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

One of the most common and serious complications 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.

<table>
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<th>UK</th>
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<td>m/f</td>
<td>m/f</td>
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<td>No</td>
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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.

<table>
<thead>
<tr>
<th>Cat.-No.</th>
<th>Description</th>
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<td>60 analysis</td>
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<td>oCheck® DNA Extraction Kit Single Column Preparation</td>
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<td>862 080 / 862 086</td>
<td>CheckReport™ Software PelvoCheck® CT/NG plugin</td>
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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.
The newly developed CE-IVD diagnostic kit PelvoCheck® CT/NG enables the identification of the two most frequently detected bacteria associated with PID, *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG), from urine as well as vaginal and cervical swab specimens. In case of urine both, single and pooled samples can be analysed to meet demands of providing cost-efficient diagnostics for CT-screening programs.

The test is based on the specific microarray detection of a short DNA fragment that was amplified from the 16S rRNA gene by polymerase chain reaction (PCR). PelvoCheck® CT/NG is offered as a complete ready-to-use kit. The additional easy-to-use Greiner Bio-One kits for specimen sampling plus stabilization (PelvoCheck® Collection Kit SAFE/STRAW and PelvoCheck® Swab Collection Kit) and DNA extraction (oCheck® DNA Extraction Kit), allow complete sample processing from patient to diagnostic result.

The DNA from a first-void urine sample or a vaginal or cervical swab collected with the PelvoCheck® collection kits is extracted with the oCheck® DNA Extraction Kit. Subsequently, a fragment of the 16S rRNA gene and a human control gene are amplified by PCR. The integration of dUTP in the PelvoCheck® CT/NG Mastermix ensures the elimination of carry-over contaminations from previous PCR reactions. After binding of the amplification products to specific DNA probes on the PelvoCheck® CT/NG chip surface, the identification of CT and/or NG is provided by detection of a fluorescent label using the CheckScanner™. This is followed by data evaluation and report generation with the CheckReport™ Software.

To assure the failure-free performance of the PelvoCheck® CT/NG assay, comprehensive on-chip controls examine the quality of DNA extraction, amplification, spot homogeneity and hybridisation efficiency.

**At a glance: PelvoCheck® CT/NG**

**CE-IVD for the simultaneous pathogen detection in pelvic inflammatory disease (PID) and screening programs: detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae***

The newly developed CE-IVD diagnostic kit PelvoCheck® CT/NG enables the identification of the two most frequently detected bacteria associated with PID, *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG), from urine as well as vaginal and cervical swab specimens. In case of urine both, single and pooled samples can be analysed to meet demands of providing cost-efficient diagnostics for CT-screening programs.

The test is based on the specific microarray detection of a short DNA fragment that was amplified from the 16S rRNA gene by polymerase chain reaction (PCR). PelvoCheck® CT/NG is offered as a complete ready-to-use kit. The additional easy-to-use Greiner Bio-One kits for specimen sampling plus stabilization (PelvoCheck® Collection Kit SAFE/STRAW and PelvoCheck® Swab Collection Kit) and DNA extraction (oCheck® DNA Extraction Kit), allow complete sample processing from patient to diagnostic result.

The DNA from a first-void urine sample or a vaginal or cervical swab collected with the PelvoCheck® collection kits is extracted with the oCheck® DNA Extraction Kit. Subsequently, a fragment of the 16S rRNA gene and a human control gene are amplified by PCR. The integration of dUTP in the PelvoCheck® CT/NG Mastermix ensures the elimination of carry-over contaminations from previous PCR reactions. After binding of the amplification products to specific DNA probes on the PelvoCheck® CT/NG chip surface, the identification of CT and/or NG is provided by detection of a fluorescent label using the CheckScanner™. This is followed by data evaluation and report generation with the CheckReport™ Software.

To assure the failure-free performance of the PelvoCheck® CT/NG assay, comprehensive on-chip controls examine the quality of DNA extraction, amplification, spot homogeneity and hybridisation efficiency.

**PelvoCheck® guarantees**

- Simultaneous detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*
- Validated for pooled urine samples to meet the needs of Chlamydia screening programs
- High clinical specificity and sensitivity
- Integrated quality control system
- Validated according international guidelines
- In the EU certified in-vitro diagnostic (CE-IVD)
Your Power for Health

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PelvoCheck® CT/NG and all mentioned oCheck® products have not been cleared or approved by the US FDA for use in the United States of America.