



GeneProof®

GeneProof Borrelia PCR Kit



HIGH SENSITIVITY

- Secured by targeting the multicopy sequence of the 16S rRNA gene
- 100% diagnostic sensitivity

WIDE RANGE OF VALIDATED CLINICAL MATERIALS

- Plasma, serum, whole blood, CSF, urine and tick

EASY-TO-USE CONCEPT

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

HIGH SPECIFICITY

- 15 *Borrelia burgdorferi sensu lato* strains worldwide
- *Borrelia burgdorferi sensu stricto*
- *Borrelia miyamotoi*

CONTAMINATION PREVENTION

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

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Borrelia PCR Kit

+ GeneProof Borrelia PCR Kit
 + GeneProof Enterovirus PCR Kit
 + GeneProof JC Virus (JCV) PCR Kit

+ GeneProof BK/JC Virus (BK/JC) PCR Kit
 + GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit

+ GeneProof Varicella-Zoster Virus (VZV) PCR Kit

INDICATION	<i>in vitro</i> diagnostic medical device
REGULATORY STATUS	CE IVD
INTENDED USER	For professional use in laboratories with trained staff
TECHNOLOGY	Real-time PCR
TYPE OF ANALYSIS	Qualitative
TARGET SEQUENCE	Gene encoding 16S rRNA
ANALYTICAL SPECIFICITY	<i>Borrelia burgdorferi sensu stricto</i> , <i>B. garinii</i> , <i>B. afzelii</i> , <i>B. andersonii</i> , <i>B. bissetii</i> , <i>B. valaisiana</i> , <i>B. lusitaniae</i> , <i>B. japonica</i> , <i>B. tanukii</i> , <i>B. turdi</i> , <i>B. sinica</i> , <i>B. mayonii</i> , <i>B. spielmanii</i> , <i>B. bavariensis</i> , <i>B. kurtenbachii</i> , <i>B. miyamotoi</i> (<i>Asian genotype</i>), 100 %
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.568 cp/μl (on Amplirun® <i>Borrelia burgdorferi</i> DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	98.15 % (CI _{95%} : 88.82 % - 99.90 %)
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 96.93 % - 100.00 %)
POSITIVE PREDICTIVE VALUE	99.35 % (CI _{95%} : 95.86 % - 99.97 %)
NEGATIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 91.58 % - 100.00 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control
VALIDATED SPECIMEN	CSF, plasma, serum, tick, urine, whole blood (EDTA)
STORAGE	(-20 ± 5) °C
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit
APPLIED INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclers QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™ / StepOne Plus™ Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX/JOE/VIC
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com