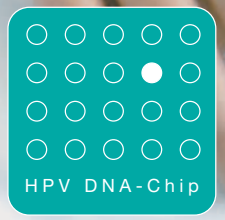
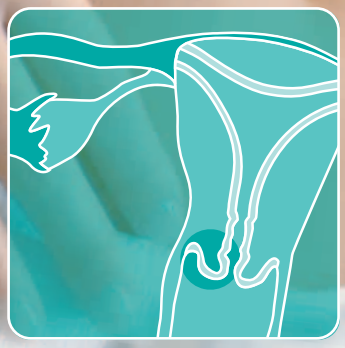




PapilloCheck® HPV-Screening

DNA-Chip for the genotyping of 24 types of genital HPV

greiner bio-one

PapilloCheck®: fast and reliable

PapilloCheck® at a glance:

- Complete kit with DNA-arrays and solutions for the HPV genotyping of 60 samples
- Simultaneous genotyping of 24 different HPV types (6 low and 18 high risk types)
- Comprehensive “on Chip” controls
- Automatic scanning, data collection and report generation with the CheckScanner™ and CheckReport™ software

The assay is based on the detection of a fragment of the E1 gene of 24 different HPV-types. At first, viral and human DNA are extracted from a cervical smear specimen. Subsequently, a PCR fragment of about 350 bp of the E1 gene is amplified in the presence of a small subset of HPV specific primers by polymerase chain reaction (PCR). To avoid false negative results, a fragment of the human “house keeping gene” ADAT1 (Adenosine deaminase1) is amplified in the same reaction.

In a second step, the amplified products are hybridised for only 15 min at room temperature to specific DNA-probes fixed on the DNA-chip. Every DNA-chip contains 12 DNA-arrays allowing the simultaneous analysis of 12 cervical samples. During hybridisation, the bound DNA is fluorescently labelled as well.
Finally, unbound DNA is washed away and the PapilloCheck® is automatically scanned, analysed and evaluated using the CheckScanner™ and CheckReport™ software, respectively.

The innovative DNA-array design of the PapilloCheck® DNA-chip permits the control of all critical steps during processing of the chip (e.g. spot homogeneity of the DNA-array, sample preparation, DNA hybridisation and PCR). Thus, false negative and false positive results are virtually excluded.

Cat.-No.	**465 060**
Description	PapilloCheck® genotyping of 24 types of genital HPV
Platform	HTA™Slide12
Tests per case	test kit for 60 reactions

Detectable low risk HPV types

6	11	40
42	43	44

Detectable high risk HPV types

16	18	31
33	35	39
45	51	52
53	56	58
59	66	68
70	73	82

Human Papillomavirus:

Genotyping of 24 types in 4 hours

Persistent infection with a carcinogenic human papillomavirus is found in virtually all cases of cervical cancer – the second most common cancer in women worldwide[1–4]. About 471,000 new cases and 233,000 deaths are reported each year[5].

Cervical HPV types are classified into a high risk and low risk group, with respect to the risk of progression from mild dysplasia to cancer. However, recent findings confirm, that even within the high risk group, the relative risk for the development of cancer or cervical intraepithelial lesions (CIN) is dependent on the type. Together, HPV16 and 18 cause 70% of all cervical cancers. Therefore, it is important to have a fast, reliable, and safe diagnostic tool for the genotyping of HPVs in cervical samples.

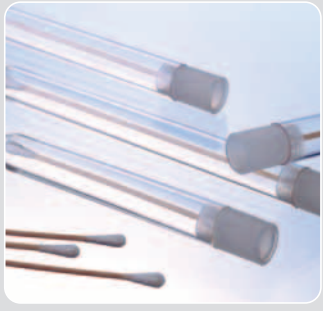
PapilloCheck® (CE-IVD)[6] is a DNA-array based diagnostic tool for the simultaneous detection and genotyping of 24 different HPV types. Of these, 18 HPV types are classified as high risk types while 6 HPV types are the causative agent of benign warts[7]. While most commercial HPV test systems allow only a crude HPV classification into a low or high risk HPV group, PapilloCheck® makes it possible to specify all 24 HPV types simultaneously, clearly improving the quality of diagnosis.

