

## 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<sup>®</sup> CT/NG is offered as a complete readyto-use kit. The additional easy-to-use Greiner Bio-One kits for specimen sampling plus stabilization (PelvoCheck<sup>®</sup> Collection Kit SAFE/STRAW and PelvoCheck<sup>®</sup> Swab Collection Kit) and DNA extraction (oCheck<sup>®</sup> 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<sup>®</sup> CT/NG chip surface, the identification of CT and/or NG is provided by detection of a fluorescent label using the CheckScanner<sup>™</sup>. This is followed by data evaluation and report generation with the CheckReport<sup>™</sup> Software.

To assure the failure-free performance of the PelvoCheck<sup>®</sup> 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)