Package insert

GeneProof
Molecular diagnostics for your routine

GeneProof Chlamydia trachomatis PCR Kit

CE 1023 IVD

In vitro diagnostic medical device

The kit has been manufactured according to EC Directive 98/79/EC as an *in vitro* diagnostic medical device and it has been designed for professional use in specialized clinical and research laboratories.

KIT CONTENT

	ISIN Version IS included in the MasterMix			ISEX Version IS supplied in a separate tube Nucleic acid isolation and PCR inhibition control		
REF	**CHT/ISIN/025** 25 rxn	**CHT/ISIN/050** 50 rxn	**CHT/ISIN/100** 100 rxn	**CHT/ISEX/025** 25 rxn	**CHT/ISEX/050** 50 rxn	**CHT/ISEX/100** 100 rxn
MasterMix *Chlamydia trachomatis*	1x750 µl	2x750 µl	4x750 µl	1x750 µl	2x750 µl	4x750 µl
Positive Control *Chlamydia trachomatis*	1x200 µl	1x200 µl	2x200 µl	1x200 µl	1x200 µl	2x200 µl
Internal Standard *Chlamydia trachomatis*	-	-	-	1x1000 µl	1x1000 µl	2x1000 µl

STORAGE AND TRANSPORTATION CONDITIONS

The kits should be transported and stored at temperatures between -85 °C and -10 °C. The kit will remain stable at least until the expiry date printed on the package, if the storage temperature is kept. Repeated freezing and thawing of the kit components may result in lower detection quality.

TECHNICAL SPECIFICATION

Target sequence	DNA conservative region encoding 16S rRNA, conservative region of the cryptic plasmid DNA
Specificity	*Chlamydia trachomatis* including mutants with deletions in the cryptic plasmid (Swedish version)
Sensitivity (LOD)	reaches 0.984 copies/µl with the probability of 95 %
Sample types	swabs (vaginal, pharyngeal, rectal), sperm, urine
Quality Control	regularly tested by QCMD and Instand e.V. External Quality Assessment Panels

METHOD PRINCIPLES

The PCR kit is designed for *Chlamydia trachomatis* detection by the real-time Polymerase Chain Reaction (PCR) method. The *C. trachomatis* detection is based on the amplification of both the cryptic plasmid multi-copy sequence and the 16S rDNA gene specific for *C. trachomatis* and on measuring the amplification product concentration using the PCR process and fluorescence labelled probes. Detection of multi-copy sequence of the cryptic plasmid enables very high sensitivity of chlamydia detection (including the Swedish variant) and the chromosomal gene detection at the same time enables high specificity and makes detection of plasmidless strains possible. *C. trachomatis* presence is indicated by FAM fluorophore fluorescence growth. An Internal Standard (IS) is included in the reaction mix, controlling the possible inhibition of the PCR reaction (ISIN version) and possibly also the DNA extraction process quality (ISEX version). IS positive amplification is detected in the HEX fluorophore fluorescence channel. The detection kit takes advantage of the "hot start" technology, minimizing non-specific reactions and assuring maximum sensitivity. Ready to Use MasterMix contains uracil-DNA-glycosylase (UDG), eliminating possible contamination of the PCR reaction by amplification products. The kit performs very sensitive *C. trachomatis* detection in clinical material (vaginal, pharyngeal, rectal swab, sperm, urine). The kit is designed for *in vitro* diagnostics and provides qualitative detection.

