



GeneProof[®]

GeneProof Mycobacterium tuberculosis PCR Kit



DUAL TARGET DETECTION

- Dual targeting prevents detection failures caused by occurrence of mutations
- Secured by targeting the multi-copy sequence IS6110 and MPB64

HIGH SPECIFICITY

- Detection of all species from Mycobacterium tuberculosis complex (*M. tuberculosis*, *M. africanum*, *M. bovis*, *M. microti*, *M. canetti*, *M. caprae*, *M. orygis*, *M. munda* and vaccination strain Bacillus Calmette-Guérin, BCG)

CONTAMINATION PREVENTION

- Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating carryover contamination

WIDE RANGE OF VALIDATED CLINICAL MATERIALS

- Enables detection from a broad spectrum of respiratory and gastrointestinal samples
- Sputum, BAL, swab, urine, CSF, plasma, stool

EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional PCR reagents pipetting necessary
- Simplifies laboratory workflow

ORDER INFORMATION

REF	PACKAGE
MT/ISEX/025	25 reactions
MT/ISEX/100	100 reactions



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Mycobacterium tuberculosis PCR Kit

- + GeneProof Adenovirus PCR Kit
- + GeneProof Aspergillus PCR Kit
- + GeneProof Bordetella pertussis/parapertussis PCR Kit
- + GeneProof Enterovirus PCR Kit
- + GeneProof Chlamydia pneumoniae PCR Kit
- + GeneProof Flu Multiplex PCR Kit
- + GeneProof Legionella pneumophila PCR Kit
- + GeneProof Mycoplasma pneumoniae PCR Kit
- + GeneProof Mycobacterium tuberculosis PCR Kit

GENEPROOF COVID-19 SOLUTION

- + GeneProof SARS-CoV-2 PCR Kit
- + GeneProof SARS-CoV-2 Screening PCR Kit
- + GeneProof SARS-CoV-2 Advanced PCR Kit

INDICATION	<i>in vitro</i> diagnostic medical device	
REGULATORY STATUS	CE IVD	
INTENDED USER	For professional use in laboratories with trained staff	
TECHNOLOGY	Real-time PCR	
TYPE OF ANALYSIS	Qualitative	
TARGET SEQUENCE	Multi-copy insertion sequence IS6110 and sequence for immunogenic protein MPB64	
ANALYTICAL SPECIFICITY	<i>Mycobacterium tuberculosis</i> complex (<i>M. tuberculosis</i> , <i>M. africanum</i> , <i>M. bovis</i> , <i>M. microti</i> , <i>M. canettii</i> , <i>M. pinnipedi</i> , <i>M. caprae</i> , <i>M. orygis</i> , <i>M. mungi</i> and vaccination strain Bacillus Calmette-Guérin, BCG), (MT) 100 %	
ANALYTICAL SENSITIVITY (LoD with probability 95 %)	0.09 cp/μl (performed on AmpliRun [®] <i>Mycobacterium tuberculosis</i> DNA control, Vircell)	
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)	
VALIDATED SPECIMEN	Sputum, swab, urine, CSF, plasma, stool*, BAL	
STORAGE	-20 ± 5 °C	
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit myCROBE/croBEE 2.0 Universal Extraction Kit QIAamp Fast Stool Mini Kit	
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab 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	Gentier 96E/96R Real-Time PCR System LightCycler [®] 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN [®] Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM (MT), HEX/JOE/VIC (IC)	
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com	

*Only in combination with QIAamp FAST Stool Mini Kit