

Package insert

GeneProof ESBL PCR Kit



In vitro diagnostic medical device

The kit has been manufactured according to 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

REF	ISIN Version IS included in the MasterMix			ISEX Version IS supplied in a separate tube Nucleic acid isolation and PCR inhibition control		
	ESBL/ISIN/025 25 rxn	ESBL/ISIN/050 50 rxn	ESBL/ISIN/100 100 rxn	ESBL/ISEX/025 25 rxn	ESBL/ISEX/050 50 rxn	ESBL/ISEX/100 100 rxn
MasterMix SHV	1x750 µl	2x750 µl	4x750 µl	1x750 µl	2x750 µl	4x750 µl
MasterMix CTX-M	1x750 µl	2x750 µl	4x750 µl	1x750 µl	2x750 µl	4x750 µl
Positive Control ESBL	1x200 µl	1x200 µl	2x200 µl	1x200 µl	1x200 µl	2x200 µl
Internal Standard ESBL	-	-	-	1x1000 µl	1x1000 µl	2x1000 µl

STORAGE AND TRANSPORTATION CONDITIONS

The kits should be transported and stored at temperatures between -85 °C and -10 °C. The kit will remain stable at least until the expiry date printed on the package, if the storage temperature is kept. Repeated freezing and thawing of the kit components may result in lower detection quality.

TECHNICAL SPECIFICATION

Target sequence	<i>bla_{SHV}</i> and <i>bla_{CTX-M}</i> gene
Specificity	the most frequently occurring polymorphisms resulting in amino acid modification and origin of SHV-ESBL in positions 179, 238 and 240. Clusters CTX-M-1, CTX-M-2, CTX-M-8, CTX-M-9, CTX-M-25
Sensitivity (LOD)	reaches 1.281 copy/µl for CTX MasterMix with 95 % probability reaches 0.365 copy/µl for SHV MasterMix with 95 % probability
Sample Type	endotracheal aspirate
Quality Control	regularly tested by QCMD External Quality Assessment Panel

