

**FOR RESEARCH USE ONLY! NOT FOR DIAGNOSTIC PURPOSE!**

## Multiplex HPV Genotyping Kit for Research in Epidemiology

Fluorescent Bead Array for research in epidemiology on 24 Human Papillomaviruses (HPV) in Polymerase Chain Reaction (PCR) Amplified Samples, according to Schmitt et al. 2006

The Multiplex HPV Genotyping Kit is a qualitative and sensitive high-throughput procedure for the identification of multiple high- and low-risk genital HPV genotypes in a single reaction.

### Intended use

More than 100 HPV of the Alphapapillomavirus genus are known. 24 of the most common types have been divided into three groups based on their association to cancer: 15 high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82), 3 putative high-risk types (26, 53, and 66), and 6 low-risk types primarily found in genital warts and low-grade cervical lesions (6, 11, 42, 43, 44, and 70) (MUNOZ et al. 2003; SCHMITT et al. 2006).

The Multiplex HPV Genotyping Kit is an in vitro test kit for research in epidemiology on Human Papillomavirus types 6, 11, 16, 18, 26, 31, 33, 35, 39, 42, 43, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73 and 82 in PCR-amplified samples of genomic DNA isolated from cervical smears.

The kit was produced in cooperation with the German Cancer Research Center (DKFZ) according to the method published by Schmitt et al. 2006. It constitutes a qualitatively superior research tool for epidemiological studies, cancer-screening programmes, the characterization of study populations in HPV trials and the evaluation of the efficacy of HPV vaccine trials.

(References: MUNOZ, N. et al., 2003, N. Engl. J. Med. 348:518-527; SCHMITT, M. et al., 2006, J. Clin. Microbiol. 44:504-512; SCHMITT, M. et al., 2008, J. Clin. Microbiology, 46:1050-1059)

### Test principle

The Multiplex HPV Genotyping Kit allows the simultaneous detection of 24 HPV types in a PCR-amplified sample.

The sample DNA, extracted from cervical scrapings, is subjected to PCR amplification, using sets of biotinylated broad range primers contained in the kit. Optionally, a pair of primers for the amplification of a  $\beta$ -globin gene fragment can be added to the PCR in order to verify the quality of the human sample DNA.

PCR products are added to the bead mix containing 26 distinct bead populations coupled to 24 HPV, one  $\beta$ -globin and one hybridization control specific oligonucleotide probe. After thermal denaturation of the double stranded PCR products, the target sequences are hybridized to HPV type-specific bead-bound probes. After a wash step the hybridized PCR products are labelled by binding of R-phycoerythrin marked streptavidin. An additional wash step eliminates the non-bound fluorescent marker.

After resuspending the beads, the read-out in the Luminex analyzer is performed. HPV types are discerned according to the unique bead signature, whereas the presence of PCR products is determined by phycoerythrin fluorescence.

An analytical sensitivity cut-off is calculated based on the negative control.

## Multiplex HPV Genotyping Kit for Research in Epidemiology

### Advantages of Multiplex HPV Genotyping Kit

- ➔ Simultaneous detection of 24 human Papillomaviruses
- ➔ Minimal sample volume
- ➔ High specificity and sensitivity
- ➔ Short incubation times
- ➔ Saves time and money

### Components of Multiplex HPV Genotyping Kit

- ➔ Bead-Mix
- ➔ Conjugate
- ➔ PCR Primer Set 1
- ➔ PCR Primer Set 2
- ➔ Hybridization Control
- ➔ Wash Buffer
- ➔ Staining Buffer
- ➔ 96 Well Hybridization Plate
- ➔ 96 Well Filtration Plate
- ➔ 96 Lock-Well Plate
- ➔ Seal Foil

Content is sufficient for 96 determinations.

### Test procedure



Amplification (PCR)



Denaturation



Hybridization to bead-bound probes



Wash & labeling



Wash & read-out of the plate  
using Luminex analyzer

### Human Papillomavirus Types:

High-risk types:

16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73,  
82

Putative high-risk types:

26, 53, 66

Low risk-types:

6, 11, 42, 43, 44, 70

### Ordering information

- ➔ Multiplex HPV Genotyping Kit 96Tests Cat. No.: MM4000  
Bead-based Assay for the Detection of 24 Human Papillomaviruses in PCR Amplified Samples.

### Distribution and Production

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