

GeneProof Mycoplasma genitalium/hominis PCR Kit



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 IS included in the MasterMix | | | ISEX Version IS supplied in a separate tube Nucleic acid extraction and PCR inhibition control | | |
|--------------------------|--|------------------------|-------------------------|--|------------------------|-------------------------|
| | MGH/ISIN/025 25 rxn | MGH/ISIN/050 50 rxn | MGH/ISIN/100 100 rxn | MGH/ISEX/025 25 rxn | MGH/ISEX/050 50 rxn | MGH/ISEX/100 100 rxn |
| MasterMix | | | | | | |
| <i>M. hominis</i> | 1x750 µl | 2x750 µl | 4x750 µl | 1x750 µl | 2x750 µl | 4x750 µl |
| <i>M. genitalium</i> | | | | | | |
| Positive Control | | | | | | |
| <i>M. hominis</i> | 1x200 µl | 1x200 µl | 2x200 µl | 1x200 µl | 1x200 µl | 2x200 µl |
| <i>M. genitalium</i> | | | | | | |
| Internal Standard | | | | | | |
| <i>M. hominis</i> | - | - | - | 1x1000 µl | 1x1000 µl | 2x1000 µl |
| <i>M. genitalium</i> | | | | | | |
| <i>U. urealyticum</i> | | | | | | |
| <i>U. parvum</i> | | | | | | |

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 | A multicopy sequence of the gene encoding the 16S rRNA (<i>M. genitalium</i>) and the housekeeping gene gap for glyceraldehyde-3-phosphate dehydrogenase (<i>M. hominis</i>) |
| Specificity | <i>M. genitalium</i> , 100 % <i>M. hominis</i> , 100 % |
| Sensitivity (LoD) | For <i>M. genitalium</i> reaches up to 1.256 cp/µl with the probability 95 % For <i>M. hominis</i> reaches up to 1.196 cp/µl with the probability 95 % |
| Validated Specimen | 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 *Mycoplasma genitalium* and *Mycoplasma hominis* detection and differentiation by the real-time Polymerase Chain Reaction method (PCR). The *M. genitalium* and *M. hominis* detection and differentiation consist in amplification of a multicopy sequence of the gene encoding the 16S rRNA (*M. genitalium*) and the housekeeping gene *gap* for glyceraldehyde-3-phosphate dehydrogenase (*M. hominis*) and in measurement of fluorescence increase. The *M. genitalium* presence is indicated by the FAM fluorophore fluorescence growth and the *M. hominis* presence is indicated by the Cy5 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.

