

CE-IVD

Tailored respiratory diagnostic solutions

Enabling clinical laboratories to identify multiple respiratory pathogens in the same sample

Respiratory tract infections (RTIs) can affect the upper and lower respiratory tract [1]. According to the World Health Organization (WHO), lower RTIs are among the leading causes of death and disability worldwide [2]. Most RTIs are caused by viruses and bacteria, but diagnosis can be difficult as many respiratory infections have similar clinical presentations [1].

The Applied Biosystems™ TaqPath™ COVID-19 solution and COVID-19, Flu A/B, RSV combo solution are designed to detect common viruses including SARS-CoV-2, the influenza A and B viruses (Flu A/B), and respiratory syncytial virus (RSV). The Applied Biosystems™ TaqPath™ Respiratory Viral Select Panel expands testing for viral RTIs by detecting

adenovirus, parainfluenza virus 1–4 (undifferentiated), human metapneumovirus, and rhinovirus/enterovirus (undifferentiated) in a single multiplex test.

The Applied Biosystems™ TaqPath™ Menu RTI testing portfolio offers a great solution for identifying additional important pathogens that can be difficult to detect. The portfolio covers viruses that can lead to serious illnesses (enterovirus, adenovirus), common pathogens that cause atypical pneumonia (*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*), and highly infectious causative agents of tuberculosis and pertussis/parapertussis (*Mycobacterium tuberculosis*, *Bordetella pertussis*, and *Bordetella parapertussis*).

Rely on a tailored portfolio of respiratory testing solutions comprising the following Applied Biosystems™ PCR kits to help meet your lab's clinical testing needs:

- TaqPath™ COVID-19 CE-IVD RT-PCR Kit
- TaqPath™ COVID-19, Flu A/B, RSV Combo Kit
- TaqPath™ Menu | GeneProof™ Adenovirus PCR Kit
- TaqPath™ Menu | GeneProof™ Bordetella pertussis/parapertussis PCR Kit
- TaqPath™ Menu | GeneProof™ Chlamydia pneumoniae PCR Kit
- TaqPath™ Respiratory Viral Select Panel
- TaqPath™ Menu | GeneProof™ Enterovirus PCR Kit
- TaqPath™ Menu | GeneProof™ Mycoplasma pneumoniae PCR Kit
- TaqPath™ Menu | GeneProof™ Mycobacterium tuberculosis PCR Kit

TaqPath COVID-19 CE-IVD RT-PCR Kit

Trusted worldwide

- More than half a billion tests distributed globally

Built-in redundancy

- Three targets compensate for emerging SARS-CoV-2 mutations and variants, helping provide confidence in your results

Compatibility

- Validated for use on some of the most-used real-time PCR instruments in the world

Wide range of validated sample types

- Bronchoalveolar lavage (BAL)
- Midturbinate swabs

- Nasal swabs
- Nasopharyngeal swabs
- Nasopharyngeal aspirate (nasal aspirate)
- Oropharyngeal swabs
- Saliva collected with a Spectrum Solutions™ SDNA saliva collection device

Product details	
Format	Single-tube multiplex
Kit size	1,000 rxns
Target	SARS-CoV-2
Throughput	1–94 on 96-well plates, 1–382 on 384-well plates
Controls	MS2 process control and included positive control
Sample types	BAL, midturbinate swabs, nasal swabs, nasopharyngeal swabs, nasopharyngeal aspirate (nasal aspirate), oropharyngeal swabs, saliva collected with a Spectrum Solutions SDNA saliva collection device
Turnaround time	Approx. 3 hours
Instruments	Applied Biosystems™ 7500 Fast Dx, 7500 Fast, and 7500 Real-Time PCR Systems Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Systems, 96-well, 0.2 mL block and 96-well, 0.1 mL block Applied Biosystems™ QuantStudio™ 5 Dx and 7 Flex Real-Time PCR Systems, 384-well block
Software	Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition
Cat. No.	A48067

