



GeneProof Varicella-Zoster Virus (VZV) PCR Kit

In vitro diagnostic medical device

The kit has been manufactured according to the EC Directive 98/79/EC as an *in vitro* diagnostic medical device and it has been designed for professional use in specialized clinical and research laboratories.

KIT CONTENT

Name	VZV/ISEX/025 25 rxn	VZV/ISEX/100 100 rxn
MasterMix		
VZV	1 x750 µl	4 x750 µl
Calibrator		
VZV 10 ⁴ cp/µl	1x200 µl	1x200 µl
Calibrator		
VZV 10 ³ cp/µl	1x200 µl	1x200 µl
Calibrator		
VZV 10 ² cp/µl	1x200 µl	1x200 µl
Calibrator		
VZV 10 ¹ cp/µl	1x200 µl	1x200 µl
Internal Standard		
VZV	1x1000 µl	2x1000 µl

STORAGE AND TRANSPORTATION CONDITIONS

The kit must be transported at a temperature of -20 °C or below. The kit will remain stable at least until the expiry date printed on the package, if the storage temperature is kept (-20 ± 5 °C). Kit is stable after 15 repeated freezing/thawing cycles.

TECHNICAL SPECIFICATION

Target Sequence	specific conservative DNA sequence of the single-copy gene ORF62
Analytical Specificity	Varicella-zoster virus (VZV), 100 %
Analytical Sensitivity (LoD with the probability of 95 %)	113.05 cp/ml (on AcroMetrix VZV High Plasma Control using manual extraction GeneProof PathogenFree DNA Isolation Kit)
Diagnostic Specificity	96.97 % (CI _{95%} : 82.49 % - 99.84 %)
Diagnostic Sensitivity	100 % (CI _{95%} : 96.50 % - 100 %)
Linear Range	10 ¹⁰ – 113.05 cp/ml with precision of ± 0.8 log
Dynamic Range	10 ¹⁰ – 113.05 cp/ml
Metrological Traceability	AcroMetrix VZV High Plasma Control (cat. n. 954514)
Validated Specimen	CSF, plasma, serum, whole blood
Quality Control	regularly tested by QCMD and INSTAND e.V. External Quality Assessment Panels
Regulatory Status	CE IVD

Quality management system is certified in compliance with the requirements of the standard ČSN EN ISO 13485 ed.2:2016.

METHOD PRINCIPLE

The PCR kit is designed for detection of Varicella-zoster virus (VZV) by the real-time Polymerase Chain Reaction (PCR) method. The VZV detection consists in amplification of a specific conservative DNA sequence of the single-copy gene *ORF62* and in the measurement of fluorescence increase. The VZV presence is indicated by the FAM fluorophore fluorescence growth. Internal Standard (IS) positive amplification is detected in the HEX fluorophore fluorescence channel. IS is controlling the possible inhibition of the PCR and the quality of DNA extraction process. The detection kit takes advantage of the "hot start" technology, minimizing non-specific reactions and assuring the maximum sensitivity. A Ready to Use Master Mix contains uracil-DNA-glycosylase (UDG), eliminating possible contamination of the PCR by amplification products. The kit is designed for *in vitro* diagnostics and provides the qualitative and quantitative detection.

USER MANUAL

SAMPLING AND SAMPLE STORAGE

Sampling of all sample types (plasma, serum, cerebrospinal fluid-CSF), except for blood, should be performed into sterile tubes without any transportation media and the samples should be transported within 12 hours at the temperature between +2 °C and +8 °C. Noncoagulating peripheral blood should be sampled into EDTA and transported to the laboratory at the temperature between +2 and +8 °C within 24 hours. In case of longer storage keep all samples frozen at the temperature below -10 °C.

NUCLEIC ACID PURIFICATION

Nucleic acid extraction should be performed by extraction kits available at the market according to protocols for the particular clinical material extraction. The manufacturer recommends the following products:

GeneProof PathogenFree DNA Isolation Kit

croBEE 201A Nucleic Acid Extraction Kit

The Internal Standard (IS) should be added directly into the sample at the beginning of the extraction process so that in the end 1 µl of the resulting elution volume contains 0.1 µl of the IS:

Elution volume	25 µl	50 µl	100 µl	200 µl
Internal Standard	2.5 µl	5 µl	10 µl	20 µl

PCR SETUP

1. Gently vortex and briefly centrifuge the kit components.
2. Add 30 µl of Master Mix into PCR tubes.
3. Add 10 µl of the isolated nucleic acid sample or 10 µl of Calibrator into the individual PCR tubes. The final reaction mix volume will be 40 µl. It is necessary to keep all components at +2 °C to +8 °C during the PCR preparation.
4. Close the tubes, centrifuge shortly, insert them into the device and let them amplify according to the following PCR profile.
Be very careful when handling the Calibrators or the clinical material; incorrect handling could result in contamination and the consequent impairment of the kit components! The manufacturer is not responsible for the kit impairment due to incorrect handling.

AMPLIFICATION PROFILE

Step	Temperature	Time	Data Collection	Cycles
Hold	37 °C	2 min		1
Hold	95 °C	10 min		1
PCR	95 °C	5 s		
	60 °C	40 s	FAM + HEX	45
	72 °C	20 s		

INSTRUMENTS

GeneProof Varicella-Zoster Virus (VZV) PCR Kit is designed for use with real-time devices from various manufacturers:

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
 LightCycler® 2.0 / 480
 LineGene 9600 / 9600 Plus


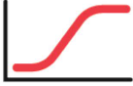



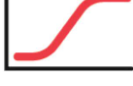




Mic qPCR Cycler

QuantStudio™ 3 / 5 Real-Time PCR System
 Rotor-Gene 3000 / Q
 SLAN® Real-Time PCR System
 StepOne™/StepOne Plus™ Real-Time PCR System

Required channels: FAM, HEX

GeneProof diagnostic kits are continually verified with various types of devices. Current list is available at www.geneproof.com or can be requested at support@geneproof.com.

CLINICAL SAMPLE ANALYSIS EVALUATION

Channel FAM	Channel HEX	Result	Interpretation
		Valid	VZV positive
		Valid	VZV positive
		Ct<38 Valid	VZV negative
		Ct>38 Invalid	
		Invalid	

QUANTITATIVE DETECTION EVALUATION

Use the following formula to calculate the virus concentration in cp/ml for **manual** extraction (using GeneProof PathogenFree DNA Isolation Kit):

$$\text{cp/ml} = \frac{\text{SC} \times \text{EV}}{\text{IV}}$$

SC - Sample concentration (cp/μl)
 EV - Elution volume (μl)
 IV - Isolation volume (ml)

To easily calculate pathogen concentrations using manual or automated extraction, you can use the calculator at www.geneproof.com.

WARNING

A single valid Instruction for Use for a specific kit is included in the package or can be requested for a particular lot from the manufacturer. Use only the combination of components from the specific PCR kit. The kit should be disposed of after use according to the current legal regulations considering the fact that the kit does not contain any dangerous, infectious or toxic components that would be subject to special safety regulations, and the packaging materials are made of paper and polypropylene. If you have any questions, please, contact our Customer care.

Customer care and Technical support

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