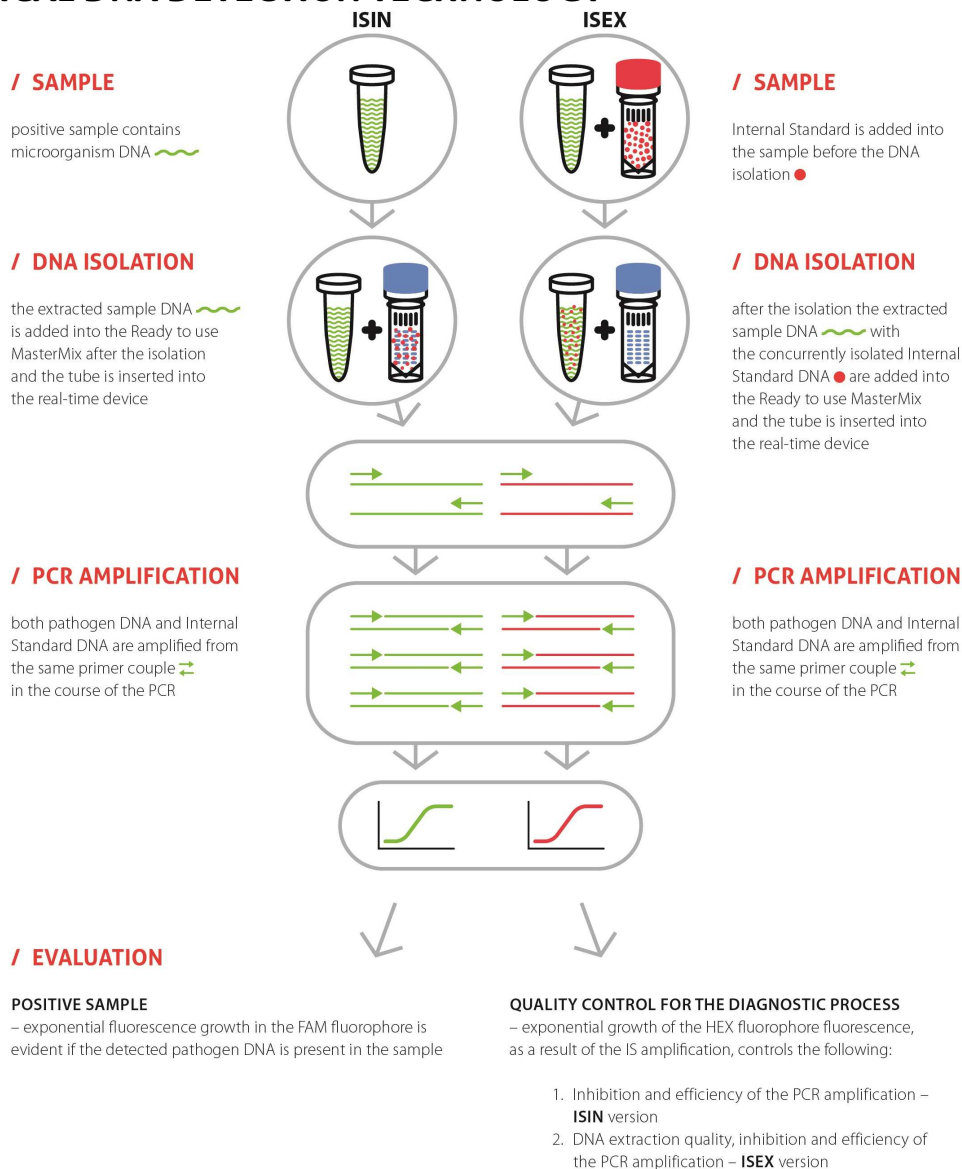
ISIN version

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

Urine - sampling of the first 10-30 ml into sterile tube. Dry urogenital swabs using sterile tampon without any transport media. Sampling should be performed into sterile tubes without any transportation media and the samples should be transported to the laboratory within 24 hours at the temperature between +2 °C and +8 °C. In case of longer storage keep all samples frozen at 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:

croBEE NA16 Nucleic Acid Extraction System

GeneProof PathogenFree DNA Isolation Kit

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 | | 45 |
| | 60 °C | 40 s | FAM+HEX+Cy5 | |
| | 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

AriaMx Real-Time PCR System

CFX Connect™ / CFX96™/ Dx Real-Time PCR Detection System

LineGene 9600 / 9600 Plus

Rotor-Gene 3000 / 6000 / Q

SLAN® Real-Time PCR System



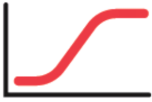



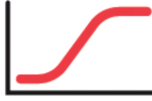



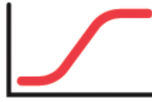



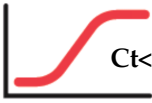


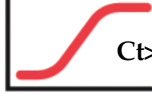



Required Detection Channels FAM, HEX, Cy5

In case of measurement on two channels device (FAM, HEX), M. genitalium is detected only.

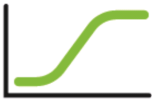
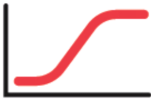


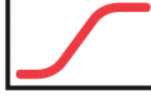


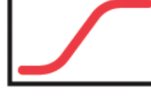


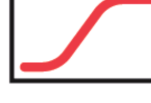

GeneProof diagnostic kits are continually validated with various types of devices. Please request the current list at support@geneproof.com.



CLINICAL SAMPLES ANALYSIS EVALUATION

| Channel FAM | Channel Cy5 | Channel HEX | Result | Interpretation |
|--|---|--|---------|--|
|  |  |  or  | Valid | <i>M. genitalium</i> positive |
|  |  |  or  | Valid | <i>M. genitalium/M. hominis</i> positive |
|  |  |  or  | Valid | <i>M. hominis</i> positive |
|  |  |  Ct<38 | Valid | negative |
|  |  |  Ct>38 | Invalid | |
|  |  |  | Invalid | |

CONTROL ANALYSIS EVALUATION

| | Channel FAM+Cy5 | 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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Package insert

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