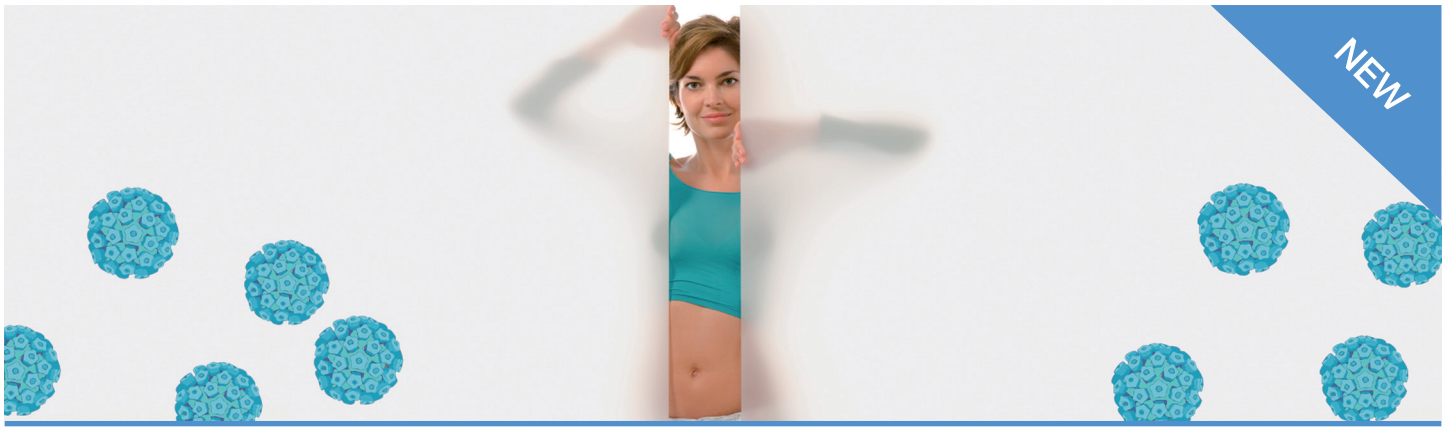

PapilloCheck® high-risk

IVD for the detection of 14 human carcinogenic high-risk papillomavirus genotypes (hrHPV)

Persistent infection with a carcinogenic high-risk human papillomavirus (hrHPV) is found in virtually all cases of cervical cancer[1]. On the basis of the nearly absolute etiologic link between HPV and cervical cancer, testing for hrHPV is now considered in primary cervical cancer screening. Only recently guidelines defining the requirements for such HPV-tests were suggested[2].

The newly developed PapilloCheck® high-risk test kit from Greiner Bio-One is designed to meet the demands of cervical cancer screening by targeting 14 of the most carcinogenic hrHPV types. The microarray-based test kit allows the simultaneous identification of all HPV types detectable, which differ in their carcinogenic potential[3]. Therefore, the PapilloCheck® high-risk genotyping result has the potential to improve the classification of women according to their relative risk for developing cervical cancer and its high-grade precursor lesions (cervical intraepithelial neoplasia - CIN).

Additionally, PapilloCheck® high-risk enables the identification of persistent hrHPV infections and the characterization of multiple infections.

In screening strategies and applications where a wider spectrum of HPV types detectable is required, the approved Greiner Bio-One PapilloCheck® (CE-IVD) is the perfect choice. PapilloCheck® is a test kit for the detection and identification of 24 pathogenic HPV types using the same technology as the new PapilloCheck® high-risk.

In a recent study PapilloCheck® showed a clinical sensitivity for the detection of ≥CIN3 of 95.8% and a clinical specificity for the detection of ≥CIN2 of 96.7%, when the 14 hrHPV types covered by the new PapilloCheck® high-risk were considered[4]. Hence, the test met important requirements for an HPV-test in cervical cancer screening.

PapilloCheck® high-risk at a glance:

- Identification of 14 human carcinogenic HPV types
- Classification according to the risk potential
- Differentiation between single and multiple infections
- High clinical sensitivity and specificity
- Integrated quality control system

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detectable hrHPV types	
16	18
31	33
35	39
45	51
52	56
58	59
66	68

The Greiner Bio-One PapilloCheck® high-risk test kit is based on the detection and genotyping of a fragment of the E1 gene of the HPV genome.

Prior to the PapilloCheck® high-risk analysis, DNA has to be extracted from a cervical specimen. Dedicated products for specimen collection (PapilloCheck® Collection Kit) and DNA extraction (oCheck® DNA Extraction Kit) are also available from Greiner Bio-One (see ordering information).

After the extraction of viral and human genomic DNA from a cervical specimen, a 350 bp fragment of the viral E1 gene is amplified by polymerase chain reaction (PCR) in the presence of a set of HPV specific primers. Implementation of dUTP in the MasterMix enables the elimination of potential carry-over contaminations from previous PCR reactions. The PCR products are then hybridized to specific DNA probes attached to the chip surface and unbound DNA is removed in the subsequent washing steps. Finally, the PapilloCheck® high-risk DNA-chip is automatically scanned, analysed and evaluated using the CheckScanner™ and CheckReport™Software, respectively. Additional features of the user-friendly software allow automatic sample tracking, report generation and data collection.

The Greiner Bio-One PapilloCheck® high-risk test kit uses comprehensive on-chip controls to monitor critical steps of the assay and chip processing, e.g. presence of human material in the cervical specimen, DNA extraction, PCR and hybridization, as well as printing quality, which render the analysis highly reliable.

[1] Walboomers, J. et al (1999). Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. J Pathol. 189(1):12-9.
[2] Meijer, C.J. et al. (2009). Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. Int J Cancer. 124(3):516-20.
[3] Bosch F.X. et al. (2008). Epidemiology and natural history of human papillomavirus infections and type-specific implications in cervical neoplasia. Vaccine. 26 Suppl 10:K1-16.
[4] Hesselink, A.T. et al. (2010). Comparison of the clinical performance of PapilloCheck human papillomavirus detection with that of the GP5+/6+-PCR-enzyme immunoassay in population-based cervical screening. J Clin Microbiol. 48(3):797-801.

Cat.-No.	505 060	465 060	465 075*)	515 040
Description	PapilloCheck® high-risk genotyping of 14 carcinogenic hrHPV	PapilloCheck® genotyping of 24 pathogenic HPV	PapilloCheck® Collection Kit	oCheck® DNA Extraction Kit, Single Column Preparation
Tests per case	test kit for 60 reactions	test kit for 60 reactions	50 samples	50 preparations

*) available March 2012

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