TaqPath COVID-19, Flu A/B, RSV Combo Kit, a multiplex diagnostic solution

Single test for SARS-CoV-2, influenza A/B viruses, and respiratory syncytial virus (RSV)

- Simultaneously differentiates between respiratory diseases
- Helps identify cases of co-infection

Affordable and scalable

- Increases testing throughput and lab efficiency

Sensitive and specific reverse transcription (RT)-PCR detection

- Robust performance for detecting SARS-CoV-2, influenza A/B viruses, and RSV

Results interpretation automated by Applied Biosystems™ Pathogen Interpretive Software

- Quickly interprets results to expedite reporting
- Helps reduce risk of user interpretation error

Product details	
Format	Single-tube multiplex
Targets	SARS-CoV-2
	Influenza A/B viruses
	RSV
Kit size	1,000 rxns
Throughput	1–94 samples on 96-well plates, 1–382 samples on 384-well plates
Controls	MS2 process control and included positive control
Sample type	Nasopharyngeal swab
Turnaround time	Approx. 3 hours
Instruments	7500 Fast Real-Time PCR System QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL block) QuantStudio 7 Flex Real-Time PCR System (384-well block)
Software	Pathogen Interpretive Software CE-IVD Edition
Cat. No.	A49867

TaqPath Respiratory Viral Select Panel

Validated workflow

- The complete workflow, from sample preparation to software-generated results, takes only 3 hours, for a fast turnaround time

Single tube

- Detecting five viruses and an endogenous internal control, all in a single well, makes it easy to perform routine patient testing

Affordable price

- Easily adopt this panel, and save on the targets you need

PCR performance

- High sensitivity for the vast majority of strains gives you confidence in results

Controls included

- Included RNase P and positive controls offer reliable runs, time after time

Flexible throughput

- Scalable to fit your needs, allowing you to test from 1–94 samples on a 96-well plate, and 1–382 samples on a 384-well plate, as needed

Product details	
Format	Single-tube multiplex
Targets	Adenovirus
	Parainfluenza viruses, subtypes 1, 2, 3, and 4 (undifferentiated)
	Rhinovirus and enterovirus (undifferentiated)
	Human metapneumovirus
Kit size	200 rxns
Throughput	1–94 samples on 96-well plates, 1–382 samples on 384-well plates
Controls	RNase P and included positive control
Sample types	Varies
Turnaround time	Approx. 3 hours
Instruments	QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL block) QuantStudio 5 Dx Real-Time PCR System
Software	Pathogen Interpretive Software CE-IVD Edition
Cat. No.	A54713

TaqPath Menu | GeneProof Adenovirus PCR Kit

High specificity

- Detection of human Adenovirus subgroups A–G
- Suitable for use in both respiratory and gastrointestinal infections

Easy-to-use concept

- Single-tube, ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs, reducing carryover contamination

