

CERTIFICATE

Survey of 31 March 2023

You have fulfilled the requirements of the External Quality Assessment with the following analysis

Virus Genome Detection - Hepatitis B Virus Program 1 (361):

Validity 12 months:

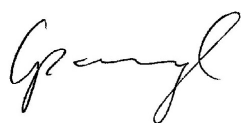
HBV (DNA) - quantitative (R: B3)

HBV (DNA) - qualitative (R: B3)

(R) analysis is subject to the RiliBÄK

Participant:
29506
GeneProof a.s.
GeneProof a.s.
Videnska 101/119
61900 Brno

Düsseldorf, 04 May 2023



Prof. Dr. med. Michael Spannagl
(Head of Reference Institution)



Prof. Dr. rer. nat. Heinz Zeichhardt
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 31 March 2023

You have participated in the External Quality Assessment with the following analysis

Virus Genome Detection - Hepatitis B Virus Program 1 (361):

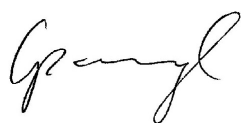
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Prof. Dr. rer. nat. Heinz Zeichhardt
(Adviser)

Listing and evaluation of the results

29506: GeneProof a.s.
GeneProof a.s.

Survey of 31 March 2023

Adviser: Prof. Dr. rer. nat. Heinz Zeichhardt
 Institut für Qualitätssicherung in der
 Virusdiagnostik - IQVD
 Potsdamer Chaussee 80
 14129 Berlin

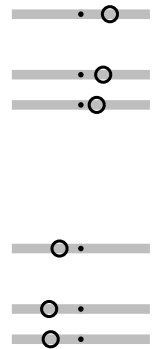
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361

Virus Genome Detection - Hepatitis B Virus Program 1

HBV (DNA) - quantitative +

Name of test	Unit	Method	Manufacturer				
HBV PCR Kit	IU/ml	PCR / NAT (395)	GENEPROOF (GP)				
Result (quant)	Sample	Your value	Lower limit	Upper limit	TV-Type	Target value	Meets criteria
	361-230314-01	5300	738	11692	SV	2937	+
	361-230314-02	0.000	0.000	0.000	SV	0.000	+
	361-230314-03	13708	2188	34675	SV	8710	+
	361-230314-04	1390	253	4013	SV	1008	+
Name of test	Unit	Method	Manufacturer				
HBV PCR Kit	IU/ml	PCR / NAT (395)	GENEPROOF (GP)				
Result (quant)	Sample	Your value	Lower limit	Upper limit	TV-Type	Target value	Meets criteria
	361-230314-01	1905	738	11692	SV	2937	+
	361-230314-02	0.000	0.000	0.000	SV	0.000	+
	361-230314-03	4575	2188	34675	SV	8710	+
	361-230314-04	546	253	4013	SV	1008	+



HBV (DNA) - qualitative +

Name of test	Unit	Method	Manufacturer				
HBV PCR Kit		PCR / NAT (395)	GENEPROOF (GP)				
Result (qual)	Sample	Your specification(s)	Correct specification(s)		TV-Type		Meets criteria
	361-230314-01	positive (3)	positive (3)		SV		+
	361-230314-02	below detection limit/negative (1)	below detection limit/negative (1)		SV		+
	361-230314-03	positive (3)	positive (3)		SV		+
	361-230314-04	positive (3)	positive (3)		SV		+
Name of test	Unit	Method	Manufacturer				
HBV PCR Kit		PCR / NAT (395)	GENEPROOF (GP)				
Result (qual)	Sample	Your specification(s)	Correct specification(s)		TV-Type		Meets criteria
	361-230314-01	positive (3)	positive (3)		SV		+
	361-230314-02	below detection limit/negative (1)	below detection limit/negative (1)		SV		+
	361-230314-03	positive (3)	positive (3)		SV		+
	361-230314-04	positive (3)	positive (3)		SV		+