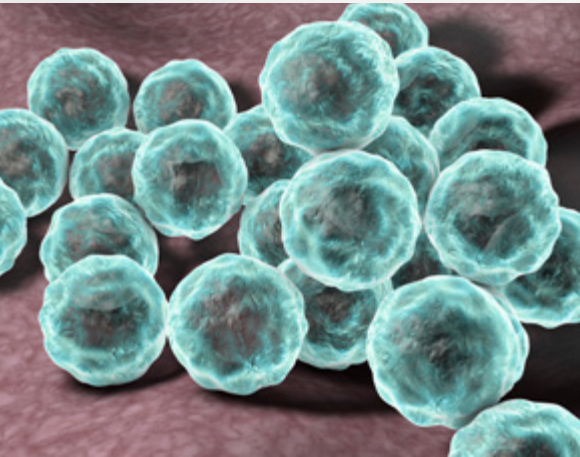




GeneProof[®]

GeneProof *Chlamydia pneumoniae* PCR Kit



HIGH SENSITIVITY

- Secured by targeting the *ompA* gene

DIAGNOSTICS OF ATYPICAL PNEUMONIAE

- Differential diagnostics of atypical bacterial respiratory pathogens
- Easily combinable with GeneProof Mycoplasma pneumoniae PCR Kit and GeneProof Legionella pneumophila PCR Kit

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

CONTAMINATION PREVENTION

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

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Chlamydia pneumoniae 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 ₁₀₂₃ IVD
INTENDED USER	For professional use in laboratories with trained staff
TECHNOLOGY	Real-time PCR
TYPE OF ANALYSIS	Qualitative
TARGET SEQUENCE	Specific conservative DNA sequence of a single-copy ompA gene
ANALYTICAL SPECIFICITY	<i>Chlamydia pneumoniae</i> , 100%
ANALYTICAL SENSITIVITY (LoD)	0.647 cp/μl with the probability of 95 % (on Amplirun [®] Chlamydia pneumoniae DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	100.00 % (CI _{95%} : 95.01 % - 100.00 %)
DIAGNOSTIC SENSITIVITY	99.08 % (CI _{95%} : 94.26 % - 99.95 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control
VALIDATED SPECIMEN	BAL, sputum, swab
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation 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 BioQuant-96 Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LightCycler [®] 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclcr QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN [®] Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSEMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com