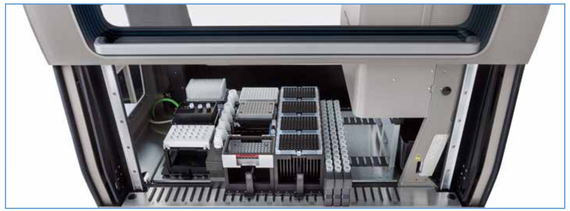
PapilloCheck® Automated Processing

CX™ NIMBUS® and CX™ STARlet Platforms - smart. efficient. accurate.



CX™ NIMBUS® and CX™ STARlet enable a streamlined use of PapilloCheck®, the HPV genotyping kit from Greiner Bio-One.

Both systems combine the advantages of automation with an outstanding methodology developed for the simultaneous screening and genotyping of human papilloma viruses:

smart.
1. ready to use load & go reagents
2. simultaneous processing of different collection media
3. modular processing of extraction, PCR and hybridisation possible
4. magnetic bead separation technology
5. intelligent waste management

efficient.
1. simultaneous HPV screening and genotyping
2. fully automated sample prep from primary tubes
3. cost & time savings due to increased lab staff productivity resulting from short hands-on time
4. LIMS compatible for automated result reporting
5. reduced tip consumption due to optimised work flow programming

accurate.
1. robust DNA array technology
2. liquid level detection, aspiration and clot detection monitoring
3. built-in controls and quality control reporting
4. capable of performing daily/weekly instrument maintenance

CX™ NIMBUS® performs DNA extraction and PCR setup for simultaneous analyses of up to 48 samples. The sealing of the PCR plate and the PCR are conducted with external devices of your laboratory.

CX™ STARlet processes 96 samples per run, integrating DNA extraction, PCR set-up, PCR plate sealing and PCR.

CX™ NIMBUS® plus and CX™ STARlet plus display an additional feature to enable hybridisation of the amplified PCR product onto the chip.

Scanning and chip evaluation is detected using CheckScanner™ and the CheckReport™ Software.

Cat.-No.	867070	867071	867072	867073
Description	CX™ NIMBUS®	CX™ NIMBUS® plus	CX™ STARlet	CX™ STARlet plus
Content	automated analysis of 48 samples	automated analysis of 48 samples, with hybridisation	automated analysis of 96 samples	automated analysis of 96 samples, with hybridisation

Your Power for Health

greiner bio-one

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

Germany (Main office)
Greiner Bio-One GmbH
Maybachstraße 2
D-72636 Frickenhausen
Phone +49 70 22 948-0
Fax +49 70 22 948-514
E-Mail info@de.gbo.com

Austria
Greiner Bio-One GmbH
E-Mail office@at.gbo.com

Belgium
Greiner Bio-One BVBA/SPRL
E-Mail info@be.gbo.com

Brazil
Greiner Bio-One Brasil
E-Mail office@br.gbo.com

China
Greiner Bio-One Suns Co. Ltd.
E-Mail ts.bio@gbo-suns.com

France
Greiner Bio-One SAS
E-Mail accueil@gbo.com

Hungary
Greiner Bio-One Hungary Kft.
E-Mail office@hu.gbo.com

Italy
Greiner Bio-One Italia S.r.l
E-Mail office@it.gbo.com

Japan
Greiner Bio-One Co. Ltd.
E-Mail info@jp.gbo.com

Netherlands
Greiner Bio-One B.V.
E-Mail info@nl.gbo.com

Portugal
Vacuette Portugal S.A.
E-Mail info@vacuette.pt

Spain
Greiner Bio-One España S.A.U.
E-Mail info@es.gbo.com

UK
Greiner Bio-One Ltd.
E-Mail info@uk.gbo.com

USA
Greiner Bio-One North America Inc.
E-Mail info@us.gbo.com

Please note: PapilloCheck® products have not been cleared or approved by the US FDA for use in the United States of America.

