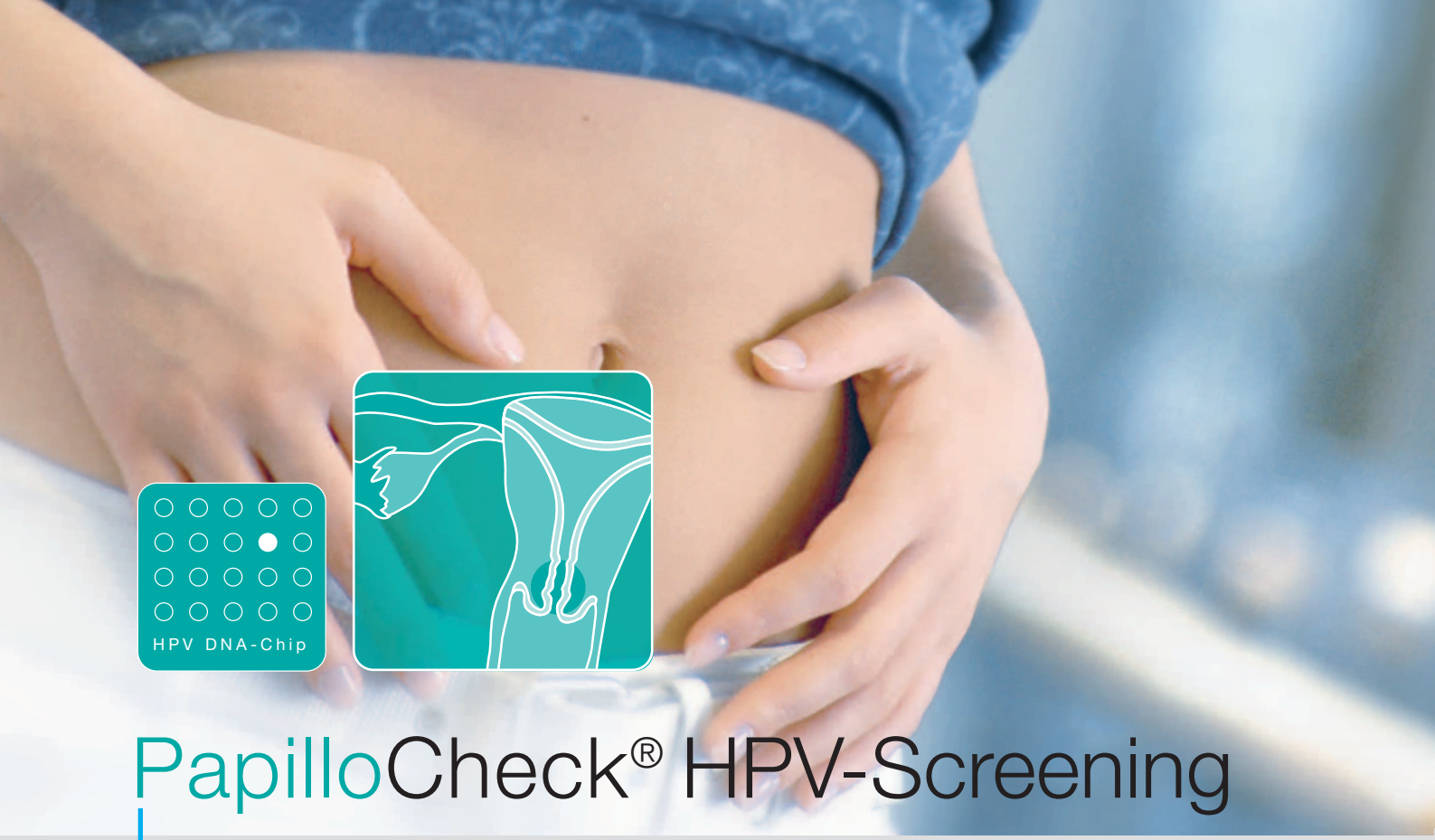

PapilloCheck® HPV-Screening

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

PapilloCheck® features:

- DNA-Chip for the type-specific identification of 18 high-risk and 6 low-risk types of HPV
- For primary or secondary cervical cancer screening
- Certified In-vitro-Diagnostica (IVD), registered in the EU for the qualitative detection of HPVs from clinical specimens

Cervical cancer is the second most common cancer in women worldwide, with almost 471,000 new cases and 233,000 deaths annually[1]. In Europe, there are 60,000 new cases and almost 30,000 deaths each year.

