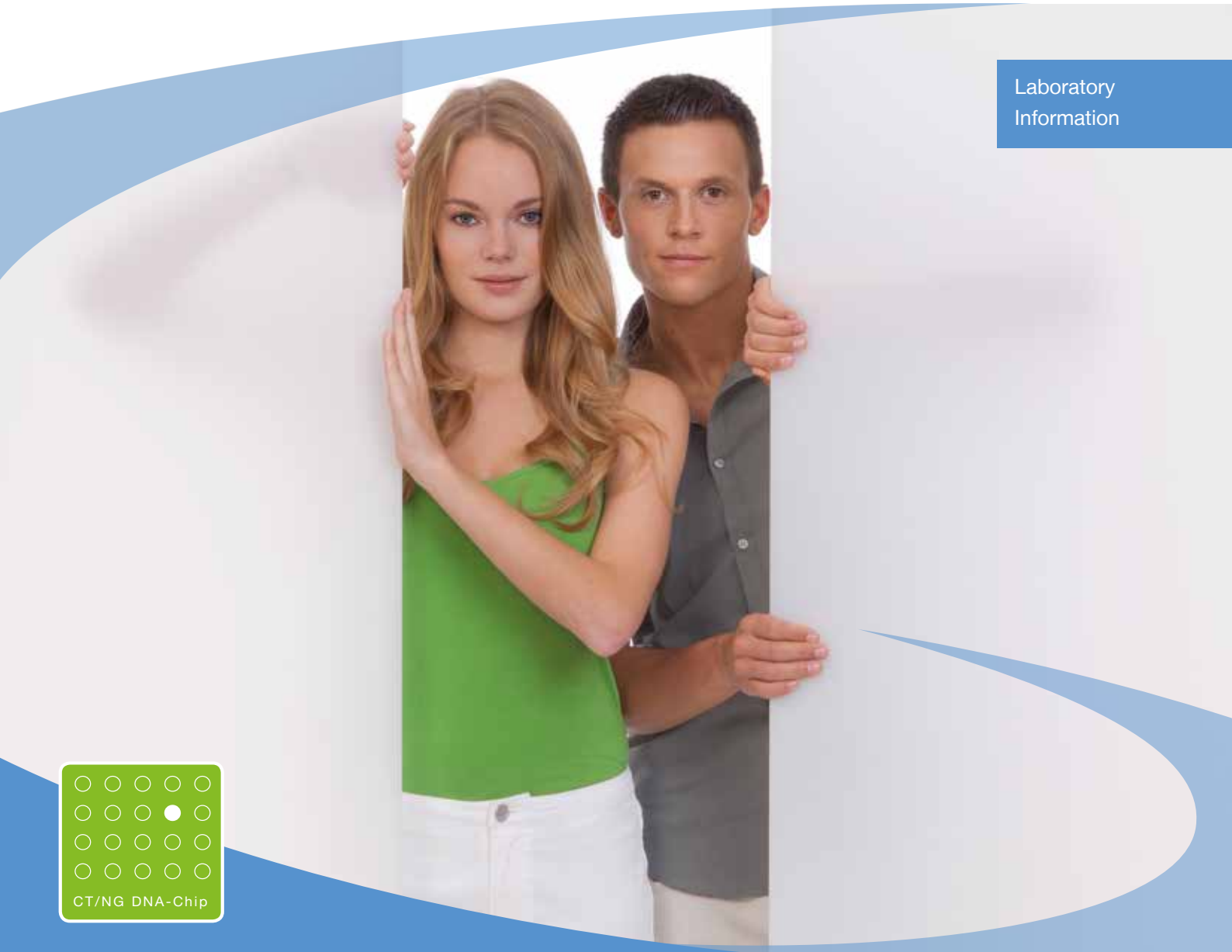
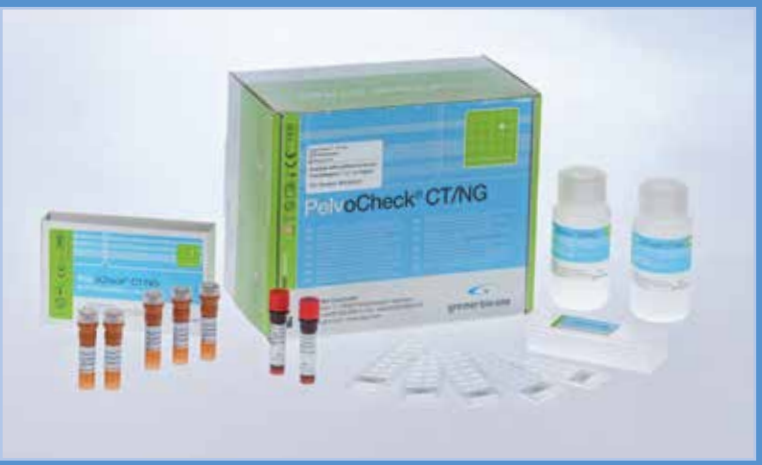
Your Power for Health

