

List of Correction Factors IVDD

Manufacturer

GeneProof a.s.,

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The correction factor (CF) is mathematically determined number for correction of quantification under different conditions (e.g. different extraction, biological material).

Extraction: GeneProof PathogenFree DNA Isolation Kit

PCR Kit	Correction factor (CF) in log						
	Whole Blood	Plasma	Urine	CSF	Serum	Aspirate	BAL
GeneProof Adenovirus PCR Kit	0	0	0	NA	NA	0	NA
GeneProof BK/JC Virus (BK/JC) PCR Kit_JCV (FAM)	0	0	0	0	NA	NA	NA
GeneProof BK/JC Virus (BK/JC) PCR Kit_BKV (Cy5)	0	0	0	0	NA	NA	NA
GeneProof Cytomegalovirus (CMV) PCR Kit	0	0	0	0	0	NA	NA
GeneProof Epstein-Barr Virus (EBV) PCR Kit	0	0	NA	0	NA	NA	0
GeneProof Hepatitis B Virus (HBV) PCR Kit	NA	0	NA	NA	0	NA	NA
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit_HSV-1 (FAM)*	-0.3	-0.3	-0.3	-0.3	-0.3	NA	NA
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit_HSV-2 (Cy5)*	0	0	0	0	0	NA	NA
GeneProof JC Virus (JCV) PCR Kit	0	0	0	0	NA	NA	NA
GeneProof Parvovirus B19 PCR Kit	0	0	NA	NA	NA	NA	NA
GeneProof Varicella-Zoster Virus (VZV) PCR Kit	0	0	NA	0	0	NA	NA

Extraction: GeneProof PathogenFree RNA Isolation Kit

PCR Kit	Correction factor (CF) in log						
	Whole Blood	Plasma	Urine	CSF	Serum	Aspirate	BAL
GeneProof Enterovirus PCR Kit	NA	NA	NA	0	NA	NA	NA
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit	NA	0	NA	NA	0	NA	NA
GeneProof HIV type 1 (HIV-1) Diagnostic PCR kit	NA	0	NA	NA	0	NA	NA

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Extraction: croBEE 201A Nucleic Acid Extraction Kit

PCR Kit	Correction factor (CF) in log						
	Whole Blood	Plasma	Urine	CSF	Serum	Aspirate	BAL
GeneProof Adenovirus PCR Kit	0.5	0.5	0.5	NA	NA	0.5	NA
GeneProof BK/JC Virus (BK/JC) PCR Kit_JCV (FAM)	0.3	0.5	0.6	0.5	NA	NA	NA
GeneProof BK/JC Virus (BK/JC) PCR Kit_BKV (Cy5)	0.9	0.5	0.6	0.5	NA	NA	NA
GeneProof Cytomegalovirus (CMV) PCR Kit	0.5	0.4	0.7	0.5	0.5	NA	NA
GeneProof Enterovirus PCR Kit	NA	NA	NA	0	NA	NA	NA
GeneProof Epstein-Barr Virus (EBV) PCR Kit	0.6	0.5	NA	0.5	NA	NA	0.5
GeneProof Hepatitis B Virus (HBV) PCR Kit	NA	0.35	NA	NA	0.5	NA	NA
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit	NA	0.5	NA	NA	0.2	NA	NA
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit_HSV-1 (FAM)*	0.4	0.2	0.2	0.2	0.2	NA	NA
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit_HSV-2 (Cy5)*	0.7	0.5	0.5	0.5	0.5	NA	NA
GeneProof HIV type 1 (HIV-1) Diagnostic PCR kit	NA	0	NA	NA	0	NA	NA
GeneProof JC Virus (JCV) PCR Kit	0	0.25	1.0	0.25	NA	NA	NA
GeneProof Parvovirus B19 PCR Kit	0.3	0.3	NA	NA	NA	NA	NA
GeneProof Varicella-Zoster Virus (VZV) PCR Kit	0	0.4	NA	0	0.5	NA	NA

Extraction: myCROBE/croBEE 2.0 Universal Extraction Kit

PCR Kit	Correction factor (CF) in log				
	Whole Blood	Plasma	Urine	CSF	Serum
GeneProof Cytomegalovirus (CMV) PCR Kit	0	0.7	0.3	0.5	0.5
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit_HSV-1 (FAM)*	0.2	0.4	0.5	0.5	0.3
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit_HSV-2 (Cy5)*	0.5	0.7	0.8	0.8	0.6
GeneProof Varicella-Zoster Virus (VZV) PCR Kit	0	0.5	NA	0.5	0.5

Extraction: MagCore® Viral Nucleic Acid Large Volume Extraction Kit (1.2 ml)

PCR Kit	Correction factor (CF) in log				
	Whole Blood	Plasma	Urine	CSF	Serum
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit	NA	0.0	NA	NA	0.3
GeneProof HIV type 1 (HIV-1) Diagnostic PCR kit	NA	0.0	NA	NA	0.0

NA Not applicable (not validated material or material for qualitative detection only)

* For GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit correction factor for different quantification between channels (in IFU listed as CF1 and CF2) is also included

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Use the following formula to calculate the viral load (choose formula according required form of result):

VLC – Viral load concentration [IU/ml or cp/ml, according to the PCR kit]

SC - Sample concentration [IU/ml or cp/ml, according to the PCR kit]

EV - Elution volume [μl]

IV - Isolation volume [μl]

CF - Correction factor

$$VLC = \left(\frac{SC \times EV \times 10^3}{IV} \right) \times (10^{CF})$$

$$\log(VLC) = \log \left(\frac{SC \times EV \times 10^3}{IV} \right) + CF$$

Brno on 03-12-2025



Mgr. Petra ŠVÁSTOVÁ

Research and Development \ Device Characterization

Head of Device Characterization

(Name, position and signature of authorized person)

Manufacturer's stamp:

