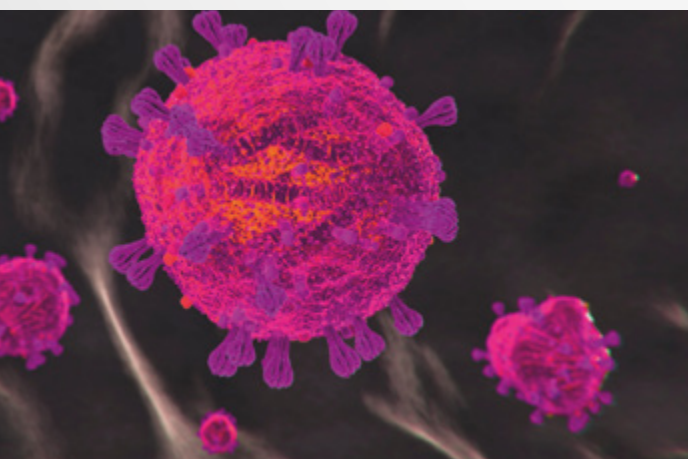




GeneProof[®]

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

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



CERTIFIED
DIAGNOSTIC TEST



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	<i>in vitro</i> 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	<i>RdRp</i> gene, <i>E</i> gene and <i>N</i> 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	1 st 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			