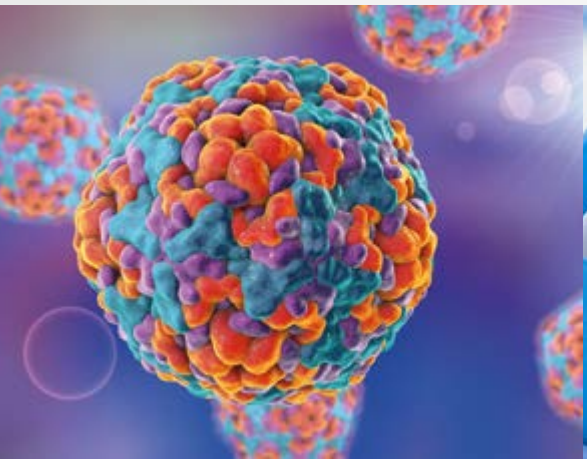
Neuroinfections

Respiratory infections

GeneProof®

GeneProof Enterovirus PCR Kit



DESIGN ACCORDING 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

HIGH SPECIFICITY

- The kit detects Enterovirus species A-D including Coxsackievirus, Echovirus, Enterovirus, Poliovirus and the newly discovered Enterovirus group EV-C104

Note: In rare cases cross-reactivity with Rhinoviruses B5, B42, B99, C3, C39 and C43 may occur. Echovirus 12 (a rare enterovirus serotype) cannot be detected by the GeneProof Enterovirus PCR Kit.

QUALITATIVE AND QUANTITATIVE DETECTION

- Monitoring of pathogen level in time

EASY-TO-USE CONCEPT

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

CONTAMINATION PREVENTION

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

ORDER INFORMATION

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

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE IVD CERTIFIED DIAGNOSTIC TEST

Respiratory infections

GeneProof Enterovirus PCR Kit

+ GeneProof® Flu Multiplex PCR Kit
+ GeneProof® Enterovirus PCR Kit
+ GeneProof® Adenovirus PCR Kit
+ GeneProof® Aspergillus PCR Kit
+ GeneProof® Bordetella pertussis/ parapertussis PCR Kit
+ GeneProof® Chlamydia pneumoniae 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 Advanced PCR Kit
+ GeneProof® SARS-CoV-2 PCR Kit
+ GeneProof® SARS-CoV-2 Screening PCR Kit

INDICATION	*in vitro* diagnostic medical device	
REGULATORY STATUS	CE IVD / EC Directive 98/79/EC	
INTENDED USER	For professional use in laboratories with trained staff	
TECHNOLOGY	Real-time PCR	
TYPE OF ANALYSIS	Qualitative and quantitative	
TARGET SEQUENCE	5‘ UTR RNA	
ANALYTICAL SPECIFICITY	Enterovirus A – D*	
ANALYTICAL SENSITIVITY (LoD with 95% probability)	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 % – 98.91 %)	
DIAGNOSTIC SENSITIVITY	98.72 % ($CI_{95\%}$: 92.09 % – 99.93 %)	
REPORTING UNITS	cp/ml	
EXTRACTION/INHIBITION CONTROL	PCR inhibition and RNA extraction efficiency control by Internal Control (IC)	
VALIDATED SPECIMEN	CSF, stool**, swab	
STORAGE	-20 ± 5 °C	
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree RNA Isolation Kit NucleoSpin® RNA Stool	
APPLIED 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	Gentier 96E/96R Real-Time PCR System LightCycler® 480 LineGene 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 (EV), HEX/JOE/VIC (IC)	
EXTERNAL QUALITY ASSESSMENT	Regularly tested using QCMD and INSTAND e.V. External Quality Assessment Panels – results at www.geneproof.com	

**NOTE: Enteroviruses and Rhinoviruses belong to the family Picornaviridae. Due to the sequence similarity, it cannot be completely excluded that the GeneProof Enterovirus PCR Kit may in rare cases show cross-reactivity with some Rhinoviruses and false positive results for Enterovirus due to cross-reactivity with Rhinoviruses B5, B42, B99, C3, C39 and C43 may occur.*
***NOTE: Only in combination with NucleoSpin® RNA Stool.*

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