

GeneProofChlamydia 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

REF	ISIN Version			ISEX Version		
	IS included in the MasterMix			IS supplied in a separate tube		
	CHT/ISIN/025	CHT/ISIN/050	CHT/ISIN/100	CHT/ISEX/025	CHT/ISEX/050	CHT/ISEX/100
	25 rxn	50 rxn	100 rxn	25 rxn	50 rxn	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 could be transported at temperature below -20 °C. The kit will remain stable at least until the expiry date printed on the package, if the storage temperature is kept (-20 ± 5 °C). Kit is stable after 15 repeated freezing/thawing cycles.

TECHNICAL SPECIFICATION

Target Sequence	The cryptic plasmid multi-copy sequence and the 16S rRNA gene
Specificity	Chlamydia trachomatis, including mutations with deletions in cryptic plasmid (including Swedish variant), 100 %
Sensitivity (LoD)	Reaches up to 0.075 cp/µl with the probability of 95 % (on Amplirun® Chlamydia trachomatis DNA control, Vircell)
Validated Specimen	Sperm, swab, urine
Quality Control	In accordance with ISO 13485, each lot of GeneProof PCR Kit is tested against predetermined specifications to ensure consistent product quality.
External Quality Assessment	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 consists in amplification of both the cryptic plasmid multi-copy sequence and the 16S rRNA gene specific for *C. trachomatis* and in measurement of fluorescence increase. 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. The *C. trachomatis* presence is indicated by the FAM fluorophore fluorescence growth. An Internal Standard (IS) is either included in the reaction mix, controlling the possible inhibition of the PCR (ISIN version) or excluded, controlling 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 by amplification products. The kit is designed for *in vitro* diagnostics and provides qualitative detection.

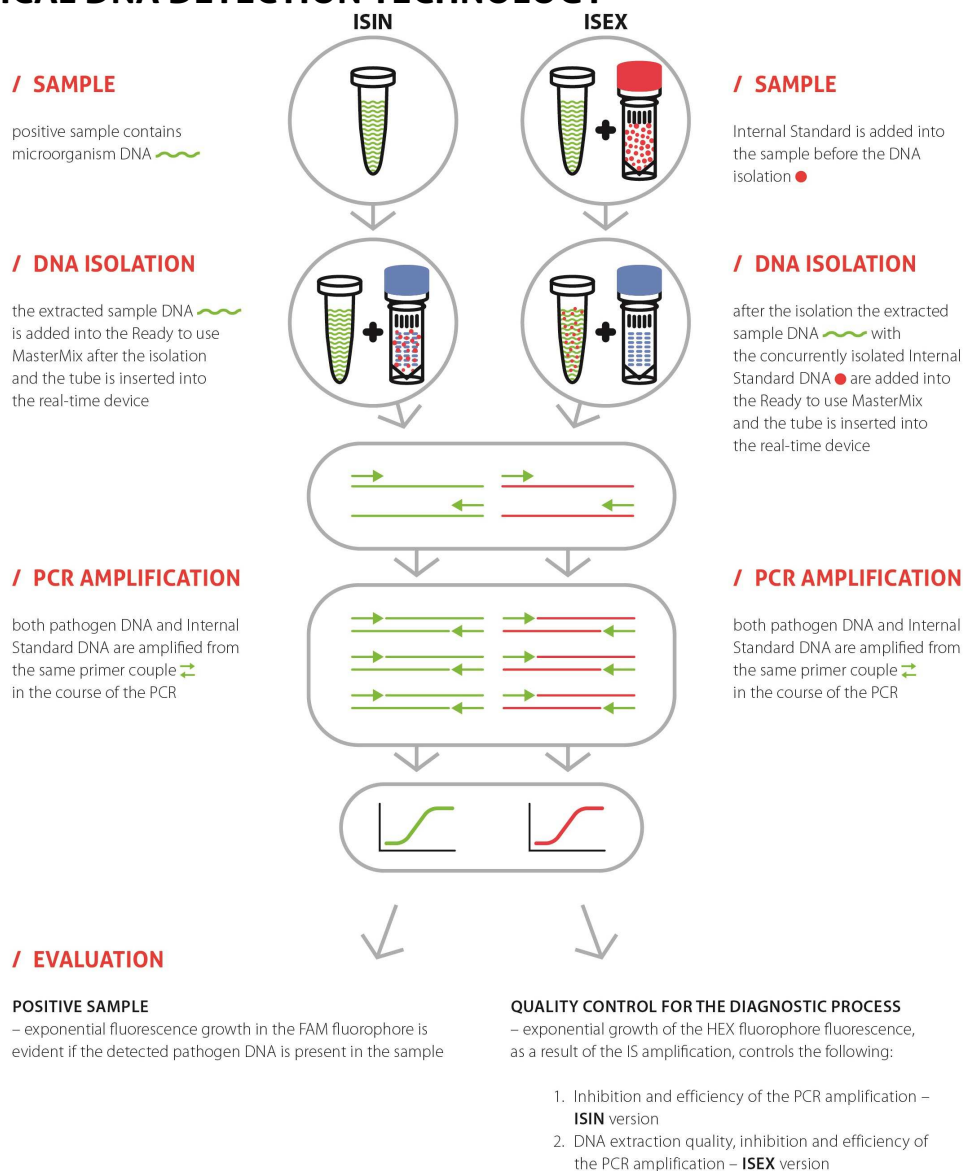
ISIN version

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 purification 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 urinate 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. Centrifuge urine sample (at least 1 ml) at 11 000 rpm for 5 minutes before DNA extraction. 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 below -10 °C.

NUCLEIC ACID PURIFICATION

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

GeneProof PathogenFree DNA Isolation Kit
croBEE NA16 Nucleic 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
Hold	37 °C	2 min		1
Hold	95 °C	10 min		1
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:

croBEE Real-Time PCR System
Applied Biosystems 7300 / 7500 Real-Time PCR System
AriaMx Real-Time PCR System
CFX Connect™ / CFX96™/ Dx Real-Time PCR Detection System
DTlite Real-Time PCR System


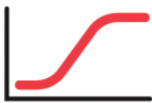





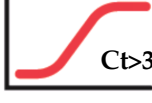


LightCycler® 2.0 / 480
LineGene 9600 / 9600 Plus
Rotor-Gene 3000 / 6000 / Q
SLAN® Real-Time PCR System
StepOne™ Real-Time PCR System

Required Detection Channels FAM, HEX

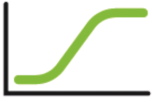
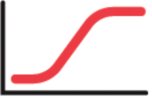


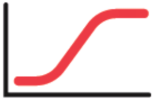





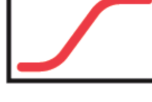

GeneProof diagnostic kits are continually validated with various types of devices. Please request the current list at support@geneproof.com.



CLINICAL SAMPLES ANALYSIS EVALUATION

Channel FAM	Channel HEX	Result	Interpretation	
		Valid	<i>Chlamydia trachomatis</i>	positive
		Valid	<i>Chlamydia trachomatis</i>	positive
		Valid	<i>Chlamydia trachomatis</i>	negative
		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.

Customer care and technical support

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Orders

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