greiner bio-one

Laboratory
Information





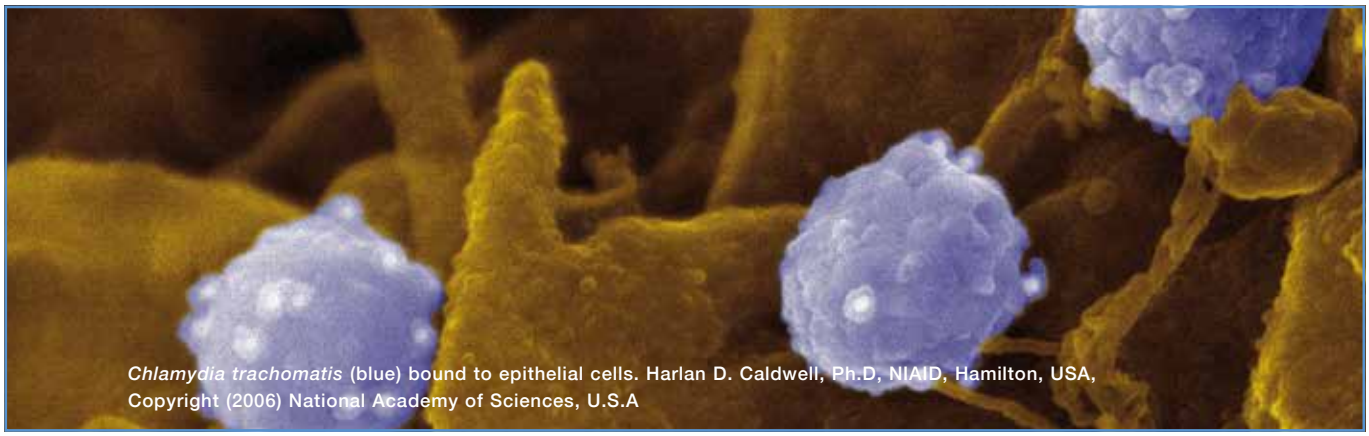
Be sure!

PelvoCheck® CT/NG

Your test kit for *Chlamydia trachomatis* screening and *Neisseria gonorrhoeae* infections

PelvoCheck® CT/NG is part of the oCheck® product line from Greiner Bio-One GmbH

www.gbo.com/diagnostics



Chlamydia trachomatis (blue) bound to epithelial cells. Harlan D. Caldwell, Ph.D, NIAID, Hamilton, USA, Copyright (2006) National Academy of Sciences, U.S.A

PelvoCheck® CT/NG

80 % of Chlamydial and 50 % of gonococcal infections in women go unnoticed

One of the most common and serious complication of sexually transmitted diseases (STDs) among women is pelvic inflammatory disease (PID), an inflammation of the upper genital tract caused by infection. *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) are the most common etiologic agents of PID and can occur alone or in combination[1]. Each year, over 100 million new cases are recorded worldwide. Although the PID infection itself may be cured, effects of the infection may be permanent. Untreated chlamydial infections in women can lead to a variety of diseases including infertility, ectopic pregnancy and blindness of the newborn[2].

Early identification and treating, including partners, will prevent re-infection or further spreading of the CT or NG infection.

However, about 80 % of all chlamydial and 50 % of gonococcal infections in women go unnoticed[3]. Symptoms do not occur or remain unspecific allowing the manifestation of the infection and its spreading to others. Several national health authorities have released recommendations calling for expanded chlamydia testing.

It is recommended that all sexually active adolescent women and men are screened for chlamydia at least once a year[4,5].

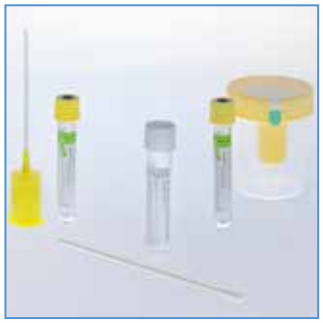
Due to this recommendation chlamydia screening programs have been initiated in Germany, United Kingdom, Netherlands, and Sweden. For managing these high amounts of analyses, pooling of up to five samples is recommended in Germany[5].
Greiner Bio-One has developed the PelvoCheck® CT/NG kit for the qualitative and highly sensitive simultaneous detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in human urine specimens as well as vaginal and cervical swabs. The kit allows the detection of CT and NG in co-infections with 1,000-fold (NG vs. CT) or 10,000-fold (CT vs. NG) excess of one pathogen vs. the other. The kit was validated for up to five pooled urine samples and, thereby, is well suited for CT screening programs to reduce effort and cost of sample analysis without loss of reliability.

