GeneProof

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:

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

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

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

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GeneProof XXX PCR Kit				Clinical material	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	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

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Sample ID	1. Reference CE IVD device / method				GeneProof XXX PCR Kit				Clinical material	Sample ID	1. Reference CE IVD device / method			
	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.YYYY	mutant/heteroz/WT		

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

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

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

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_ hereby confirm the impartial
h CE IVD diagnostic assays.

Stamp and Signature