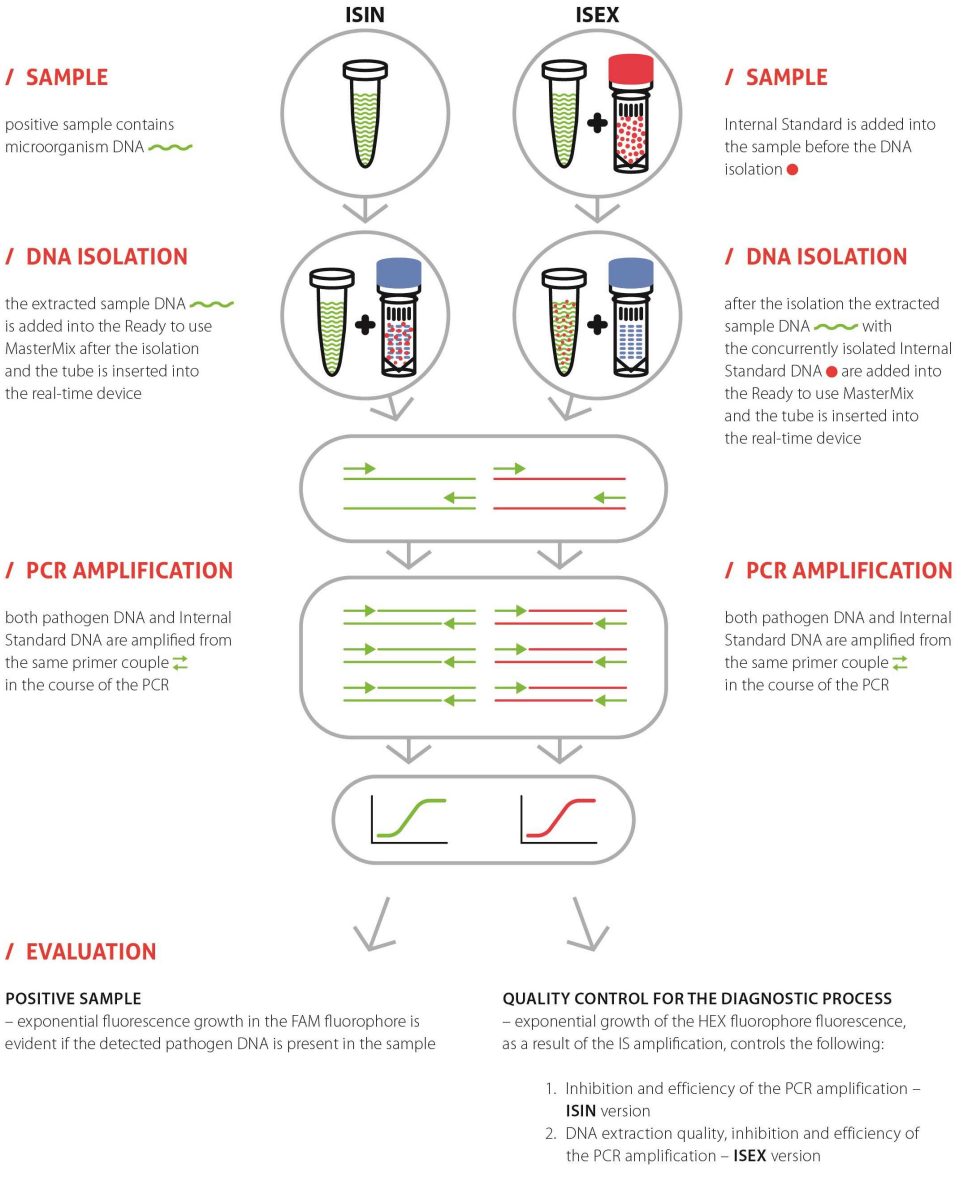
ISIN version

Internal Standard is included in the MasterMix tube. This PCR kit version enables PCR inhibition control.

ISEX version

Internal Standard is provided as independent item within the package. This PCR kit version enables both PCR inhibition control and nucleic acid purificaion process efficiency control.

MICROBIOLOGICAL DNA DETECTION TECHNOLOGY



USER MANUAL

SAMPLING AND SAMPLE STORAGE

Swabs and scrapings - urethral and cervical sampling should be performed by a screw-like insertion of a tampon (DacronR, Rayon, etc) into the depth of 3-4 cm; the patient should not urine for 2 hours preceding the sampling. Urine - the first 10-30 ml of urine into a sterile tube without any transportation media should be sampled for urine testing. Sperm - sampling into a sterile tube without any transportation media or spermicide substances should be performed 2 to 3 days after any previous ejaculation. Preservation and transport - tubes without any transportation media; the samples should be preserved at the temperature between +2 °C and +8 °C and transported within 24 hours. In case of longer storage period freeze the samples to the temperature between -85 °C and -10 °C.

