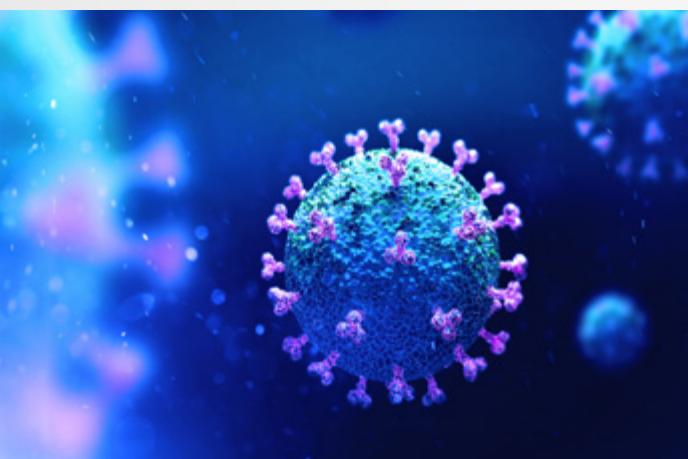




# GeneProof<sup>®</sup>

## GeneProof SARS-CoV-2 Screening PCR Kit



### UNIQUE SPECIFICITY AND SENSITIVITY

- Excellent QCMD panel results
- 100% diagnostic sensitivity and specificity

### W.H.O. RECOMMENDED DESIGN



- Three targets (*RdRp/E/N* genes) in one reaction
- Robust and reliable screening solution for two-channel thermocyclers
- Triple protection against detection failures caused by virus mutations

### MADE IN EU

- Developed and manufactured in the Czech Republic, the member of the European Union



COMPATIBLE WITH A WIDE  
RANGE OF REAL-TIME PCR  
DEVICES

### EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents necessary
- Suitable for direct detection without NA extraction

### CONTAMINATION PREVENTION

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

#### ORDER INFORMATION

REF	PACKAGE
COV2S/GP/025	25 reactions
COV2S/GP/100	100 reactions



CERTIFIED  
DIAGNOSTIC TEST



# GeneProof SARS-CoV-2 Screening 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, E and N genes		
ANALYTICAL SPECIFICITY	SARS-CoV-2, 100 %		
ANALYTICAL SENSITIVITY (LoD with 95% probability)	<b>Sample Processing</b>	<b>Sensitivity</b>	<b>Material</b>
	GeneProof PathogenFree RNA Isolation Kit	86.96 IU/ml	PBS
	croBEE 201A Nucleic Acid Extraction Kit	183.79 IU/ml	PBS
	Direct detection (Bi-CoV <sup>®</sup> )	417.97 IU/ml	anterior nasal swab in Bi-CoV <sup>®</sup>
	croBEE <sup>®</sup> max Nucleic Acid Extraction Kit	450.51 IU/ml	PBS
DIAGNOSTIC SPECIFICITY	100 % (CI <sub>95%</sub> : 95.68 % – 100 %)		
DIAGNOSTIC SENSITIVITY	100 % (CI <sub>95%</sub> : 91.58 % – 100 %)		
POSITIVE PREDICTIVE VALUE	100 % (CI <sub>95%</sub> : 91.58 % – 100 %)		
NEGATIVE PREDICTIVE VALUE	100 % (CI <sub>95%</sub> : 95.68 % – 100 %)		
REPORTING UNITS	IU/ml		
METROLOGICAL TRACEABILITY	1 <sup>st</sup> WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146)		
EXTRACTION/INHIBITION CONTROL	PCR inhibition and RNA extraction efficiency control by Internal Control (IC)		
VALIDATED SPECIMEN	Nasopharyngeal swab (in transport media UTM (Copan), PBS or Physiological saline solution); anterior nasal swab, saliva in Bi-CoV <sup>®</sup>		
STORAGE	-20 ± 5 °C		
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree RNA Isolation Kit croBEE <sup>®</sup> max Nucleic Acid Extraction Kit		
INSTRUMENTS	croBEE Real-Time PCR System		
	Applied Biosystems 7300 / 7500 Real-Time PCR System		
	AriaMx Real-Time PCR System		
	CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System		
	Mic qPCR Cyclers		
	LightCycler <sup>®</sup> 480		
	LineGene 9600 Plus		
	Mic qPCR Cyclers		
	QuantStudio™ 5 Real-Time PCR System		
	Rotor-Gene 3000 / 6000 / Q		
	SLAN <sup>®</sup> Real-Time PCR System		
REQUIRED DETECTION CHANNELS	FAM (RdRp/N/E), HEX/JOE/VIC (IC)		
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and INSTAND e.V. External Quality Assessment Panels – results at <a href="http://www.geneproof.com">www.geneproof.com</a>		