What's in your assay?

RNA may distort

Roche cobas® HBV

Unlike others, the Roche **cobas®** HBV only amplifies DNA to deliver an accurate viral load result.

A new study demonstrates that HBV test platforms are not interchangeable. If your HBV DNA assay amplifies RNA to measure viral loads, it could be over-quantifying. This can lead to the mis-classification of treatment responses and unnecessary clinical interventions due to perceived treatment failure. Clinicians may question a patient's diligence to take their medications, order resistance testing, and potentially start costly and disruptive treatment changes that could be associated with increased toxicity.

Maasoumy et. al. Hepatology Communications 2020. https://aasldpubs.onlinelibrary.wiley.com/doi/full/10.1002/hep4.1520. Access 26June2020.

The aim of HBV treatment with nucleot(s)ide analogs (NAs) is complete HBV DNA suppression and treatment guidelines recommend monitoring HBV DNA viral loads. An accurate read-out of HBV DNA viral load is essential for reliable monitoring of treatment responses. A recent study compared real time PCR and transcription mediated amplification technologies for HBV DNA quantification to determine whether any significant differences existed between the two and to evaluate the potential impact of the type of test on clinical decision-making.

The viral loads from all tests were concordant at baseline (week 1). However, at week 12 of therapy, the mean results begin to diverge and were significantly different across tests. The cobas RT and Hologic mean results were comparable from weeks 24 to 96, but were significantly higher than the cobas viral loads. The cobas mean results were comparable to the reference HPS test.

The difference observed between viral load results of cobas vs cobas RT and Hologic is due to the presence of HBV RNA in the plasma of subjects undergoing NAs treatment. The data suggest cobas is specific for DNA, while the Hologic and cobas RT tests lack specificity for HBV DNA with concurrent amplification of RNA.

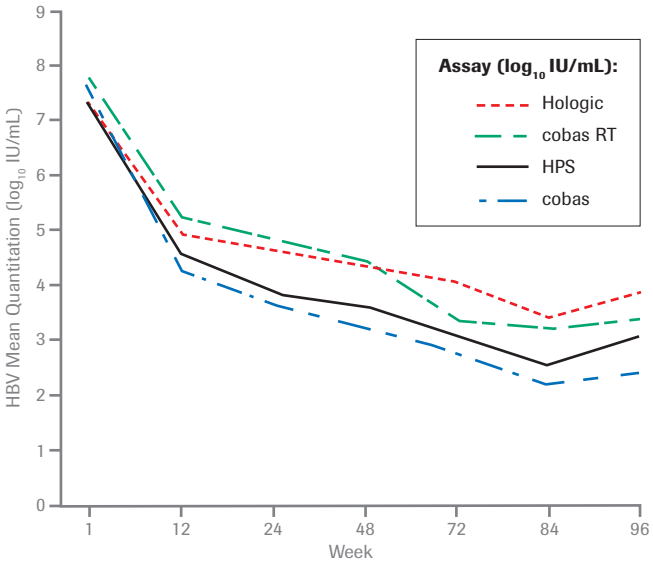
This study demonstrates that HBV test platforms are not interchangeable. If your HBV DNA assay amplifies RNA to measure viral loads, it could be over-quantifying. This can lead to the mis-classification of treatment responses and unnecessary clinical interventions due to perceived treatment failure. ***Be sure what is in your HBV viral load result. RNA Distorts.***

The HBV viral loads were evaluated for 346 samples from 50 patients with lamivudine-resistant chronic HBV using 3 different assays

	cobas® HBV (cobas)	**cobas® HBV with reverse transcription step (cobas RT)**	**Hologic® Aptima® HBV Quant Assay (Hologic)**
System	**cobas®** 6800 System	**cobas®** 6800 System	Hologic® Panther® System
Amplification	Real time PCR	Real time PCR	Transcription Mediated Amplification
Nucleic Acid Amplified	DNA	RNA and DNA	RNA and DNA

Note: These tests were compared to historical viral load results obtained with the COBAS® TaqMan® HBV Test (HPS)

HBV viral load comparison



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