



## Protocol

### Genital Ulcer Screening GPack

(REF: GU/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 Herpes Simplex Virus (HSV-1/2) PCR Kit

- HSV Master Mix (blue cap)
- Calibrator HSV 10<sup>2</sup> cp/μl (white cap)
- Negative Control (NFW\* – not included)

#### GeneProof Treponema Pallidum PCR Kit

- TP Master Mix (blue cap)
- TP 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 HSV Master Mix + 10 μl Calibrator HSV 10<sup>2</sup> cp/μl
  - b) B1: 30 μl HSV Master Mix + 10 μl Negative Control
  - c) C1: 30 μl HSV Master Mix + 10 μl extracted DNA
  - d) A2: 30 μl TP Master Mix + 10 μl TP Positive Control
  - e) B2: 30 μl TP Master Mix + 10 μl Negative Control
  - f) C2: 30 μl TP Master Mix + 10 μl extracted DNA

#### PCR Plate layout

|   | 1        | 2     | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|----------|-------|---|---|---|---|---|---|---|----|----|----|
| A | HSV Cal2 | TP PC |   |   |   |   |   |   |   |    |    |    |
| B | HSV NC   | TP NC |   |   |   |   |   |   |   |    |    |    |
| C | HSV S1   | TP S1 |   |   |   |   |   |   |   |    |    |    |
| D | HSV S2   | TP S2 |   |   |   |   |   |   |   |    |    |    |
| E | ...      | ...   |   |   |   |   |   |   |   |    |    |    |
| F |          |       |   |   |   |   |   |   |   |    |    |    |
| G |          |       |   |   |   |   |   |   |   |    |    |    |
| H |          |       |   |   |   |   |   |   |   |    |    |    |

Cal 2 = Calibrator HSV 10<sup>2</sup> cp/μl ; TP = Treponema pallidum; PC = Positive Control; NC = Negative Control;  
S1 = unknown sample 1; S2 = unknown sample 2

## Genital Ulcer Screening GPack

- Centrifuge the PCR plate briefly.
- Set up the Universal PCR Profile on the PCR cyclor according to the GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit.

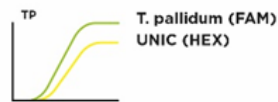
| Step | Process                                       | Temperature °C | Time    |
|------|---|----------------|---------|
| 1    | UNG decontamination/<br>Reverse Transcription | 42             | 15 mins |
| 2    | Initial denaturation                          | 95             | 10 mins |
| 3    |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

## EVALUATION

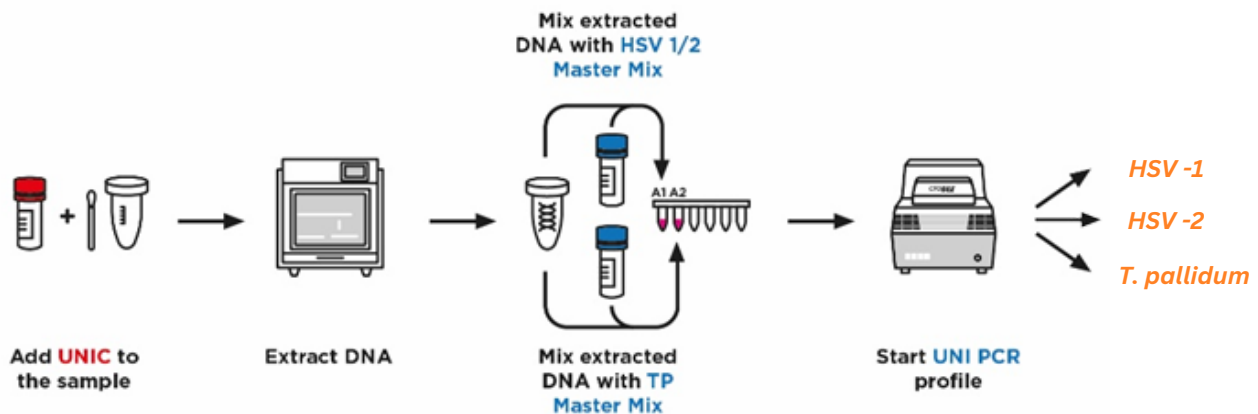
Column 1 - HSV - 1, HSV - 2



Column 2 - *T. pallidum*



## GPack STI Genital Ulcer 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*