

Performance Evaluation Report for GeneProof
SARS-CoV-2 PCR Kit

DEPARTMENTAL SECRECY LEVEL

ADDRESSED TO ALL DEPARTMENTS

PURPOSE	The document describes specific part of technical documentation for relevant IVD medical device.
SCOPE	GeneProof SARS-CoV-2 PCR Kit
RESPONSIBILITY	Chief QA & RA Officer

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ABBREVIATION LIST AND CONCEPTS DEFINITION

CI	Confidential Interval
EQA	External Quality Assessment
IC	Internal Control
LoD	Limit of Detection
MM	MasterMix
PK	Positive Control
SSTE	salmon sperm Tris-EDTA buffer

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1. INTENDED PURPOSE

The GeneProof SARS-CoV-2 PCR Kit is intended to be a diagnostic test. The GeneProof SARS-CoV-2 PCR Kit is intended as qualitative test. The GeneProof SARS-CoV-2 PCR Kit is intended for detection of SARS-CoV-2 from clinical specimens: swab. The GeneProof SARS-CoV-2 PCR Kit can be used in combination with a manual or fully automated extraction system. The kit is designed for human in vitro diagnostics and provides qualitative detection of the pathogen. The kit is intended for diagnosis and aid to diagnosis test and it is designed for professional use in laboratories with trained personnel. The diagnostics is designed to test patients regardless of age and gender.

Kit technical specification

Technology	real-time PCR
Type of analysis	qualitative
Target Sequence	specific region in <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)	reaches up to 65.44 cp/μl using UNI PCR program (material quantified on standard 1 (SARS CoV (Frankfurt 2003, EVAg., Corman)) reaches up to 23.89 cp/μl using COVID SCREEN program (material quantified on standard 1 (SARS CoV (Frankfurt 2003, EVAg., Corman)) reaches up to 1.77 cp/μl using UNI PCR program on synthetic positive control
Diagnostic Specificity	100.00% (CI _{95%} : 95.06% - 100.00%)
Diagnostic Sensitivity	77.36% (CI _{95%} : 63.45% - 87.27%)
Positive predictive value	100.00% (CI _{95%} : 89.33% - 100.00%)
Negative predictive value	88.57% (CI _{95%} : 80.52% - 93.70%)
Extraction/Inhibition Control	PCR inhibition and RNA extraction efficiency control
Validated Specimen	swab, transport medium
Storage	-20 ± 5 °C
Validated Extraction Methods	GeneProof PathogenFree RNA Isolation Kit GeneProof Universal Nucleic Acid Extraction Kit
Instruments	croBEE Real-Time PCR System Applied Biosystems 7500 Real-Time PCR System CFX96™/ Dx Real-Time PCR Detection System LineGene 9600 Plus SLAN® Real-Time PCR System
Required Detection Channels	FAM, HEX, Cy5
External Quality Assessment	
Regulatory Status	CE IVD

