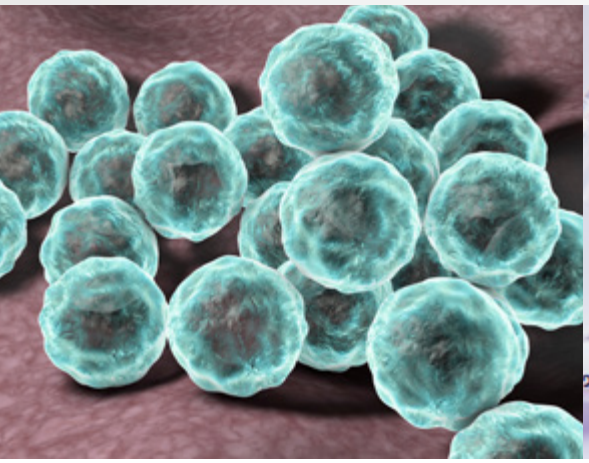
GeneProof®

Respiratory Infections

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

CE 1023 IVD CERTIFIED DIAGNOSTIC TEST

www.geneproof.com

GUARANTEED CONTROL OVER THE COMPLETE PROCESS OF DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF ALL THE OFFERED GENEPROOF PRODUCTS

Respiratory Infections

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	*in vitro* 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	*Chlamydia pneumoniae,* 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 Cycler 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

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