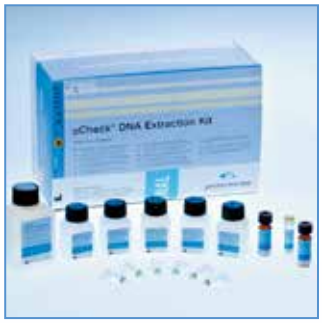
	UK	Sweden	Netherlands	Germany
Start/end	Since 2005	Since 1988/2000	2007-2010	Since 2008
Age group	16-25	Program dependent	15-19	15-25
Sex	m/f	m/f	m/f	f
Sample type	Urine/ swabs	Urine/ swabs	Urine/ swabs	Urine
Method	NAATs	NAATs	NAATs	NAATs
Pooling	No	No	No	≤5

[1] Pellati, D. et al. (2008) Genital tract infections and infertility, Eur. J. Obstet. Gynecol. Reprod. Biol., 140(1):3-11.
[2] Gray-Swain, M.R., Peipert, J.F. (2006) Pelvic inflammatory disease in adolescents, Curr. Opin. Obstet. Gynecol., 18(5):503-10.
[3] http://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Chlamydia_Teil1.html#doc2382764bodyText7 and http://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Gonorrhoe.html#doc3763050bodyText8
[4] European Centre for Disease Prevention and Control (2009) ECDC Guidance: Chlamydia control in Europe, Stockholm, June 2009, ISBN 978-92-9193-165-1, doi 10.2900/11364
[5] Gemeinsamer Bundesausschuss (2008) Screening auf genitale Chlamydia trachomatis-Infektionen bei Frauen, Abschlussbericht des Unterausschusses „Familienplanung“ des G-BA, January 2008, http://www.g-ba.de/informationen/abschlussberichte/533/

Working schedule for PelvoCheck® CT/NG

CT/NG detection from 48 samples within 6.5 hours





1 Sample Collection

Human urine or swabs

With the PelvoCheck® Collection Kit SAFE (Cat.-No. 453 100) or STRAW (Cat.-No. 453 101) first-void urine is collected, stabilised and transported. Vaginal or cervical swabs can be collected, stabilised and transported using the PelvoCheck® Swab Collection Kit (Cat.-No. 453 103).

2 DNA Extraction

Duration: 60-210 min

Extraction of bacterial and human genomic DNA from human urine samples is performed using the oCheck® DNA Extraction Kit Single Column (Cat.-No. 515 040). The required time depends on the sample number.

3 PCR

Duration: 120 min

A PCR reaction is used to amplify a part of the 16S rRNA gene of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* applying specific PCR primers. An implemented control system monitors the presence of human sample material. PCR carry-over contaminations are prevented by using the dUTP/Uracil-N-Glycosylase (UNG) system. All reagents for the PCR reaction are supplied with the kit except for the enzymes (*Taq*-Polymerase, UNG).

4 Hybridisation

Duration: 30 min

Hybridisation of the PCR product is performed in a water vapour saturated atmosphere at room temperature, using the oCheck® Hybridisation Chamber (Cat.-No. 447 070). All reagents necessary are supplied with the kit.

Pooling

Pooling of up to five human urine samples is allowed for *Chlamydia trachomatis* detection. The samples have to be pooled before DNA extraction. The extraction is performed with the oCheck® DNA Extraction Kit (Single Column) using the support protocol for pooling.

All further working steps with the PelvoCheck® CT/NG kit are identical with the analysis of single samples.

Single samples of positive pools have to be re-tested separately.

Cat.-No.	504 002	515 040	862 080 / 862 086
Description	PelvoCheck® CT/NG Kit	oCheck® DNA Extraction Kit Single Column Preparation	CheckReport™ Software PelvoCheck® CT/NG plugin
Platform	HTA™Slide 12		
Content	60 analysis	50 preparations	

5 Washing

Duration: 2 min

Two rapid and stringent washing steps performed at room temperature and 50 °C remove unbound DNA from the PelvoCheck® CT/NG DNA-chip. All reagents are supplied with the kit. For a convenient washing procedure use the oCheck® Washboxes (Cat.-No. 447 020).

6 Scanning

Duration: 15 min/slide

The PelvoCheck® CT/NG DNA-chip is scanned using the CheckScanner™ (Cat.-No. 862 070), a two-colour laser microarray scanner with excitation wavelengths of 532 and 635 nm, detecting the fluorescent labels. Functions of the scanner are monitored with the CheckScanner™ Verification Kit (Cat.-No. 862 030).

7 Evaluation

Duration: 5 min

The easy to use CheckReport™Software (Cat.-No. 862 080 and 862 081) automatically evaluates all on-chip controls and pathogen-specific signals and generates a detailed and a summary report. Results are converted into user-friendly graphics and tables.

Cat.-No.	453 103	453 100	453 101
Description	PelvoCheck® Swab Collection Kit	PelvoCheck® Collection Kit SAFE	PelvoCheck® Collection Kit STRAW
Platform			
Content	60 samples	50 samples	70 samples