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		

Sample ID	1. Reference extraction device: croBEE NA16 201, GeneProof XXX PCR Kit			
	PCR date	Result	Ct value FAM	Ct value HEX
	DD.MM.YYYY	mutant/heteroz/WT		

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	

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

ice: CB 2.0 Genomic DNA Exctraction kit				Clinical material	Sample ID	1. Reference extraction device: croBEE NA16 201, GeneProof XXX PCR Kit				ce: CB 2.0 Genomic DNA Exctraction ki			
PCR date	Result	Ct value FAM	Ct value HEX			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			DD.MM.YYY	mutant/heteroz/WT		

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

Clinical material	Sample ID	1. Reference extraction device: croBEE NA16 201, GeneProof XXX PCR				ce: CB 2.0 Genomic DNA Exctraction kit				Clinical material	Sample ID	1. Reference extraction device: NA16 201, GeneProof XXX PC		
		PCR date	Result	Ct value FAM	Ct value HEX	PCR date	Result	Ct value FAM	Ct value HEX			PCR date	Result	Ct value FAM
		DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT					DD.MM.YYYY	mutant/heteroz/\	

											N - Negative, P - Positive, NA - Not Available			
											I _____			
											comparision of analysis results frc			
											Place			

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

croBEE CR Kit	vice: CB 2.0 Genomic DNA Exctraction kit				Clinical material
Ct value HEX	PCR date	Result	Ct value FAM	Ct value HEX	
WT	DD.MM.YYYY	mutant/heteroz/WT			

_____ hereby confirm the impartial
›m both CE IVD diagnostic assays.

Date Stamp and Signature