



Abbott RealTime HBV

The Abbott RealTime HBV is an in vitro polymerase chain reaction (PCR) assay for the quantitation of Hepatitis B Virus (HBV) DNA in human plasma or serum from HBV-infected individuals. The Abbott RealTime HBV assay is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis and for use as an aid in assessing viral response to antiviral treatment as measured by changes in plasma or serum HBV DNA levels.

Development Philosophy

Today's clinical molecular diagnostics laboratory must have confidence in the quality of HBV patient results. As a result of our real-time PCR development philosophy, Abbott RealTime HBV is engineered to quantify all HBV genotypes A–H.

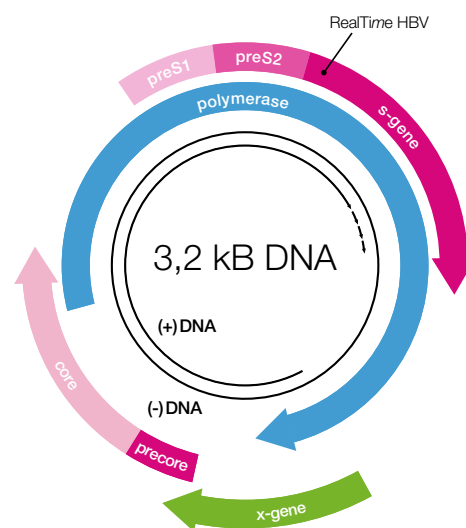
Critical Target Region Selection

The selection of a highly conserved region within the Surface gene provides for the accurate detection of genotypes A–H.

The location of the target region in the N terminal third of the Surface gene ensures that the assay is not impacted by YMDD mutants, HBsAg escape mutants, or drug-resistant mutants, as this region is essential for the assembly and secretion of subviral particles, and tolerates only minor structural changes.

Hepatitis B Virus Genome and Target Region

Primers and probe are targeted within an essential segment of the surface gene.



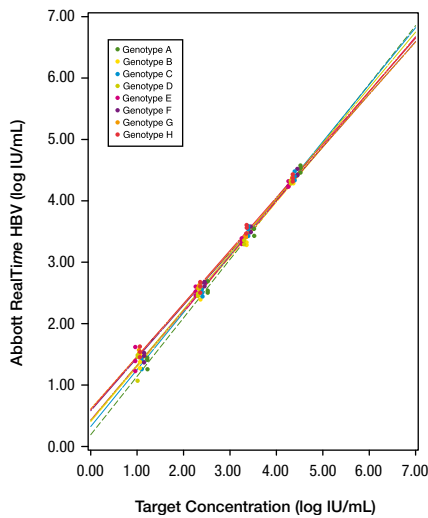
Abbott RealTime HBV Performance*

Sensitivity	10 IU/mL for 0.5 mL input, 15 IU/mL for 0.2 mL input
Linear Range	10 IU/mL (1.00 log IU/mL) to 1 billion IU/mL (9.00 log IU/mL)
Precision	Inter-assay SD \leq 0.25 log IU/mL
Specificity	> 99.5 % [†]
Genotype Detection	Equal quantitation of genotype A, B, C, D, E, F, G, H
Specimen Type	Serum (collected in serum separator tubes), and Plasma (EDTA, ACD and plasma preparation tubes)
Standardization	World Health Organization (WHO) International Standard for Hepatitis B Virus DNA (97/746)
Internal Control	Added to lysis buffer during extraction and detected at all levels

* Performance data shown from internal verification. The Abbott RealTime HBV assay is not intended for use as a screening test for HBV or as a diagnostic test to confirm the presence of HBV infection.

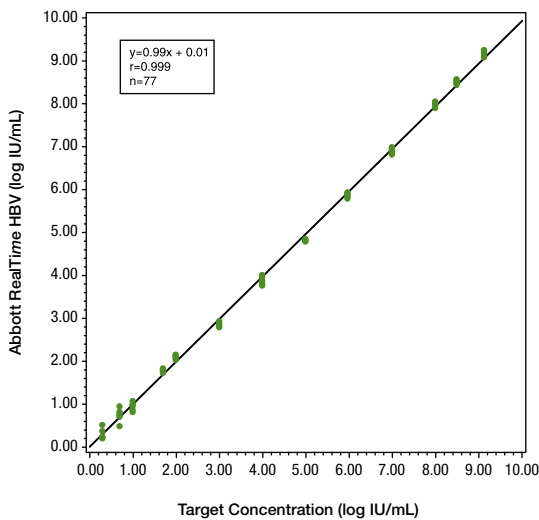
[†] The specificity of the RealTime HBV assay was evaluated by testing 59 HBV seronegative serum and 58 HBV seronegative plasma specimens.

Detection and Quantitation of HBV Genotypes*

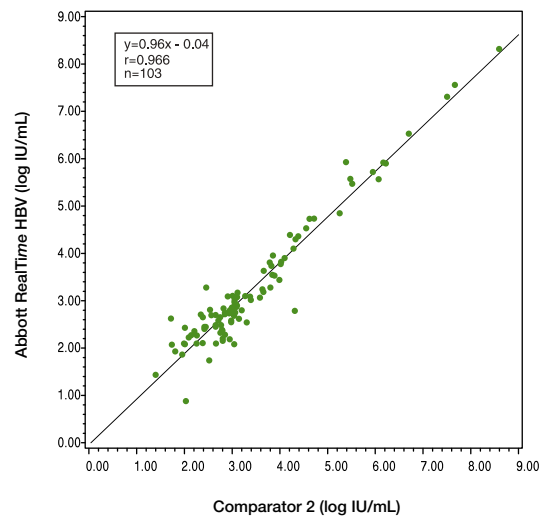


Genotype dilution linearity was demonstrated by diluting eight specimens, one of each genotype A through H, to target concentrations of 4.47 log IU/mL, 3.47 log IU/mL, 2.47 log IU/mL, and 1.17 log IU/mL. Three replicates were tested at each concentration for each genotype. The correlation coefficients ranged from 0.995 to 0.999.

Linear Range*



Correlation*



Specimens from 106 HBV positive patients were tested with the RealTime HBV assay and a comparator assay (Comparator 2). Three samples were above the comparator assay's upper limit of detection and were excluded from the correlation.

The upper limit of quantitation (ULQ) for the Abbott RealTime HBV assay is 1 billion IU/mL and the lower limit of quantitation is equivalent to LOD (10 IU/mL for the 0.5 mL sample preparation procedure, 15 IU/mL for the 0.2 mL sample preparation procedure).

A 13-member panel prepared by diluting an HBV positive specimen targeted from 9.13 log IU/mL to 0.29 log IU/mL in HBV negative human plasma was tested. Six replicates of each panel member were tested (3 replicates per run, 2 runs total).

The RealTime HBV assay was shown to be linear in plasma across the range of HBV DNA concentrations tested.

Ordering Information

Product	List Number	Configuration
Abbott RealTime HBV Amplification Reagent Kit	2G34-90	96 Assays (4 packs x 24 assays)
Abbott RealTime HBV Control Kit	2G34-80	8 Low Positive, 8 High Positive, 8 Negative
Abbott RealTime HBV Calibrator Kit	2G34-70	12 Cal A, 12 Cal B (4 Complete Calibration Sets)
Abbott RealTime HBV Application CD-ROM	8L35	1 each

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* Source: Abbott RealTime HBV Instructions for Use