Your Power for Health

greiner bio-one

smart. efficient. accurate.

Automated Solutions for HPV Genotyping CX™ NIMBUS® and CX™ STARlet

powered by HAMILTON

www.gbo.com

PapilloCheck® HPV Genotyping

Fast and Reliable Genotyping of 24 Human Papillomavirus Types

Persistent infection with a carcinogenic human papillomavirus (HPV) is found in virtually all cases of cervical cancer[1-4]. HPV testing is currently being investigated as the primary tool in cervical cancer screening.

Cervical HPV types are classified into a high risk (hrHPV) and a low risk (lrHPV) group, with respect to the risk of progression from mild dysplasia to cancer[5]. Therefore, it is important to have a rapid and reliable diagnostic tool for the identification of HPV types in cervical samples.

PapilloCheck® (CE-IVD) 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 and 6 HPV types as low risk, with the later types being the causative agent of benign warts[6].

PapilloCheck® - Detectable HPV types

high risk [hrHPV]

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

low risk [lrHPV]

6	11	40	42	43	44/55

PapilloCheck® - At a glance

- High sensitivity and specificity
- Simultaneous genotyping and monitoring of 24 HPV types
- Classification according to risk potential
- Integrated quality control system
- Validated according to international guidelines for HPV tests in cervical cancer screening

Due to the simultanous identification of the 24 detectable HPV types, the result from a PapilloCheck® analysis allows for the characterisation of multiple infections. It can help to identify type-specific persistent HPV infections and clarify the status of a patient in the course of HPV vaccination. Therefore, it has the potential to improve the classification of women according to their relative risk for developing cervical cancer and its high-grade precursor lesions.

PapilloCheck® was validated according to international guidelines for HPV test requirements in cervical cancer screening. It meets the demands regarding clinical sensitivity and specificity as well as reproducibility[6,7]. As clinical studies have proven PapilloCheck® is a robust HPV genotyping assay with the potential for high throughput of specimens in a clinical setting[8].

PapilloCheck® samples can be processed manually as well as on various newly developed automation platforms which allow a high sample throughput with minimal manual handling.

[1] Zur Hausen H. (2002), Nat Rev Cancer, 2(5):342-50.
[2] Walnoomers J. et al., (1999), J. Pathol. 189:12-19.
[3] Bosch X. & Ithner T. (2005), NHSCSP Publication No. 22.
[4] Burd EM. (2003), Clinical Microbiology Reviews, 16:1-17.
[5] Muñoz et al., (2003), N. Engl. J Med, 348:518-527.
[6] Meijer, C.J. et al. (2009), Int J Cancer. 124(3):516-20.
[7] Hesselink, A.T. et al. (2010), J Clin Microbiol. 48(3):797-801.
[8] Jones J. et al. (2009), J Clin Virol. 45(2): 100-4.

Cat.-No.	465 060	465 075	515 040	517 070
Description	PapilloCheck® genotyping of 24 pathogenic HPV	PapilloCheck® Collection Kit	oCheck® DNA Extraction Kit Single Column Preparation	CX™ Extraction Kit
Content	test kit for 48 reactions	50 samples	50 preps	48 preps

CX™ NIMBUS® platform

CX™ NIMBUS® can perform time-consuming pipetting steps that support routine use of Greiner Bio-One PapilloCheck® to enable in tandem use of other external devices (e.g. thermal cycler, sealer device). Hands-on time is reduced and productivity is increased, facilitating a cost-efficient solution for rapid workflow.

CX™ NIMBUS® includes four pipetting channels, a CO-RE paddle system for a fast and safe transfer of plates, a heater shaker, magnetic separator and a cooling block for enzymes.

CX™ NIMBUS® plus additionally integrates a hybridisation carrier.

