

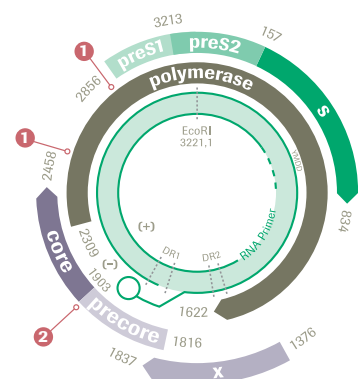
cobas[®] HBV

Better information for patient management

cobas[®] HBV, test for use on the cobas[®] 4800 System provides robust, clinically relevant assay performance with a broad linear range and high sensitivity. cobas[®] HBV delivers optimal results throughout critical medical decision points and across all genotypes combined with a highly efficient laboratory workflow.

cobas[®] HBV offers:

- Broad coverage of all known HBV genotypes (A-H) including pre-core mutations
- Tight precision at medically relevant decision points
- Excellent performance with serum and plasma specimens
- Built-in contamination control with AmpErase enzyme to prevent carryover contamination
- Excellent correlation to Roche COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HBV Test, v2.0



- 1 Approximate location of mutations
- 2 Approximate location of primer and probe binding sites

Roche primers and probes target the highly conserved pre-core and core regions of the HBV genome. The amplified region of the genome will not be affected by mutations that arise due to drug resistance.²

Limit of detection for Genotype A in EDTA plasma (400 µL) using the WHO international standard and PROBIT analysis

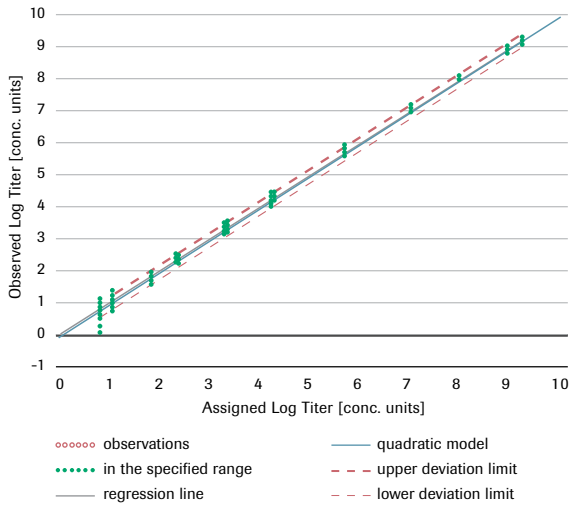
Input titer concentration (HBV DNA IU/mL)	Number of valid replicates	Number of positives	Hit rate
25.0	126	126	100%
15.0	126	126	100%
10.0	126	126	100%
5.0	126	122	96.8%
2.0	125	94	75.2%
0.5	126	38	30.2%
0.0	36	0	0.0%
LoD by PROBIT at 95% hit rate		4.4 IU/mL 95% confidence range: 3.6 – 5.7 IU/mL	

1 EASL clinical practice guidelines: Management of chronic hepatitis B virus infection. Journal of hepatology, 2012. 57(1)

2 Hunt, C.M., et al., Clinical relevance of hepatitis B viral mutations. Hepatology, 2000. 31(5): p. 1037-44

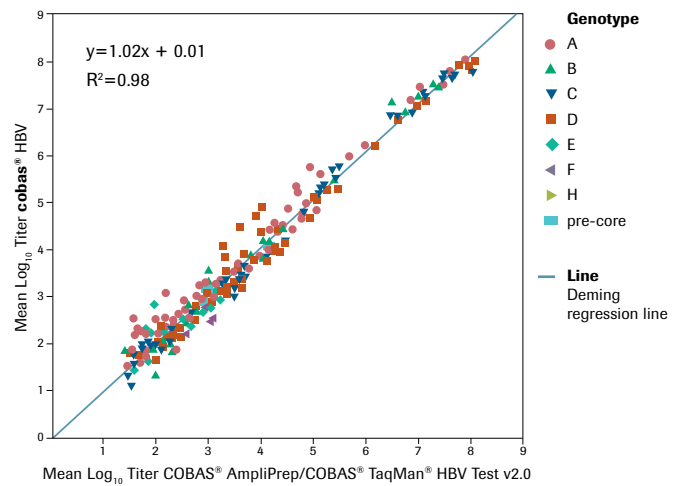


Linearity for cobas® HBV (400 µL EDTA plasma)



Broad linear range of **cobas**® HBV (10 - 1.0E+09 IU/mL) ensures sensitive viral load results and decreases the need for dilution

Correlation (400 µL EDTA plasma)



Excellent correlation of **cobas**® HBV and the COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0

Amplifying the potential of HBV DNA testing

Roche has been at the forefront of viral load monitoring tests for Hepatitis B and continues to provide a robust assay design to ensure accurate and reliable results to improve patient management and treatment success.

cobas® HBV performance summary

Parameter	Performance
Sample type	EDTA plasma, serum
Minimum amount of sample required	Please refer to the cobas ® 4800 Systems Operator's Manual for cobas ® HBV
Sample processing volume	400 µL or 200 µL
Analytical sensitivity	EDTA plasma: 4.4 IU/mL (400 µL) 7.6 IU/mL (200 µL) Serum: 2.8 IU/mL (400 µL) 5.5 IU/mL (200 µL)
Linear range	400 µL: 10.0 IU/mL - 1.0E+09 IU/mL 200 µL: 10.0 IU/mL - 1.0E+09 IU/mL
Specificity	100.0% (one-sided 95% confidence interval: 99.5%)
Genotypes detected	HBV genotypes A-H, precore mutant
Cross Contamination	0.0% (one-sided 95% confidence interval of 1.3%)

cobas® HBV ordering information

Material number	Product name	Package size (120 (10×12) tests)
06979564190	cobas ® HBV	120 tests

Comprehensive menu for viral load testing

- cobas**® HIV-1*
- cobas**® HBV*
- cobas**® HCV*
- cobas**® HCV Genotyping*

*For use with the **cobas**® 4800 Systems

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