

Fast Track

DIAGNOSTICS

A Siemens Healthineers Company

Syndromic real-time PCR multiplexing kits

Reliable

Lyophilised

Sensitive

FTD HPV High Risk

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

Although over 90% of HPV infections are resolved within 2 years, a small proportion of infections from any of the 14 High Risk HPV genotypes can persist and progress into neoplastic lesions. Cervical cancer screening based on cytology, despite being specific, has a high rate of false negatives and often fails to prevent adenocarcinoma of the cervix.

Features

- **Quality:** 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.

Amplification Plot

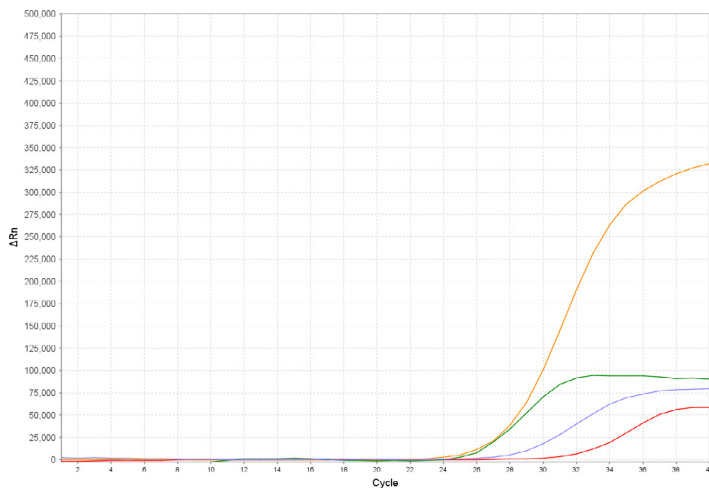


Figure 1. Amplification curves representing all targets

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

Competitor comparison

Clinical samples and external quality control panels were tested with FTD HPV High Risk assay. All samples were confirmed leading to 100% overall agreement.

	QCMD 2017		Clinical samples	
	Samples confirmed	Overall agreement	Samples confirmed	Overall agreement
FTD HPV High Risk	12/12	100.00%	64/64	100.00%
Competitor 1	n.a.*	n.a.*	63/64	98.44%

*n.a.: non applicable as the competitor did not participate to QCMD programme 2017

Quotes from publications

“The present data indicate that women at high risk could be identified accurately using qRT-PCR [...] as an alternative to cytological screening and/or cervical viral load measurement.”

A. Daponte et al., *Journal Compilation 2008 European Society of Clinical Microbiology and Infectious Diseases, CMI, 14, 605–624* “Use of real-time PCR to detect human papillomavirus-16 viral loads in vaginal and urine self-sampled specimens”

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