

RoboGene[®] HBV DNA Quantification Kit

Pathogen Detection | Quantification by real-time PCR



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Intended use

The RoboGene® HBV DNA Quantification Kit is intended for real-time PCR quantification of Hepatitis B Virus (HBV) DNA in human EDTA plasma or serum samples. HBV is an organism which infects the liver of humans, causes an inflammation called hepatitis, proliferates in liver cells and destroys them. Chronic carriers are at high risk of long term health complications including liver cirrhosis and cancer. The level of HBV DNA in plasma or serum can be used in conjunction with other clinical markers and clinical findings to distinguish between acute and chronic HBV infection and to assess the viral response to antiviral treatment. The quantification kit is not intended for screening of blood or blood products for HBV DNA or for confirmation of a HBV infection.

Kit contents and recommended DNA purification kits

Lyophilized reagent mix¹ containing HBV and Internal control DNA (IC) specific primers, probes and dNTPs, PCR vessels stably coated with synthetic HBV standard DNA² (ready-to-use reference curves) or amplification enhancer (sample vessels), stabilized IC DNA contained in the nucleic acids extraction tubes³, extra reagent to run up to 32 quantification standards. The RoboGene® HBV DNA Quantification Kit is validated together with the INSTANT Virus DNA Kit (AJ Innuscreen, Cat.No. 845-KS-4150050) and the QIAamp DSP Virus Kit (Qiagen, Cat.No. 60704).

Performance assessment

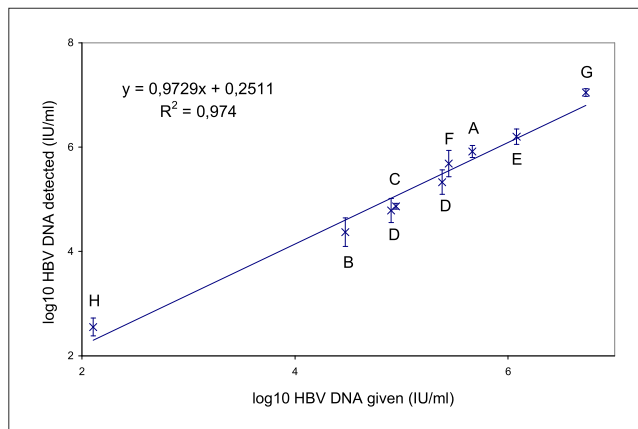
The RoboGene® HBV DNA Quantification Kit was evaluated according to the common technical specifications (CTS) for in vitro diagnostic medical devices (2009/108/EC).

Assessment criterion	Sample type/purification	Assessment criterion
Analytical sensitivity	Synthetic HBV DNA INSTANT QIAamp DSP	≥ 5 copies/run 50 IU/ml 17 IU/ml
Linear range	Synthetic HBV DNA INSTANT QIAamp DSP	9 logs >5 logs 6 logs
Recovery rate	Synthetic HBV DNA INSTANT	100% over 6 logs 92% over >4 logs
Genotype recognition	INSTANT	Genotyp A, B, C, D, E, F, G, H; linearity over 2-6 logs
Analytical specificity	INSTANT	100%
Diagnostic specificity	INSTANT	100%
Robustness: failure rate of the system	INSTANT	0%
Serum/ plasma equivalence	INSTANT	99%

■ ¹⁻³ on demand available also as single component reagents & consumables

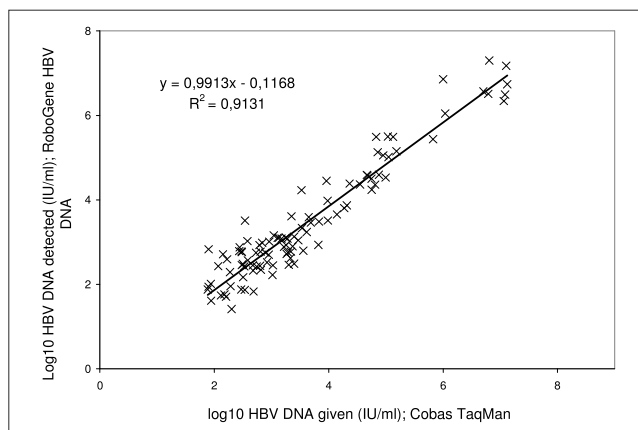
Ordering information

Kit version for	ABI PRISM 7000/7300	Rotor-Gene 3000/6000	7500 Fast CFX96	Smart Cycler RUO	Spartan Dx-12 RUO
Cat.No. 100 tests	0207300102	0207300142	0207300162	0207300152	0207300172
Cat.No. 50 tests	0207300104	0207300144	0207300164	0207300154	0207300174



Quantitative detection of relevant HBV genotypes.

The RoboGene® HBV DNA Quantification Kit allows correct detection of all tested genotypes as measured on Rotor-Gene 3000. The linearity of the assay was given by inclusion of all genotype samples as determined by a linear regression of the log₁₀ calculated with the log₁₀ nominal concentrations. The equation of the respective regression lines is included in the figure.



Diagnostic evaluation: comparison of the RoboGene® HBV DNA Quantification Kit (sample purification with the INSTANT Virus DNA Kit) with the the Cobas TaqMan HBV kit.

The correlation of quantitative results from both tests (n=101) was analyzed by linear regression. The equation of the respective regression lines is included in the figure.