

Bloodborne GPacks



Price beneficial combination of GeneProof PCR kits.

one sample
one extraction
one run



many results

ONE WORKFLOW - MANY RESULTS

1. Hepatitis GPack

Detection of 2 pathogens : **Hepatitis B Virus, Hepatitis C Virus**

REF: HEP/GPACK/100

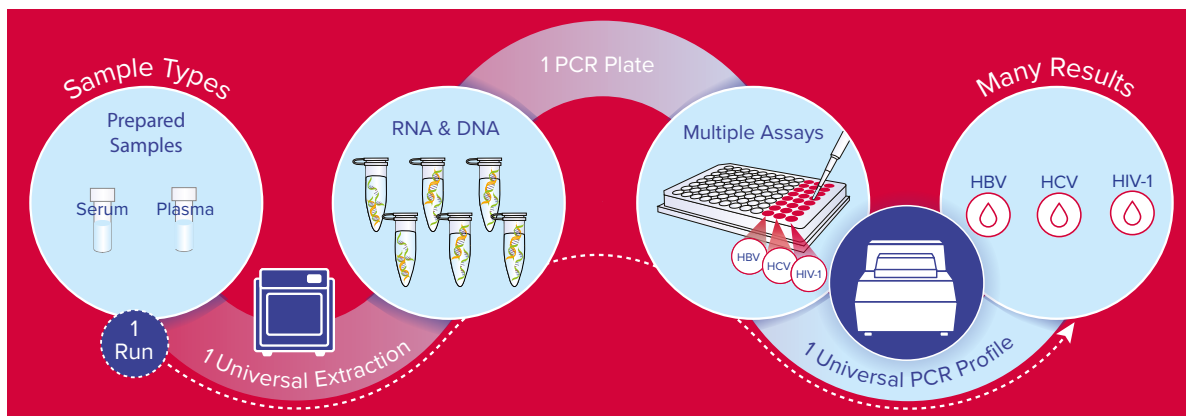
GeneProof Hepatitis B Virus (HBV) PCR Kit, 1x 100 rxn
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit, 1x 100 rxn
GeneProof Universal Internal Control, 1x 100 NAE

2. Bloodborne GPack

Detection of 3 pathogens : **Hepatitis B Virus, Hepatitis C Virus, HIV type 1**

REF: BB/GPACK/100

GeneProof Hepatitis B Virus (HBV) PCR Kit, 1x 100 rxn
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit, 1x 100 rxn
GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit, 1x 100 rxn
GeneProof Universal Internal Control, 1x 100 NAE



UNI PCR PROFILE = ONE WORKFLOW

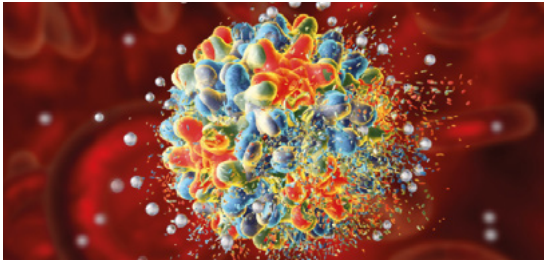
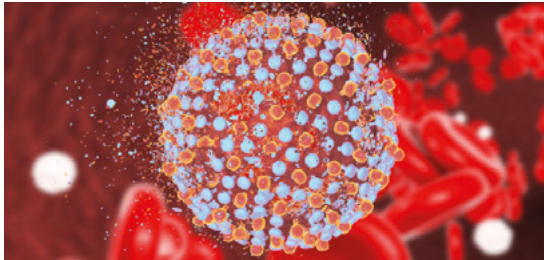
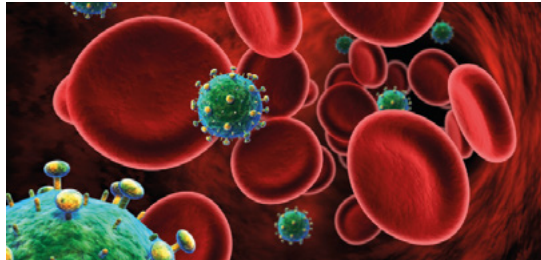


COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TESTS

Bloodborne GPacks

	Hepatitis B Virus PCR Kit	Hepatitis C Virus Diagnostic PCR Kit	HIV type 1 Diagnostic PCR Kit												
															