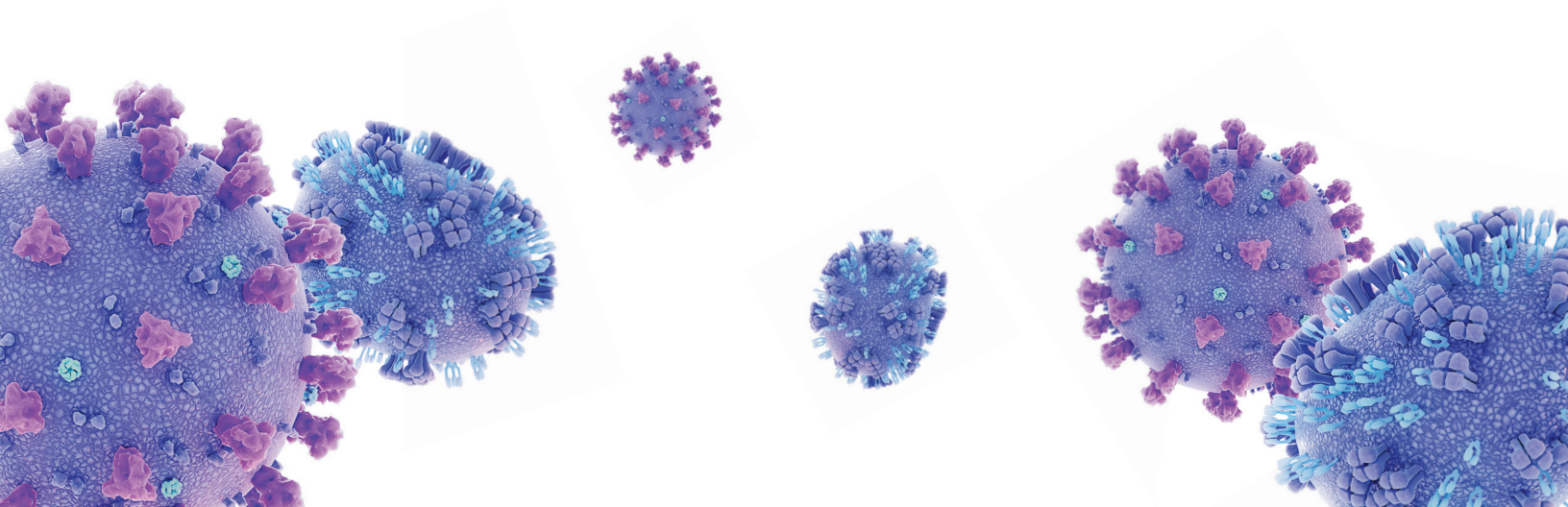
Wide range of validated clinical materials

- Enables detection from a broad spectrum of respiratory and gastrointestinal samples
- Aspirate, plasma, stool, swab, urine, and whole blood

Compatible with a wide range of real-time PCR devices

Product details	
Technology	Qualitative and quantitative real-time PCR
Target sequence	Highly conservative DNA sequence of <i>E2B</i> gene
Sample type	Plasma, stool*, swab, urine, whole blood (EDTA), aspirate
Analytical specificity	Adenovirus, 100%; 2371.645 copies (cp)/mL (on Qnostics ADV Molecular Q Panel using manual extraction with the GeneProof PathogenFree DNA Isolation Kit)
Analytical sensitivity (LoD)	81.41 cp/mL (on Thermo Scientific™ AcroMetrix™ Adenovirus Plasma Panel using manual extraction with the GeneProof PathogenFree DNA Isolation Kit)
Diagnostic specificity	87.98% (CI _{95%} : 82.16%–92.15%)
Diagnostic sensitivity	100.00% (CI _{95%} : 91.11%–100.00%)
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control by internal standard
Instruments	Applied Biosystems™ 7300 and 7500 Real-Time PCR Systems Applied Biosystems™ QuantStudio™ 3 and QuantStudio 5 Real-Time PCR Systems croBEE Real-Time PCR System AMPLiLab Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX Connect/CFX96/Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LightCycler 480 System LineGene 9600/9600 Plus instrument Mic qPCR Cycler Rotor-Gene 3000/Q instrument SLAN Real-Time PCR System StepOne™/StepOnePlus™ Real-Time PCR System
Validated extraction methods	Refer to the Instructions for Use (IFU)
Detection channel	FAM, HEX/JOE/VIC
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels
Cat. No.	A58213

*Only in combination with QIAamp DNA Stool Mini Kit.



TaqPath Menu | GeneProof *Bordetella pertussis*/parapertussis PCR Kit

High specificity

- Amplification of the multicopy insertion sequences IS1002, specific for both *Bordetella pertussis* and *B. parapertussis*, and IS1001, specific only for *B. parapertussis*
- No demonstrated false positive results for *B. holmesii*

Easy-to-use concept

- Single-tube, ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs, reducing carryover contamination

