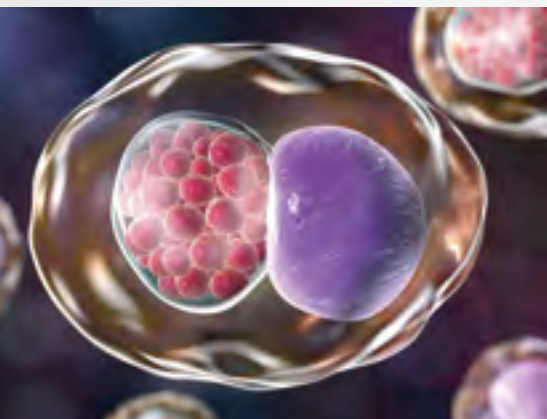




The clinical study comparing the new GeneProof CT/NG/MG multiplex assay with FTD Urethritis basic on sex workers specimens

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BACKGROUND

Chlamydia trachomatis (CT), *Neisseria gonorrhoeae* (NG) and *Mycoplasma genitalium* (MG) are common agents of sexually transmitted infections (STI). Sex workers are traditionally considered as important vectors transmitting STIs.

The current trend on the Czech borders is to move street prostitutes into brothel-houses where better medical care could be provided. GeneProof CT/NG/MG multiplex assay enables highly sensitive detection in a single well. The aim of this pilot study was to prove clinical relevance of the new GeneProof assay.

METHODS

Total of 137 cervical swabs were obtained from female sex workers in the western border area of the Czech Republic during the period January 2017 to December 2017. All swabs were isolated by NucleoSpin Blood silica-membrane isolation kit (Machery-Nagel, Germany).

GeneProof CT/NG/MG multiplex (GeneProof, Czech Republic) was compared to CE-marked FTD Urethritis basic (Fast-Track Diagnostics, Malta). GeneProof assay is based on Ready To Use MasterMix containing all components including a hot-start polymerase.

GeneProof CT/NG/MG Multiplex PCR Kit

Detection target	<i>Chlamydia trachomatis</i> – 16S rRNA and cryptic plasmid region
	<i>Neisseria gonorrhoeae</i> – 16S rRNA and porA plasmid
	<i>Mycoplasma genitalium</i> – 16S rRNA
Ready To Use MasterMix – no premixing necessary, only add an isolated DNA	
Sample type: urine, genital swabs	

GeneProof CT/NG/MG PCR Kit vs. FTD Urethritis basic (FAST-TRACK DIAGNOSTICS)

Chlamydia trachomatis detection

		Fast-Track Diagnostics		
		Positive	Negative	Total
GeneProof	Positive	11	0	11
	Negative	0	126	126
Total		11	126	137

Specificity: 100% Sensitivity: 100%

Neisseria gonorrhoeae detection

		Fast-Track Diagnostics		
		Positive	Negative	Total
GeneProof	Positive	2	0	2
	Negative	0	135	135
Total		2	135	137

Specificity: 100% Sensitivity: 100%

Mycoplasma genitalium detection

		Fast-Track Diagnostics		
		Positive	Negative	Total
GeneProof	Positive	7	0	7
	Negative	0	130	130
Total		7	130	137

Specificity: 100% Sensitivity: 100%

The results demonstrate 100% concordance with the results of FTD Urethritis basic.

CONCLUSIONS

In this pilot study, the new GeneProof CT/NG/MG multiplex assay was evaluated with the FTD Urethritis basic. For all tested STI pathogens (CT, NG and MG) 100% clinical sensitivity and specificity

was observed. Finally, the GeneProof multiplex assay provided user-friendly and robust performance approach which could be beneficial in higher throughput with additional cost savings.



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