The clinical evaluation of GeneProof Chlamydia trachomatis and Neisseria gonorrhoeae PCR Kits with cobas 4800 CT/NG Test

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Sexually Transmitted Infections

INTRODUCTION

Chlamydia trachomatis (CT) and ***Neisseria gonorrhoeae*** (NG) are common agents of sexually transmitted infections (STI). The aim of this study was to prove clinical relevance of the GeneProof Chlamydia trachomatis and Neisseria gonorrhoeae PCR assays.

According to CDC recommendation, laboratories should use nucleic acids amplification tests for routine diagnostics of CT and NG in women and men with and without symptoms. We have evaluated GeneProof Chlamydia trachomatis PCR Kit and GeneProof Neisseria gonorrhoeae PCR Kit (GeneProof, Czech Republic) in comparison with cobas® 4800 CT/NG Test (Roche Molecular Diagnostics, USA). For the analysis of discrepant samples FTD Urethritis basic (Fast-track Diagnostics, Malta) which enables detection of *C. trachomatis, N. gonorrhoeae* and *M. genitalium* was used.

CONCLUSION

GeneProof CT and NG PCR kits appear to be convenient diagnostic tools for routine testing in the clinical laboratory. Both kits demonstrated a high level of clinical sensitivity and specificity in comparison with FDA approved diagnostics cobas 4800 CT/NG test. Three discrepant samples were tested with an independent FTD Urethritis basic assay in parallel which confirmed the relevance of GeneProof CT PCR kit results.

Detection targets

	GeneProof	Roche cobas® 4800 CT/NG Test	Fast-Track FTD Urethritis basic
Chlamydia trachomatis	16S rRNA, cryptic plasmid	*ompA* gene, cryptic plasmid	cryptic plasmid
Neisseria gonorrhoeae	16S rRNA, *porA* pseudogene	DR-9 region	*opaK* gene

GeneProof PCR kits vs. cobas® 48000 CT/NG Test

GeneProof CT PCR Kit	cobas® 4800 CT/NG Test		
	Positive	Negative	Total
Positive	20	2	22
Negative	1	293	294
Total	21	295	316

Specificity: 99.32% (95% CI 97.30–99.75%)
Specificity: 100% (95% CI 98.45–100%)

GeneProof NG PCR Kit	cobas® 4800 CT/NG Test		
	Positive	Negative	Total
Positive	10	0	10
Negative	0	306	306
Total	21	295	316

Sensitivity: 95.24% (95% CI 74.13–99.75%)
Sensitivity: 100% (95% CI 65.55–100%)
Neisseria gonorrhoeae results were 100% concordant.

No. of clinical samples: 316 **Sample type**: cervical swabs, urethral swabs and urine

Analysis of discrepant samples

		GeneProof	Cobas® 4800 CT/NG Test	FTD Urethritis basic
Target	Discrepant	PCR result	PCR result	PCR result
Chlamydia trachomatis	1. Urethral swab	Positive	Negative	Positive
	2. Urethral swab	Positive	Negative	Positive
	3. Urine	Negative	Positive	Negative

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