INDICATION	<i>In vitro</i> diagnostic medical device	<i>In vitro</i> diagnostic medical device	<i>In vitro</i> diagnostic medical device												
REGULATORY STATUS	CE ₁₀₂₃ IVD / EC Directive 98/79/EC	CE ₁₀₂₃ IVD / EC Directive 98/79/EC	CE ₁₀₂₃ IVD / EC Directive 98/79/EC												
INTENDED USER	For professional use in laboratories with trained staff	For professional use in laboratories with trained staff	For professional use in laboratories with trained staff												
TECHNOLOGY	Real-time PCR	Real-time PCR	Real-time PCR												
TYPE OF ANALYSIS	Qualitative and quantitative	Qualitative and quantitative	Qualitative and quantitative												
ANALYTICAL SPECIFICITY	HBV genotype A-H, precore mutants HBV (HBeAg negative), 100 %	HCV genotype 1-8, 100 %	HIV subtypes A – D, AE, F, G, AG-GH, BF, H, K, CRF03_AB, Group N, Group O – 100 %												
ANALYTICAL SENSITIVITY (LoD with probability 95%)	36.9792 IU/ml (on HBV NIBSC 05/148 using GeneProof PathogenFree DNA Isolation Kit) 64.067 IU/ml (on HBV NIBSC 10/266 using croBEE 201A Nucleic Acid Extraction Kit) 13.9 IU/ml (on HBV NIBSC 10/266 using manual extraction SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)	53.505 IU/ml (on HCV NIBSC 14/150 using GeneProof PathogenFree RNA Isolation Kit) 170.062 IU/ml (on HCV NIBSC 14/150 using croBEE 201A Nucleic Acid Extraction System) 33.473 IU/ml (on Acrometrix HCV-S Panel using MagCore Automated NA Extractor) 7.95 IU/ml (on Acrometrix HCV-S Panel using SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)	<table border="1"> <thead> <tr> <th>Sample Processing</th> <th>Plasma</th> <th>Serum</th> </tr> </thead> <tbody> <tr> <td>GeneProof PathogenFree RNA Isolation Kit</td> <td>129.6 IU/ml, tj. 71.3 cp/ml</td> <td>213.5 IU/ml, tj. 117.4 cp/ml</td> </tr> <tr> <td>croBEE 201A Nucleic Acid Extraction Kit</td> <td>404.5 IU/ml, tj. 222.5 cp/ml</td> <td>253.9 IU/ml, tj. 139.65 cp/ml</td> </tr> <tr> <td>MagCore Automated NA Extractor</td> <td>58.8 IU/ml, tj. 32.4 cp/ml</td> <td>70.6 IU/ml, tj. 38.84 cp/ml</td> </tr> </tbody> </table>	Sample Processing	Plasma	Serum	GeneProof PathogenFree RNA Isolation Kit	129.6 IU/ml, tj. 71.3 cp/ml	213.5 IU/ml, tj. 117.4 cp/ml	croBEE 201A Nucleic Acid Extraction Kit	404.5 IU/ml, tj. 222.5 cp/ml	253.9 IU/ml, tj. 139.65 cp/ml	MagCore Automated NA Extractor	58.8 IU/ml, tj. 32.4 cp/ml	70.6 IU/ml, tj. 38.84 cp/ml
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DIAGNOSTIC SPECIFICITY	100 % (CI _{95%} : 99.06 % – 100 %)	100 % (CI _{95%} : 99.07 % – 100 %)	100 % (CI _{95%} : 99.05 % – 100 %)												
DIAGNOSTIC SENSITIVITY	100 % (CI _{95%} : 95.90 % – 100 %)	100 % (CI _{95%} : 95.39 % – 100 %)	95,41 % (CI _{95%} : 89.10 % – 98.30 %)												
REPORTING UNITS	IU/ml	IU/ml	IU/ml												
METROLOGICAL TRACEABILITY	4 th HBV International Standard NIBSC 10/266	5 th HCV International Standard NIBSC 14/150	4 th HIV-1 International Standard NIBSC 16/194												
VALIDATED SPECIMEN	Plasma, serum	Plasma (EDTA, citrate), serum	Plasma (EDTA, citrate), serum												

GeneProof a.s. Manufacturer and Global Distribution

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