Simple laboratory workflow

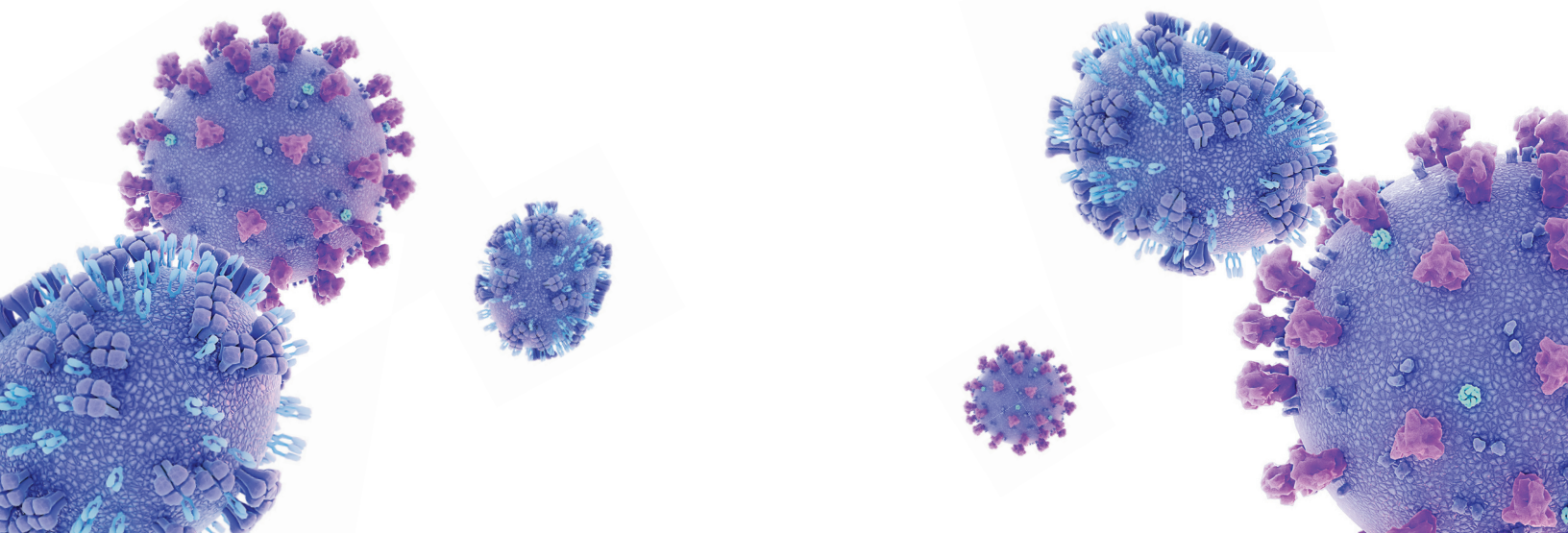
- Easily combinable with other TaqPath Menu | GeneProof PCR kits in one workflow

More information with less samples

- Detects and distinguishes *B. pertussis* and *B. parapertussis* in a single reaction tube

Compatible with a wide range of real-time PCR devices

Product details	
Technology	Qualitative real-time PCR
Target sequence	The multicopy insertion sequences IS1002 (specific for both <i>B. pertussis</i> and <i>B. parapertussis</i>) and IS10001 (specific only for <i>B. parapertussis</i>)
Sample type	Aspirate, sputum, swab
Analytical specificity	<i>B. pertussis</i> , 100% <i>B. parapertussis</i> , 100%
Analytical sensitivity (LoD)	0.212 cp/μL (on AmpliRun <i>Bordetella pertussis</i> DNA Control, Vircell)
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control by internal control
Instruments	7500 Real-Time PCR System QuantStudio 5 Real-Time PCR System croBEE Real-Time PCR System AMPLilab Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX96/Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LightCycler 480 System LineGene 9600/9600 Plus instrument Mic qPCR Cycler Rotor-Gene 3000/Q/6000 instrument SLAN Real-Time PCR System
Validated extraction methods	Refer to the Instructions for Use (IFU)
Detection channel	FAM, HEX/JOE/VIC, Cy5
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels
Cat. No.	A58208