NUCLEIC ACID PURIFICATION

Nucleic acid isolation should be performed by isolation kits available at the market according to protocols for the particular clinical material isolation. The manufacturer recommends the following isolation kits:

GeneProof PathogenFree DNA Isolation Kit
croBEE NA16 Nucleid Acid Extraction System

When using the ISEX versions of the PCR kits the IS should be added directly into the sample at the beginning of the isolation process so that in the end 1 µl of the resulting elution volume contains 0.1 µl of the IS:

Elution volume	**25 µl**	**50 µl**	**100 µl**	**200 µl**
Internal Standard	2,5 µl	5 µl	10 µl	20 µl

PCR SETUP

1. Add 30 µl of MasterMix into PCR tubes.

2. Add 10 µl of the isolated nucleic acid sample or 10 µl of Positive Control into the individual PCR tubes. The final reaction mix volume will be 40 µl.
It is necessary to keep all components at +2°C to +8°C during the PCR preparation.

3. Close the tubes, centrifuge shortly, insert them into the device and let them amplify according to the following PCR profile.
Be very careful when handling the Positive Control or the clinical material, incorrect handling could result in contamination and the consequent impairment of the kit components or the MasterMix! The manufacturer is not responsible for the kit impairment due to incorrect handling.

AMPLIFICATION PROFILE

Step	Temperature	Time	Data collection	Cycles
1. Hold	37 °C	2 min		1
2. Hold	95 °C	10 min		1
3. PCR	95 °C	5 s	FAM+HEX	45
	60 °C	40 s		
	72 °C	20 s		

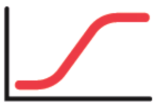
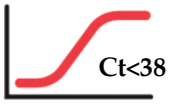
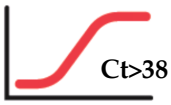
VALIDATED INSTRUMENTS

GeneProof PCR kits are designed for use with real-time devices from various manufacturers. This PCR kit has been validated with the following devices:

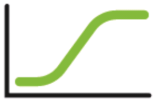
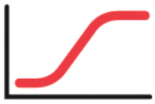
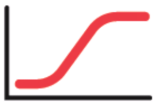
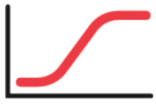
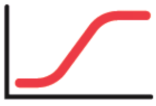
Applied Biosystems 7300/7500 Real-Time PCR System
AriaMx Real-Time PCR System
Dx/CFX96™/CFX Connect™ Real-Time PCR Detection System
LightCycler ® 2.0, LightCycler ® 480
LineGene 9600
Mx3000P/3005P QPCR System
Rotor-Gene 3000, Rotor-Gene 6000, Rotor-Gene Q
SLAN® Real-Time PCR System
StepOne™ Real-Time PCR System

GeneProof diagnostic kits are continually validated with various types of devices. Please request the current list at support@geneproof.com.

CLINICAL SAMPLES ANALYSIS EVALUATION

Channel FAM	Channel HEX	Result	Interpretation	
		**Valid**	*Chlamydia trachomatis*	**positive**
		**Valid**	*Chlamydia trachomatis*	**positive**
	 Ct<38	**Valid**	*Chlamydia trachomatis*	**negative**
	 Ct>38	**Invalid**		
		**Invalid**		

CONTROL ANALYSIS EVALUATION

	Channel FAM	Channel HEX			Result
Positive Control			or		**Valid**
Negative Control			or		**Valid**
Positive Control			or		**Invalid**
Negative Control			or		**Invalid**

WARNING

A single valid package insert for a specific kit is included in the package or to be requested for the particular lot from the manufacturer. The kit should be disposed of after use according to the current legal regulations considering the fact that the kit doesn't contain any dangerous, infectious or toxic components that would be subject to special safety regulations, and the packaging materials are made of paper and polypropylene. If you have any questions please contact our Customer Service.

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Orders
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