Since its introduction, the Pap cytology has significantly decreased cervical cancer in developed countries due to screening programs and advances in the treatment of early-stage disease.

However, during the last 20 years the incidence and mortality rates of cervical cancer did not drop further, but remained unchanged. The rather low sensitivity of the Pap cytology, which is in the range of 43.5% – 58%, is one reason for the observed stagnation in cervical cancer decline[2]. In addition, Pap cytology is limited since it detects the symptoms but not the cause for cervical cancer, which is a persistent infection with carcinogenic human papillomavirus (HPV). It has now been firmly established that infection with high-risk papilloma-virus (HPV) types is the primary cause of almost all cervical cancers[3].

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Detectable low risk HPV types		Detectable high risk HPV types		
6	11	16	18	31
40	42	33	35	39
43	44	45	51	52
		53	56	58
		59	66	68
		70	73	82

HPV infections are among the most common sexually transmitted infections in most populations, and estimates of exposure range from 15-20% in many European countries to 70% in the US or 95% in high-risk populations in Africa.

Although most infections resolve within 2 years (80%), persistant genital HPV infection can lead to both squamous cell carcinomas (SCCs), adenocarcinomas and the vast majority (i.e. ≥95%) of their immediate precursors, namely high grade squamaus intraepithelial lesions (HSIL)/cervical intraepithelial neoplasia 3 (CIN3)/carcinoma in situ[4].

Epidemiological data from combined case-control studies suggest that some types should be regarded high-risk or carcinogenic (e.g. HPV 16, -18, -31, -33, -35, -39, -45, -51, -52, -56, -58, -59, -68, -73, -82) and that some should be considered probably carcinogenic (HPV 53, -66, -70). Although persistent infection with each of the different hrHPV types increases the risk for developing cervical cancer in general, different risk potentials among the hrHPV types have been observed. Depending on the hrHPV type, the risk for developing cervical cancer with persistent infection is in the range of OR (odds ratio) = 435 (HPV 16) to OR = 54 (HPV 68)[5].

The observed differences in the risk potential among the hrHPV types makes an HPV test system for the genotyping of the different hrHPV types absolutely essential. Only the type specific identification of the different hrHPV types allows a reasonable risk management in triaging borderline and mild dyskaryosis.

To meet this need, Greiner Bio-One has developed the PapilloCheck®, a new HPV-genotyping test for the simultaneous detection of 24 different HPV types. Of those, 18 HPV types are classified as high risk types while 6 HPV types are the causative agent of benign warts. PapilloCheck® is a certified IVD, registered in the European Union for the qualitative detection of HPVs from clinical specimens.

PapilloCheck® is based on the hybridization of HPV DNA to DNA-Arrays or so called Biochips. This technique allows a rapid, sensitive but specific detection of HPV infections.

PapilloCheck® is implicated for:

- Risk estimation/management of the persistent infection with a specific HPV genotype
- Risk estimation/management in HPV vaccinations
- Epidemiological studies

Please ask your medical laboratory for further information on PapilloCheck®.

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Germany (Main office): Greiner Bio-One GmbH · (+49) 7022 948-0 · info@de.gbo.com, **Austria:** Greiner Bio-One GmbH · (+43) 7583 6791-0 · office@at.gbo.com,
Belgium: Greiner Bio-One N.V. · (+32) 2-4 61 09 10 · info@be.gbo.com, **France:** Greiner Bio-One SAS · (+33) 1 69-86 25 50 · infos@fr.gbo.com,
Japan: Greiner Bio-One Co. Ltd. · (+81) 3-35 05-88 75 · info@jp.gbo.com, **Netherlands:** Greiner Bio-One B.V. · (+31) 172-42 09 00 · info@nl.gbo.com,
UK: Greiner Bio-One Ltd. · (+44) 14 53-82 52 55 · info@uk.gbo.com, **USA:** Greiner Bio-One North America Inc. · (+1) 7 04-2 61-78 00 · info@us.gbo.com

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