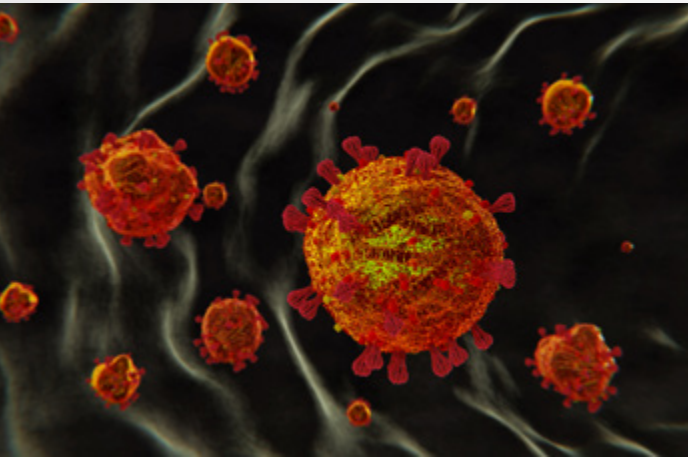




GeneProof SARS-CoV-2 PCR Kit



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
- Confirmation in an independent channel
- Reliable detection of all virus variants
- 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

EASY-TO-USE CONCEPT

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

CONTAMINATION PREVENTION

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

ORDER INFORMATION

REF	PACKAGE
COV2/GP/025	25 reactions
COV2/GP/100	100 reactions



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof SARS-CoV-2 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	Sensitivity	Material
	GeneProof PathogenFree RNA Isolation Kit (FAM)	381.28 IU/ml	PBS
	croBEE 201A Nucleic Acid Extraction Kit (FAM)	1600.41 IU/ml	PBS
	Direct detection (Bi-CoV [®]) (FAM)	2589.8 IU/ml	Anterior nasal swab in Bi-CoV [®]
DIAGNOSTIC SPECIFICITY	100 % (CI _{95%} : 95.68 % - 100 %)		
DIAGNOSTIC SENSITIVITY	100 % (CI _{95%} : 91.58 % - 100 %)		
POSITIVE PREDICTIVE VALUE	100 % (CI _{95%} : 91.58 % - 100 %)		
NEGATIVE PREDICTIVE VALUE	100 % (CI _{95%} : 95.68 % - 100 %)		
REPORTING UNITS	IU/ml		
METROLOGICAL TRACEABILITY	1 st 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 transport medium Bi-CoV [®]		
STORAGE	-20 ± 5 °C		
VALIDATED EXTRACTION METHODS	ccroBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree RNA Isolation Kit		
INSTRUMENTS	croBEE Real-Time PCR System Applied Biosystems 7500 Real-Time PCR System AriaMx Real-Time PCR System CFX96™/ Dx Real-Time PCR Detection System LightCycler [®] 480 LineGene 9600 Plus Rotor-Gene 3000 Rotor-Gene Q QuantStudio™ 5 Real-Time PCR System SLAN [®] Real-Time PCR System		
REQUIRED DETECTION CHANNELS	FAM, HEX/JOE/VIC, Cy5		
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and INSTAND e.V. External Quality Assessment Panels - results at www.geneproof.com		