TaqPath Menu | GeneProof Chlamydia pneumoniae PCR Kit

High specificity

- Secured by targeting the *ompA* gene

Easy-to-use concept

- Single-tube, ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs, reducing carryover contamination

Simple laboratory workflow

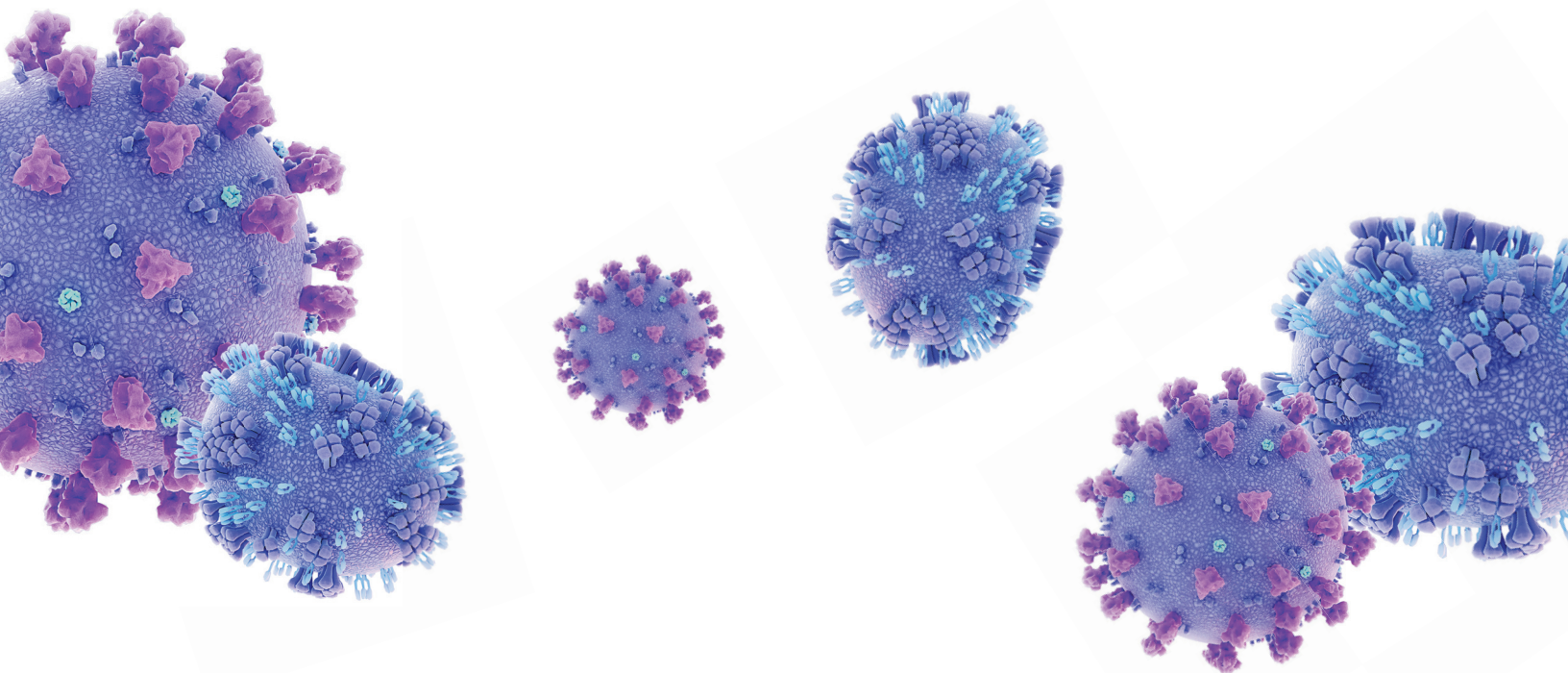
- Easily combinable with other TaqPath Menu | GeneProof PCR kits in one workflow