CX™ NIMBUS® - simultanous processing of 48 samples

CX™ NIMBUS®

- automated sample extraction and pre-PCR set-up
- simultaneous analysis of 48 samples
- space saving and budget effective
- less than 60 minutes hands-on time per routine run

For more information on CX™ NIMBUS® and CX™ NIMBUS® plus, please contact us:
support.dx@gbo.com

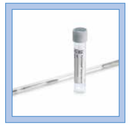
Workflow Timetable	CX™ NIMBUS® plus 48 samples	
Working step	**in min.**	**in hours**
Sample preparation	20	00:20
Software configuration	10	00:10
Extraction of HPV samples	135	02:15
Pre-PCR	15	00:15
PCR	180	03:00
Hybridisation preparation	15	00:15
Hybridisation incubation	15	00:15
Washing & drying	10	00:10
CheckReport™ analysis	48	00:48
Data evaluation	5	00:05
TAT = total analysis time	453	07:33
Hands-on time (total)	60	01:00
Walk-away time (total)	393	06:33

Specifications	CX™ NIMBUS®
Width	709 mm
Height	831 mm
Length	1046 mm
Weight	approx. 98,6 kg
Maximum power consumption	≤ 600 W
Power supply	100V~ /240V~ 5A

HPV detection and genotyping with PapilloCheck®

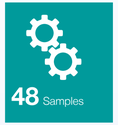
Manual and automated workflow

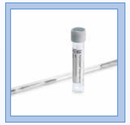
PapilloCheck® HPV Genotyping - manual workflow



1 Sample Collection **2** DNA Extraction **3** PCR **4** Hybridisation **5** Washing **6** Scanning **7** Evaluation

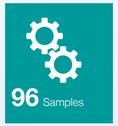
CX™ NIMBUS® and CX™ NIMBUS® plus - simultanous processing of 48 samples

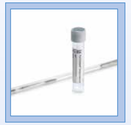




CX™ NIMBUS® plus - including hybridisation

CX™ STARlet and CX™ STARlet plus - simultanous processing of 96 samples





CX™ STARlet plus - including hybridisation

CX™ STARlet platform

CX™ STARlet is the ultimate solution to optimize your HPV routine. The platform performs all pipetting steps and is also equipped with an automated Hamilton plate sealer and an integrated on-deck thermal cycler from INHECO.

CX™ STARlet allows processing of more than 800 HPV samples per week with a minimum amount of manual interaction, thus providing the ideal choice for laboratories who want to be more efficient and profitable within their HPV routine.

CX™ STARlet plus is delivered with an additional hybridisation carrier.

CX™ STARlet - simultanous processing of 96 samples

CX™ STARlet

- fully automated sample extraction, PCR set-up, PCR and plate sealing
- simultaneous analysis of 96 samples
- Barcode tracking of samples and reagents
- iSWAP gripper to access items on or off the deck
- thermal cycler from INHECO with new VCM® technology
- less than 90 minutes hands-on time per routine run
- included UV kit for DNA residue decontamination

For more information on CX™ STARlet and CX™ STARlet plus, please contact us:
support.dx@gbo.com

Workflow Timetable	CX™ STARlet plus 96 samples	
Working step	**in min.**	**in hours**
Sample preparation	30	00:30
Software configuration	10	00:10
Extraction of HPV samples	165	02:45
Pre-PCR	20	00:20
PCR	180	03:00
Hybridisation preparation	25	00:25
Hybridisation incubation	15	00:15
Washing & drying	15	00:15
CheckReport™ analysis	96	01:36
Data evaluation	10	00:10
TAT = total analysis time	566	09:26
Hands-on time (total)	90	01:30
Walk-away time (total)	476	07:56

Specifications	CX™ STARlet
Width	1124 mm
Height	1028 mm
Length	795 mm (without loading desk), 1010 mm (with loading desk)
Weight	approx. 140 kg
Dimensions desk (W x H x D)	1124 x 850 x 795 mm
Weight desk	approx. 90 kg
Maximum power consumption	≤ 600 W
Power supply	115V~ /230V~