

GeneProof

GeneProof Chlamydia trachomatis PCR Kit



DUAL TARGET DETECTION

• Dual target detection of the 16S rRNA gene and a cryptic plasmid

HIGH SENSITIVITY

• Secured by targeting the multicopy sequence of the 16S rRNA gene

RELIABLE DETECTION OF SWEDISH **VARIANT OF C. TRACHOMATIS**

• Elimination of false-negative results caused by a sequence variation in the cryptic plasmid

CONTAMINATION ELIMINATION

• Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating contamination with amplification products







CERTIFIED **DIAGNOSTIC TEST**



Sexually Transmitted

GeneProof Chlamydia trachomatis PCR Kit

- + CT/NG/MG Multiplex PCR Kit
- + Mycoplasma genitalium/hominis PCR Kit
- Herpes Simplex Virus 1 (HSV-1)
 PCR Kit
- + Chlamydia trachomatis PCR Kit
- + Human Papillomavirus (HPV) PCR
- Herpes Simplex Virus 2 (HSV-2)
 PCR Kit
- + Neisseria gonorrhoeae PCR Kit
- + Ureaplasma PCR Kit
- Herpes Simplex Virus (HSV-1/2)
 PCR Kit

TECHNOLOGY	real-time PCR
TYPE OF ANALYSIS	qualitative
TARGET SEQUENCE	the cryptic plasmid multi-copy sequence and the 16S rRNA gene
ANALYTICAL SPECIFICITY	${\it Chlamydia\ trachomatis}, including\ mutations\ with\ deletions\ in\ cryptic\ plasmid\ (including\ Swedish\ variant),\ 100\ \%$
ANALYTICAL SENSITIVITY (LOD)	reaches up to 0.075 cp/µl with the probability of 95 % (on Amplirun* <i>Chlamydia trachomatis</i> DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	99.21 % (Cl _{95 %} : 99.07 % - 99.34 %)
DIAGNOSTIC SENSITIVITY	100 % (Cl _{95 %} : 99.58 % - 100 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control (ISEX version)
VALIDATED SPECIMEN	sperm, swab, urine
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	croBEE Real-Time PCR System* Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System DTlite Real-Time PCR System LightCycler* 2.0 / 480 LineGene 9600 / 9600 Plus Rotor-Gene 3000 / 6000 / Q SLAN* Real-Time PCR System StepOne™ Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSEMENT	regularly tested by QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com
REGULATORY STATUS	CE ₁₀₂₃ IVD

^{*} Validated instruments

	TECHNOLOGY	ORDER NO.		
PRODUCT NAME		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof Chlamydia trachomatis PCR Kit	real-time PCR	CHT/ISEX/025	CHT/ISEX/050	CHT/ISEX/100