Diagnostic of atypical pneumoniae

- Differential diagnostics of atypical bacterial respiratory pathogens

Compatible with a wide range of real-time PCR devices

Product details	
Technology	Qualitative real-time PCR
Target sequence	Specific conservative DNA sequence of a single-copy <i>ompA</i> gene
Sample type	BAL, sputum, swab
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 by internal control
Instruments	7300 and 7500 Real-Time PCR Systems QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems croBEE Real-Time PCR System AMPLilab 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 System LineGene 9600/9600 Plus instrument Mic qPCR Cycler Rotor-Gene 3000/6000/Q instrument SLAN Real-Time PCR System
Validated extraction methods	Refer to the Instructions for Use (IFU)
Detection channel	FAM, HEX
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels
Cat. No.	A58209



TaqPath Menu | GeneProof Enterovirus PCR Kit

High specificity

- Detect Enterovirus species A–D including Coxsackievirus, Echovirus, Enterovirus, Poliovirus, and the newly discovered Enterovirus group EV-C104
- Not affected by the presence of Rhinovirus

Easy-to-use concept

- Single-tube, ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs, reducing carryover contamination

Simple laboratory workflow

- Easily combinable with other TaqPath Menu | GeneProof PCR kits in one workflow

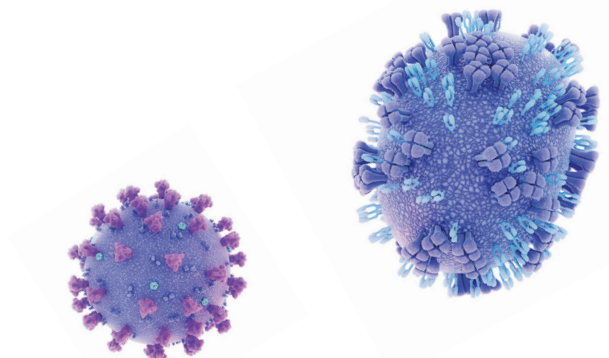
Design according to ENPEN requirements

- Amplification of a single-copy 5' UTR RNA sequence which is required as the target sequence by European Non-Polio Enterovirus Network (ENPEN)
- Suitable for use as a primary screening method

Compatible with a wide range of real-time PCR devices

Product details	
Technology	Qualitative and quantitative real-time PCR
Target sequence	5' UTR RNA sequence
Sample type	Cerebrospinal fluid (CSF), stool*, swab
Analytical specificity	Enterovirus A–D, 100%
Analytical sensitivity (LoD)	reaches up to 158.34 cp/μL with the probability of 95% (on AmpliRun Enterovirus 68 RNA Control, Vircell) reaches up to 0.57 cp/μL with the probability of 95% (on AmpliRun Enterovirus 71 RNA Control, Vircell) reaches up to 0.59 cp/μL with the probability of 95% (on AmpliRun Coxsackie B5 RNA Control, Vircell)
Diagnostic specificity	93.75% (CI _{95%} : 77.78%–98.9%)
Diagnostic sensitivity	98.72% (CI _{95%} : 92.09%–99.93%)
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control by internal control
Instruments	7300 and 7500 Real-Time PCR Systems QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems croBEE Real-Time PCR System AMPLiLab 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 480 System LineGene 9600 Plus instrument Mic qPCR Cyclers Rotor-Gene 3000/6000/Q instrument Gentier 96E/96R Real-Time PCR System SLAN Real-Time PCR System
Validated extraction methods	Refer to the Instructions for Use (IFU)
Detection channel	FAM, HEX/JOE/VIC
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels
Cat. No.	A58211

*Only in combination with QIAamp DNA Stool Mini Kit.



