

cobas[®] HBV

Better information for patient management

The **cobas[®]** HBV test for use on the **cobas[®]** 6800/8800 Systems 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

Highly optimized primer-probe selection

HBV DNA detection and viral load measurement are essential for the diagnosis, decision to treat and subsequent monitoring of patients.¹

Roche primers and probes target the highly conserved pre-core and core regions of the HBV genome.

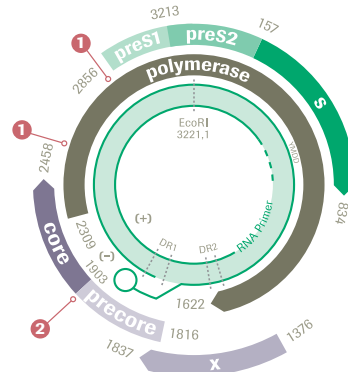
The amplified region of the genome will not be affected by mutations that arise due to drug resistance.²

cobas[®] HBV limit of detection (500 µL)

Genotype	EDTA plasma (IU/mL)	Serum (IU/mL)
A	2.7	2.4
B	3.45	3.3
C	4.13	3.34
D	4.52	2.59
E	3.21	2.67
F	1.87	1.98
G	2.49	2.07
H	6.55	3.48
Pre-Core Mutant	2.38	1.65

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

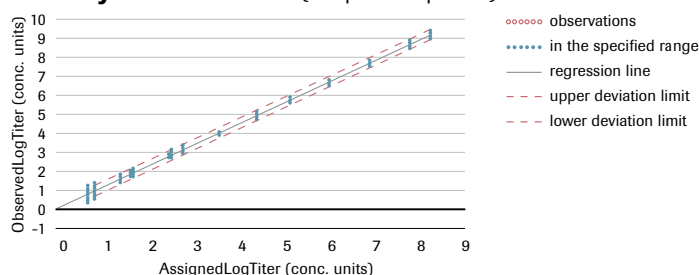


- 1 Approximate location of mutations
- 2 Approximate location of primer and probe binding sites



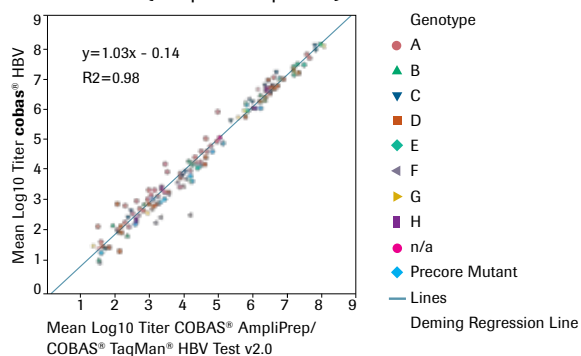
Broad linear range of **cobas**[®] HBV (10 – 1.0E+09 IU/mL) ensures sensitive viral load results and decreases the need for dilution.

Linearity for **cobas**[®] HBV (500 µL EDTA plasma)



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

Correlation (500 µL EDTA plasma)



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	650 µL or 350 µL	
Sample processing volume	500 µL or 200 µL*	
Analytical sensitivity (LoD by hit rate of ≥95%)	500 µL	200 µL
EDTA plasma (IU/mL)	2.7	15.5
Serum (IU/mL)	2.4	12.5
Linear range (IU/mL)	500 µL: 10 – 1.0E+09 IU/mL 200 µL: 25 – 1.0E+09 IU/mL	
Specificity	100% (one-sided 95% confidence interval: 99.5%)	
Genotypes detected	HBV Genotype A-H, and predominant precore mutant	

cobas[®] HBV ordering information

Material number	Product name	Tests per unit (cassette/bottle)
07000979190	cobas [®] HBV	96
06997767190	cobas [®] HBV/HCV/HIV control kit	8 runs
07002220190	cobas [®] NHP negative control kit	16 runs

Comprehensive menu for viral load testing

cobas[®] HIV-1*
cobas[®] HBV*
cobas[®] HCV*
cobas[®] CMV*

*200 µL processing volume not commercially available in the United States

*For use with the **cobas**[®] 6800/8800 Systems