PapilloCheck® guarantees:

- high specificity
- high sensitivity
- genotyping of 24 HPV types simultaneously
- monitoring of the most common genital HPV types

[1] Zur Hausen H. 2002, Papillomavirus and Cancer: From Basic Stduies to Clinical Application., Nat Rev Cancer, 2(5):342-50.
[2] Walnoomers J. et al., 1999, Human Papillomavirus is a necessary cause of invasive cervical cancer worldwide, J. Pathol. 189:12-19.
[3] Bosch X. & Iftner T., The aetiology of cervical cancer, 2005, NHSCSP Publication No. 22.
[4] Burd EM. 2003, Human Papillomavirus and Cervical Cancer, Clinical Microbiology Reviews, 16:1-17.
[5] Parkin DM. et al., Cancer burden in the year 2000. The global picture. Eur J Cancer 2001; 37(suppl 8):S4-S66.
[6] In US available for RESEARCH ONLY
[7] Munoz et al., 2003, Epidemiologic classification of human papillomavirus types associated with cervical cancer, N. Engl. J Med, 348:518-527.

Working schedule for PapilloCheck®



1
Sample collection

- cervical scrape
- biopsy

2
DNA Extraction

Duration: 30 min

Fast DNA extraction from cervical scrapes or biopsy specimens.

3
PCR

Duration: 120 min

Amplification of part of the E1 gene of all listed HPV types by using a small subset of E1 specific PCR primers.
All reagents for the PCR reaction are supplied except Taq-Polymerase.

4
Hybridisation

Duration: 15 min

Hybridisation and fluorescent labelling of the amplified E1 PCR product to the PapilloCheck® DNA-chip. The hybridisation is performed in a water vapour saturated atmosphere at room temperature. All reagents are supplied with the kit.

5
Washing

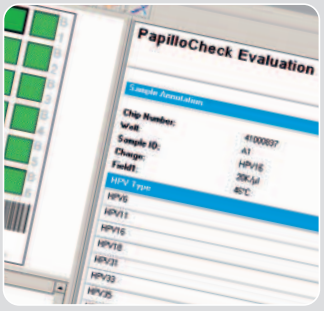
Duration: 2 min

Unbound HPV sample DNA is removed from the PapilloCheck® DNA-chip by three rapid and stringent washing steps perfomed at room temperature and 50°C respectively.

6
Scanning

Duration: 10 min

PapilloCheck® is automatically being scanned using the CheckScanner™, a two-colour laser scanner with excitation wavelength of 532nm and 635nm.



7
Evaluation

Duration: 5min

Automatic evaluation and HPV report generation is done with the easy to use CheckReport™ software.

For further information, please visit our website www.gbo.com/bioscience or contact us:

Germany (Main office)
Greiner Bio-One GmbH
Maybachstraße 2
D-72636 Frickenhausen
Phone: (+49) 7022 948-0
Fax: (+49) 7022 948-514
E-Mail: info@de.gbo.com

Greiner Bio-One GmbH
Rosenkamper Straße 6
D-42719 Solingen
Phone: (+49) 212 23007-12/13
Fax: (+49) 212 23007-20
E-Mail: info@de.gbo.com

Austria
Greiner Bio-One GmbH
Bad Haller Straße 32
A-4550 Kremsmünster
Phone: (+43) 7583 6791-0
Fax: (+43) 7583 63 18
E-Mail: office@at.gbo.com

Netherlands
Greiner Bio-One B.V.
Phone: (+31) 172-42 09 00
Fax: (+31) 172-44 38 01
E-Mail: info@nl.gbo.com

Belgium
Greiner Bio-One N.V.
Phone: (+32) 2-4 61 09 10
Fax: (+32) 2-4 61 09 05
E-Mail: info@be.gbo.com

UK
Greiner Bio-One Ltd.
Phone: (+44) 14 53-82 52 55
Fax: (+44) 14 53-82 62 66
E-Mail: info@uk.gbo.com

France
Greiner Bio-One SAS
Phone: (+33) 1 69-86 25 50
Phone: (+33) 1 69-86 25 36
E-Mail: infos@fr.gbo.com

USA
Greiner Bio-One North America Inc.
Phone: (+1) 7 04-2 61-78 00
Fax: (+1) 7 04-2 61-78 99
E-Mail: info@us.gbo.com

Japan
Greiner Bio-One Co. Ltd.
Phone: (+81) 3-35 05-88 75
Fax: (+81) 3-35 05-89 74
E-Mail: info@jp.gbo.com

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