TaqPath Menu | GeneProof Mycobacterium tuberculosis PCR Kit

High specificity

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

Easy-to-use concept

- Single-tube, ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs, reducing 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

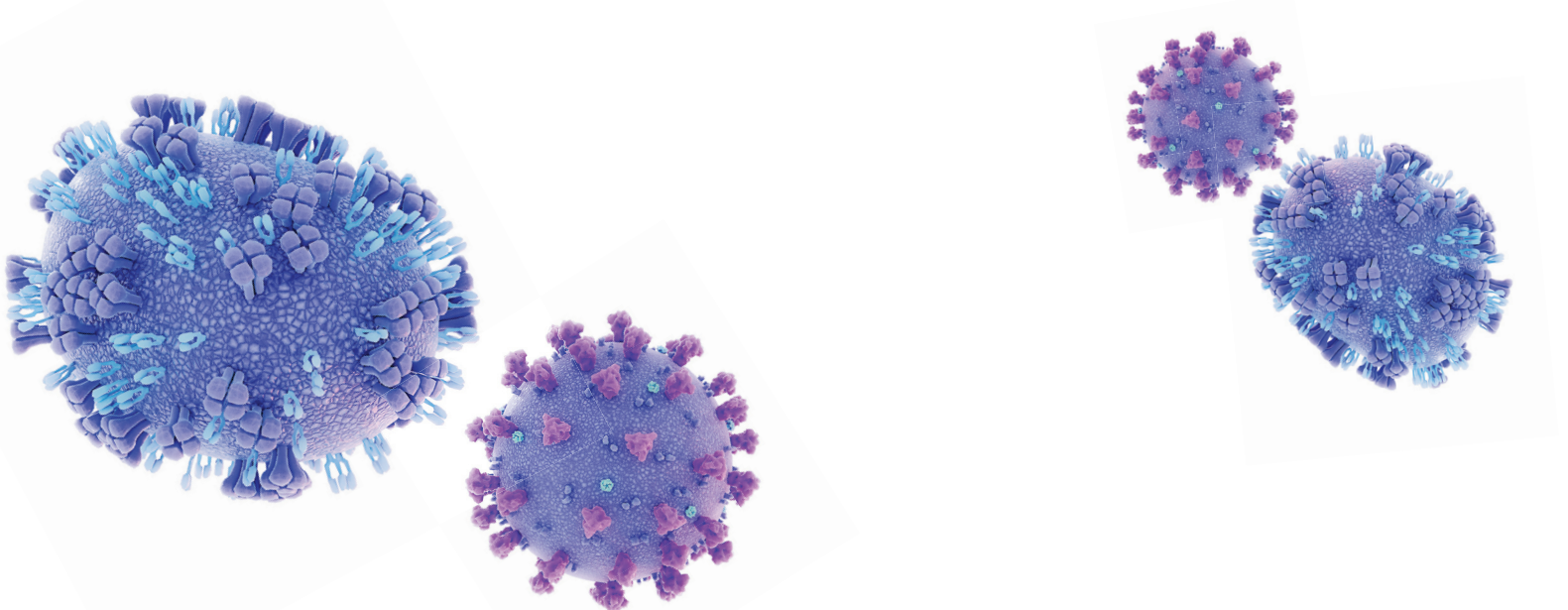
Dual target detection

- Dual targeting helps prevent detection failures caused by the occurrence of mutations
- Secured by targeting the multicopy insertion sequence IS6110 and the *MPB64* gene

