

## Product specification affigene® HBV trender

### Technical specification

<b>Code No</b>	71000939 (48 tests)
<b>Intended use</b>	Monitoring of Hepatitis B virus (HBV) DNA in clinical samples
<b>Regulatory status</b>	CE labelled according to IVD Directive 98/79/EC Annex II List A for the complete process from sample preparation to result
<b>Total kit size</b>	48 determinations
<b>Flexible run size</b>	8-48 determinations per run (5-45 clinical samples)
<b>Ready to use</b>	All reagents provided in a ready-to-use format
<b>Compatible profiles</b>	Compatible profiles with other affigene® trender/ tracer assays enabling multitarget runs
<b>Contamination prevention</b>	UDG technology, Single-use reagents
<b>Prev. of false neg. results</b>	Internal Control introduced during sample preparation
<b>Software provided</b>	Results reported by the affigene® analysis software
<b>Sample</b>	Plasma (ACD, EDTA) and Serum
<b>PCR instrument compatibility</b>	Validated according to CE/IVD standards for: Mx3000P/Mx3005P (Agilent/Stratagene) iCycler iQ/iQ5 (BioRad) Rotor-Gene 3000/6000 (Qiagen/Corbett Research) ABI 7300 (Applied Biosystems)
<b>Sample preparation compatibility</b>	Validated according to CE/IVD-standards for: affigene® DNA extraction (Cepheid AB) NucliSens easyMAG (bioMérieux)

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### Performance characteristics

**Dynamic range** ~ 3 -1x10<sup>8</sup> IU/ml  
~ 20 -1x10<sup>9</sup> copies/ml

**Limit of Detection (LOD)** Using affigene® DNA extraction:  
1000 µl protocol:  
3.3 IU/ml (95% confidence interval:2.4-13 IU/ml)  
23 copies/ ml (95% confidence interval:16-87 copies/ml)  
200 µl protocol:  
51 IU/ml (95% confidence interval: 21-151 IU/ml)  
342 copies/ml (95% confidence interval:141-1012 copies/ml)  
Using easyMAG: 500 µl protocol:  
62 IU/ml (95% confidence interval: 38-135 copies/ml) or  
416 copies/ml (95% confidence interval:255-905 copies/ml)

**Quantitative range** Using affigene® DNA extraction:  
172 - 1.72x10<sup>8</sup> IU/ml  
1152 - 1.15x10<sup>9</sup> copies/ml  
Using easyMAG:  
100 - 1.72x10<sup>8</sup> IU/ml  
670 - 1.15x10<sup>9</sup> copies/ml

**Precision** ≤ 0.25 log<sub>10</sub> throughout the quantitative range. Determined with different lots, different operators at different test occasions.

**Subtype Inclusivity** Equal sensitivity, specificity and amplification efficiency for HBV subtypes A-H.

**Exclusivity and Microorganism Interference** No cross-reactivity with CMV, EBV, VZV, HSV-1, and -2, HHV-6 A and B, HHV-7, HHV-8, other DNA and RNA viruses, human DNA, bacterial or fungal DNA.