy	Number of tests performed on samples	Overall agreement**
FTD HPV High Risk	66	97.0%*	492	99.8%*

** The vast majority of the discrepant results were obtained from low positives or educational samples*
*** In comparison with competitor kits and/or reference methods*

For complete quality data, please refer to the product manuals and validation files available on FTD´s website.

Quotes from publications

“A recent statement from the International Agency for Research on Cancer (IARC) concluded that there is sufficient evidence that HPV testing can reduce the incidence and mortality from cervical cancer and that it is likely to be at least as effective as cytology.”

Cuzick, J. *et al.* (2006) *Journal of Cancer*, 119(5), pp. 1095-1101

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