Compatible with a wide range of real-time PCR devices

Product details															
Technology	Qualitative real-time PCR														
Target sequence	Multicopy insertion sequence IS6110 and the sequence for the immunogenic protein MPB64														
Sample type	Sputum, swab, urine, CSF, plasma, stool*, BAL														
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 the vaccination strain Bacillus Calmette-Guérin, BCG), 100%														
Analytical sensitivity (LoD)	0.09 cp/μL (performed on AmpliRun Mycobacterium tuberculosis DNA Control, Vircell)														
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control by internal control														
Instruments	<table border="0"> <tr> <td>7300 and 7500 Real-Time PCR Systems</td> <td>LightCycler 480 System</td> </tr> <tr> <td>QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems</td> <td>LineGene 9600 Plus instrument</td> </tr> <tr> <td>croBEE Real-Time PCR System</td> <td>Mic qPCR Cycler</td> </tr> <tr> <td>AMPLiLab Real-Time PCR System</td> <td>Rotor-Gene 3000/6000/Q instrument</td> </tr> <tr> <td>AriaMx Real-Time PCR System</td> <td>Gentier 96E/96R Real-Time PCR System</td> </tr> <tr> <td>BioQuant-96 Real-Time PCR System</td> <td>SLAN Real-Time PCR System</td> </tr> <tr> <td>CFX Connect/CFX96/Dx Real-Time PCR Detection System</td> <td></td> </tr> </table>	7300 and 7500 Real-Time PCR Systems	LightCycler 480 System	QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems	LineGene 9600 Plus instrument	croBEE Real-Time PCR System	Mic qPCR Cycler	AMPLiLab Real-Time PCR System	Rotor-Gene 3000/6000/Q instrument	AriaMx Real-Time PCR System	Gentier 96E/96R Real-Time PCR System	BioQuant-96 Real-Time PCR System	SLAN Real-Time PCR System	CFX Connect/CFX96/Dx Real-Time PCR Detection System	
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Validated extraction methods	Refer to the Instructions for Use (IFU)														
Detection channel	FAM, HEX/JOE/VIC														
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels														
Cat. No.	A58212														

* Only in combination with QIAamp DNA Stool Mini Kit.



TaqPath Menu | GeneProof Mycoplasma pneumoniae PCR Kit

High specificity and sensitivity

- Secured by targeting the multicopy sequence of the *M181* gene

Easy-to-use concept

- Single-tube, ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs, reducing carryover contamination

Simple laboratory workflow

- Easily combinable with other TaqPath Menu | GeneProof PCR kits in one workflow

Compatible with a wide range of real-time PCR devices

Product details															
Technology	Qualitative real-time PCR														
Target sequence	The <i>M181</i> gene encoding the CARDS toxin														
Sample type	BAL, sputum, swab														
Analytical specificity	<i>M. pneumoniae</i> , 100%														
Analytical sensitivity (LoD)	0.46 cp/μL														
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control by internal control														
Instruments	<table border="0"> <tr> <td>7300 and 7500 Real-Time PCR Systems</td> <td>LightCycler 480/2.0 System</td> </tr> <tr> <td>QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems</td> <td>LineGene 9600 Plus instrument</td> </tr> <tr> <td>croBEE Real-Time PCR System</td> <td>Mic qPCR Cycler</td> </tr> <tr> <td>AMPLilab Real-Time PCR System</td> <td>Rotor-Gene 3000/6000/Q instrument</td> </tr> <tr> <td>AriaMx Real-Time PCR System</td> <td>Gentier 96E/96R Real-Time PCR System</td> </tr> <tr> <td>BioQuant-96 Real-Time PCR System</td> <td>SLAN Real-Time PCR System</td> </tr> <tr> <td>CFX Connect/CFX96/Dx Real-Time PCR Detection System</td> <td>StepOne™/StepOne Plus™ Real-Time PCR System</td> </tr> </table>	7300 and 7500 Real-Time PCR Systems	LightCycler 480/2.0 System	QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems	LineGene 9600 Plus instrument	croBEE Real-Time PCR System	Mic qPCR Cycler	AMPLilab Real-Time PCR System	Rotor-Gene 3000/6000/Q instrument	AriaMx Real-Time PCR System	Gentier 96E/96R Real-Time PCR System	BioQuant-96 Real-Time PCR System	SLAN Real-Time PCR System	CFX Connect/CFX96/Dx Real-Time PCR Detection System	StepOne™/StepOne Plus™ Real-Time PCR System
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Validated extraction methods	Refer to the Instructions for Use (IFU)														
Detection channel	FAM, HEX/JOE/VIC														
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels														
Cat. No.	A58210														

References

- Dasaraju PV, C Liu (1996) Infections of the respiratory system. In: Medical Microbiology; S Baron, Ed.; University of Texas Medical Branch at Galveston. pubmed.ncbi.nlm.nih.gov/21413304/
- World Health Organization. Global health Estimates: Life expectancy and leading causes of death and disability. who.int/data/gho/data/themes/mortality-and-global-health-estimates



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