

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			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	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
LOT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT		
Expiration																										
Sample volume (µl)																										
Elution volume (µl)																										
PCR																										
Investigated device (GeneProof)			1. Reference CE IVD device / method																							
PCR Kit Name			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	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
LOT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT		
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			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	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
LOT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT			DD.MM.YYYY	mutant/heteroz/WT		
Expiration																										
Type of PCR cycler																										

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

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

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

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

I _____

comparison of analysis results fro

Place

Gene

hereby confirm the impartial
in both CE IVD diagnostic assays.

Date Stamp and Signature