

Protocol

Urethritis GPack

(REF: URE/GPACK/100)

PRINCIPLE OF METHOD

GeneProof PCR kits offer our innovative One Workflow solution allowing the detection of multiple parameters in one run using our Universal PCR Profile for majority of the GeneProof PCR kits (RNA and DNA pathogens).

WORKFLOW

1. Use the required sample volume in accordance with the extraction manual.
2. Thaw the Universal Internal Control (purple cap) in the refrigerator (2 - 8 °C) for about 15 minutes. Vortex and briefly centrifuge the thawed solution before use. Add Universal Internal Control at 10% of the elution volume to each sample.
3. Perform sample extraction according to the appropriate protocol.
4. Thaw the PCR reagents in a refrigerator (2 - 8 °C) for 15 to 30 min. Vortex and centrifuge briefly before use:

GeneProof CT/NG/MG Multiplex PCR Kit

- CNMX Master Mix (blue cap)
- CNMX Positive Control (white cap)
- Negative Control (NFW\* – not included)

GeneProof Trichomonas vaginalis PCR Kit

- TV Master Mix (blue cap)
- TV Positive Control (white cap)
- Negative Control (NFW\* – not included)

\*NFW= Nuclease-free water

5. **PCR preparation** (total reaction volume is 40 µl), pipette:
  - a) A1: 30 µl CNMX Master Mix + 10 µl CNMX Positive Control
  - b) B1: 30 µl CNMX Master Mix + 10 µl Negative Control
  - c) C1: 30 µl CNMX Master Mix + 10 µl extracted DNA
  - d) A2: 30 µl TV Master Mix + 10 µl TV Positive Control
  - e) B2: 30 µl TV Master Mix + 10 µl Negative Control
  - f) C2: 30 µl TV Master Mix + 10 µl extracted DNA

PCR Plate layout

	1	2	3	4	5	6	7	8	9	10	11	12
A	CNMX PC	TV PC										
B	CNMX NC	TV NC										
C	CNMX S1	TV S1										
D	CNMX S2	TV S2										
E	...	...										
F												
G												
H												

CNMX = CT/NG/MG; TV = Trichomonas vaginalis; PC = Positive Control; NC = Negative Control; S1 = unknown sample 1; S2 = unknown sample 2

Urethritis GPack

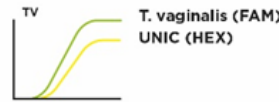
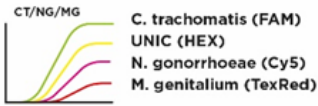
- 6. Centrifuge the PCR plate briefly.
- 7. Set up the Universal PCR Profile on the PCR cyclor according to the GeneProof Trichomonas vaginalis PCR Kit.

Step	Process	Temperature °C	Time
1	UNG decontamination/ Reverse Transcription	42	15 mins
2	Initial denaturation	95	10 mins
3	Denaturation	95	5 s
	Annealing	60	40 s
	Extension	72	20 s

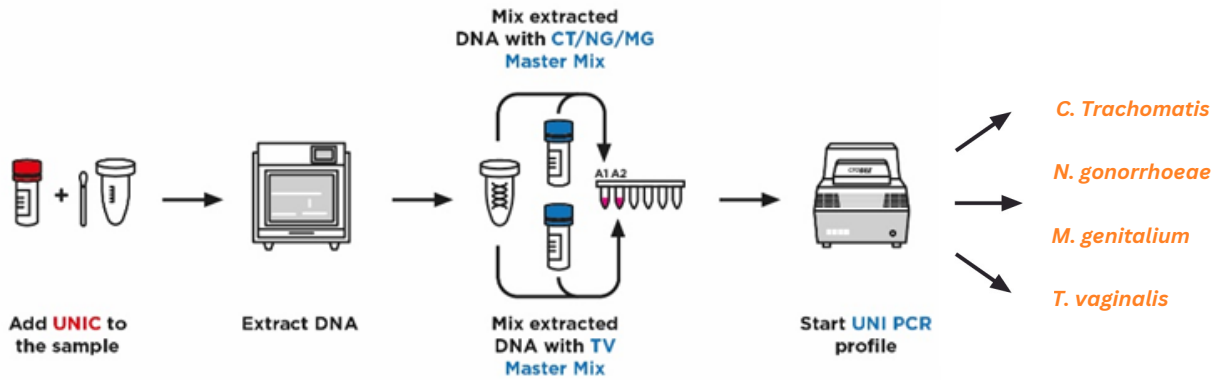
EVALUATION

Column 1 - *C. trachomatis*, *N. gonorrhoeae*, *M. genitalium*

Column 2 - *T. vaginalis*



Urethritis GPack Workflow



\*Add appropriate number of Positive and Negative Controls according to the IFU

Choose from the whole STI G Packs Portfolio.  
 For the results that matter most.

1. Urethritis GPack: detection of 4 pathogens

*Chlamydia trachomatis*, *Neisseria gonorrhoeae*,  
*Mycoplasma genitalium*, *Trichomonas vaginalis*

2. Urethritis Plus GPack: detection of 7 pathogens

*Chlamydia trachomatis*, *Neisseria gonorrhoeae*,  
*Mycoplasma genitalium*, *Trichomonas vaginalis*,  
*Mycoplasma hominis*,  
*Ureaplasma urealyticum/parvum*

3. Genital Ulcer GPack: detection of 3 pathogens

*Herpes Simplex Virus 1*, *Herpes Simplex Virus 2*,  
*Treponema pallidum*

4. CT/NG Screening GPack: detection of 2 pathogens

*Chlamydia trachomatis*, *Neisseria gonorrhoeae*

5. MGH/UUP/TV Diagnostic GPack: detection of 5 pathogens

*Mycoplasma genitalium*, *Trichomonas vaginalis*, *Mycoplasma hominis*,  
*Ureaplasma urealyticum/parvum*