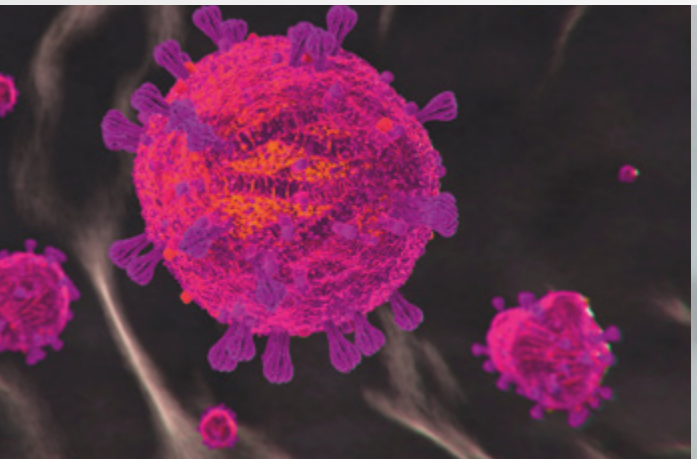
GeneProof®

Respiratory Infections

GeneProof SARS-CoV-2 Advanced PCR Kit



W.H.O. RECOMMENDED DESIGN

- Three targets (*RdRp/E/N* genes) in one reaction
- Confirmation in an independent channel (*RdRp* gene)
- Triple protection against detection failures caused by virus mutations

TIME SAVING EXAMINATION

- Direct detection possibility with unique sampling set Bi-CoV™
- Fast PCR profile – less than 1 hour

CONTAMINATION PREVENTION

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

ENDOGENOUS INTERNAL CONTROL

- Human *RNase P* gene for the control of the whole diagnostic process including of proper sampling
- Simplifies laboratory workflow

EASY-TO-USE CONCEPT

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

ORDER INFORMATION

REF	PACKAGE
COV2A/GP/025	25 reactions
COV2A/GP/100	100 reactions

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE IVD CERTIFIED DIAGNOSTIC TEST

www.geneproof.com

ISO 13485

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

Respiratory Infections

GeneProof SARS-CoV-2 Advanced 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 IVD / EC Directive 98/79/EC			
INTENDED USER	For professional use in laboratories with trained staff			
TECHNOLOGY	Real-time PCR			
TYPE OF ANALYSIS	Qualitative			
TARGET SEQUENCE	*RdRp* gene, *E* gene and *N* gene			
ANALYTICAL SPECIFICITY	SARS-CoV-2, 100 %			
ANALYTICAL SENSITIVITY (LoD with 95% probability)	**Sample processing**	**Channel**	**Sensitivity**	**Material**
	GeneProof PathogenFree RNA Isolation Kit (FAM)	FAM	691.08 IU/ml	PBS
		Cy5	127.24 IU/ml	
	croBEE 201A Nucleic Acid Extraction Kit (FAM)	FAM	1404.51 IU/ml	PBS
		Cy5	1654.57 IU/ml	
	croBEE®max Universal Extraction Kit	FAM	1127.56 IU/ml	PBS
		Cy5	1779.36 IU/ml	
	Direct detection (Bi-CoV®) (FAM)	Cy5	5943.21 IU/ml	Bi-CoV®
DIAGNOSTIC SPECIFICITY	100 % ($CI_{95\%}$: 99.16 % – 100 %)			
DIAGNOSTIC SENSITIVITY	100 % ($CI_{95\%}$: 97.10 % – 100 %)			
POSITIVE PREDICTIVE VALUE	100 % ($CI_{95\%}$: 97.10 % – 100 %)			
NEGATIVE PREDICTIVE VALUE	100 % ($CI_{95\%}$: 99.16 % – 100 %)			
REPORTING UNITS	IU/ml			
METROLOGICAL TRACEABILITY	1st WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146)			
INHIBITION/EXTRACTION CONTROL	Proper sampling, RNA extraction efficiency, reverse transcription and PCR inhibition control by endogenous Internal control (RNase P gene)			
VALIDATED SPECIMEN	Swab in transport medium (PBS, physiological saline solution and UTM) or in Bi-CoV®			
STORAGE	-20 ± 5 °C			
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree RNA Isolation Kit croBEE®max Universal Extraction Kit			
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab AriaMx Real-Time PCR CFX96™/ Dx Real-Time PCR Detection System LightCycler® 480 LineGene 9600 Plus Rotor-Gene 3000 / Q QuantStudio™ 5 Real-Time PCR System SLAN® Real-Time PCR System SystemBioQuant-96, Fluorescent Quantitative Detection PCR system			
REQUIRED DETECTION CHANNELS	FAM (RdRp), Cy5 (E/N), HEX/VIC (RNase P)			
EXTERNAL QUALITY ASSESSMENT	Regularly tested in **QCMD** and **INSTAND e.V.** External Quality Assessment Panels – results at www.geneproof.com			

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