Gene

RESULTS RECORD

Clinical Performance Study

GeneProof XXX PCR Kit

Laboratory name	Name Adress Country
Responsible person:	Name

Extraction		
	Investigated device (GeneProof)	**1. Reference CE IVD device / method**
Extraction name		
LOT		
Expiration		
Sample volume (µl)		
Elution volume (µl)		

PCR		
	Investigated device (GeneProof)	**1. Reference CE IVD device / method**
PCR Kit Name		
LOT		
Expiration		
Type of PCR cycler		

In case of discrepancies, the results are verified by third independant diagnostic assay:

PCR	
	2. Reference CE IVD diagnostic assay / method
PCR Kit Name	
LOT	
Expiration	
Type of PCR cycler	

Sample ID	1. Reference device: GeneProof XXX PCR Kit				GeneProof XXX PCR Kit				Clinical material
	PCR date	Result	Ct value FAM	Ct value HEX	PCR date	Result	Ct value FAM	Ct value HEX	
	DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			

N - Negative, P - Positive, NA - Not Available

Sample ID	1. Reference CE IVD device / method				GeneProof XXX PCR Kit				Clinical material
	PCR date	Result	Ct value FAM	Ct value HEX	PCR date	Result	Ct value FAM	Ct value HEX	
	DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			

N - Negative, P - Positive, NA - Not Available

Sample ID	1. Reference CE IVD device / method				GeneProof XXX PCR Kit				Clinical material
	PCR date	Result	Ct value FAM	Ct value HEX	PCR date	Result	Ct value FAM	Ct value HEX	
	DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			

N - Negative, P - Positive, NA - Not Available

Sample ID	1. Reference CE IVD device / m		
	PCR date	Result	Ct value FAM
	DD.MM.YYYY	mutant/heteroz/	

N - Negative, P - Positive, NA - Not Available

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comparision of analysis results fro

Place

Gene

ıethod	GeneProof XXX PCR Kit				Clinical material
Ct value HEX	PCR date	Result	Ct value FAM	Ct value HEX	
ΛT	DD.MM.YYYY	mutant/heteroz/WT			

_____ hereby confirm the impartial
ım both CE IVD diagnostic assays.

Date Stamp and Signature