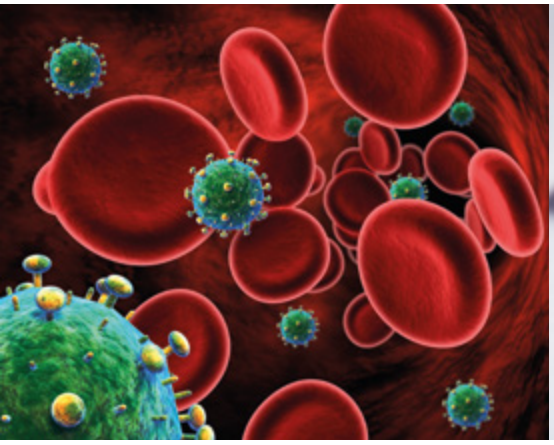
Clinical Performance of GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit

Koldínská Z.[1], Le Duff Y.[2], Boboková A.[1], Jansová E.[1]

1 GeneProof, Brno, Czech Republic **2** National Institute for Biological Standards and Control, South Mimms, United Kingdom

Bloodborne Infections



INTRODUCTION

HIV is one of the most serious global public health issues. An estimated 1.5 million individuals worldwide acquired HIV, and 680 000 died from AIDS-related illnesses in 2020. According to the published guidelines by FDA and CDC, nucleic acid tests directly detecting HIV must be used to diagnose HIV infection in infants and children younger than 18 months with perinatal or postnatal HIV exposure which diagnosis cannot be established by conventional antibody tests and HIV RNA PCR assays represent gold standard for diagnosis. Regarding safety health regulation, all tests for HIV should demonstrate the highest possible standard of clinical performance relative to the intended purpose of the test.

AIM

The aim of the study was to evaluate clinical performance characteristic of GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit intended for diagnosis of HIV-1 virus from clinical samples. The clinical validation was performed on 609 samples in total, 109 samples HIV-1 positive and 500 samples negative.

METHOD

HIV positivity of 109 plasma samples was confirmed at the Centre for AIDS Reagents (CFAR) using Cobas Ampliprep/Cobas Taqman HIV-1 Test, v2.0 (Roche). The samples were provided to GeneProof to be tested using GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit. Clinically HIV negative plasma previously tested for HIV, HCV and HBV negativity by University Hospital Brno were used to set diagnostic specificity of negative samples by GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit. The extraction of samples was done by GeneProof PathogenFree RNA Isolation Kit and croBEE NA16 Nucleic Acid Extraction System.

RESULTS

The statistical evaluation of results demonstrated 95.41% diagnostic sensitivity and 100% positive predictive value of GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit compared to samples diagnosed by Cobas Ampliprep/Cobas Taqman HIV-1 Test, v2. 0.

The test of diagnostic specificity demonstrated 100% diagnostic specificity of GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit compared to samples diagnosed by ELECSYS HIV Combi PT and Cobas TaqScreen MPX Test V.2. 0. All 500 plasma samples were determined as negative by both assays. False negativity was controlled by positive internal control in all samples.

EVALUATION OF TOTAL DIAGNOSTIC SENSITIVITY

		Cobas Ampliprep/ Cobas Taqman HIV-1 Test, v2.0		
		Positive	**Negative**	**Total**
GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit	**Positive**	104	0	104
	Negative	5	0	5
	Total	109	0	109

	GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit	
	Results (%)	**95% CI (%)**
Diagnostic sensitivity	95.41	89.1–98.3
Positive predictive value	100	95.56–100

EVALUATION OF TOTAL DIAGNOSTIC SPECIFICITY

		ELECSYS HIV Combi PT and Cobas TaqScreen MPX Test V.2. 0.		
		Positive	**Negative**	**Total**
GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit	**Po sitive**	0	0	0
	Negative	0	500	500
	Total	0	500	500

	GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit	
	Results (%)	**95% CI (%)**
Diagnostic Specificity	100	99.05–100
Negative predictive value	100	99.05–100

CONCLUSION

The results of clinical performance study **demonstrate very good diagnostic parameters** of the GeneProof assay. GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit have proved to be a convenient diagnostic tool for HIV-1 testing.

CONTACT

Zuzana Koldínská
zuzana.koldinska@geneproof.com