



# ULTRAGENE **HBV**

## QUAL & QUANT VIRAL LOAD ASSAY

**RAPID & ULTRA SENSITIVE MOLECULAR  
TESTING FOR HBV**



Providing Lab Efficiency for Optimized  
Patient Monitoring

Research Use Only - Proprietary, ABL S.A.

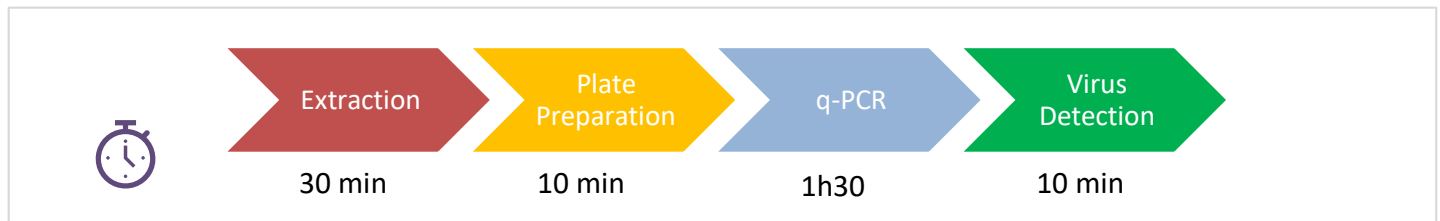
## THE SOLUTION

The ULTRAGENE HBV QUAL & QUANT Viral Load Assay is a fast and ultra-sensitive real-time PCR test that provides qualitative detection and quantification of HBV DNA from plasma, serum, whole blood or dried blood spot samples.

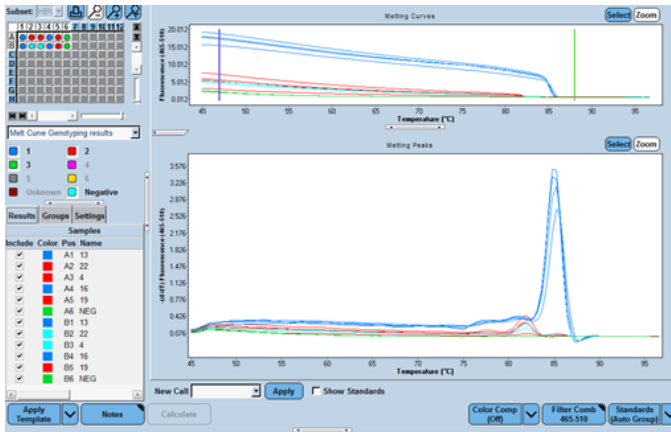
The ULTRAGENE HBV QUAL & QUANT Viral Load Assay generates PCR amplicon of the polymerase HBV gene which can be used as a reflex testing on positive samples for genotyping and drug resistance analyses.

## Intended uses

- Detection of acute infection
- Adherence monitoring
- Treatment monitoring
- Drug resistance assessment



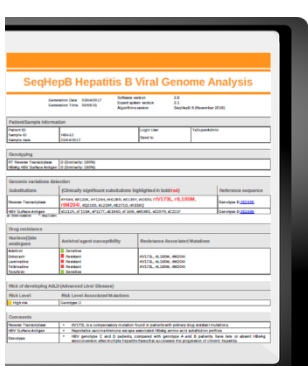
## QUAL ASSAY



**Negative**  
Viral load not detectable

**Positive => Viral load > 15 UI/mL**

**Reflex Genotyping Testing**



**GENOTYPING DRUG RESISTANCE**

**DEEPCHEK®-HBV RT ASSAY**

**EFFICIENCY**

**Amplicons ready for sequencing:**

- Genotyping, drug resistance...
- Time efficiency
- Cost efficiency
- Sample volume efficiency
- Patient does come twice at the lab

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## COMPOSITION



### FORMAT

- From 1 to 24 sample reactions per assay
- Format suited to 96 reactions is available

### CONTENT

- Real-time PCR enzyme
- Real-time PCR Master Mix
- HBV RT amplification primers
- Water
- Calibrated positive controls (QUANT version only)

## PERFORMANCES



### LIMIT OF DETECTION

- Serum/Plasma samples: 15 cp/mL (95% CI 20-30)
- Dried Blood Spot: 400 cp/mL (95% CI 380-420)

### CHARACTERISTICS

- 500µL plasma/serum/whole blood
- Pan-genotypic
- Reproducibility >99%
- Covered regions: reverse transcriptase region of the polymerase gene

### EASY & RAPID

- 140 minutes run time
- Hands-on time: <30 min

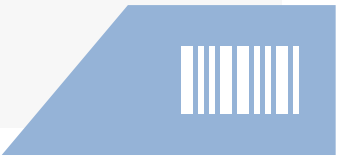
### EFFICIENCY

- Cost-effective
- From 1 to 96 samples per run
- Reflex genotyping testing on RT (using the DeepChek®-HBV RT assay), compatible with SANGER & Next Generation Sequencing CE-IVD software for genotyping analysis



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 **REFERENCES & CONTACT**



**ULTRAGENE HBV Viral Load QUAL Assay (RUO)**

- Up to 24 samples . . . . . K-17-UHBV24
- Up to 96 samples . . . . . K-17-UHBV96

**ULTRAGENE HBV Viral Load QUANT Assay (RUO)**

- Up to 24 samples . . . . . K-17-UQTHBV24
- Up to 96 samples . . . . . K-17-UQTHBV96

**RELATED PRODUCTS**

- DeepChek®-HBV RT Genotyping Assay (RUO) . . . . . K-17-B-RT
- DeepChek®-HBV Software (CE-IVD) . . . . . S-12-023 (BUS)

**ULTRAGENE Viral Load Assays (RUO) also available for: HCV, HIV, Tuberculosis**



**IMPROVE DISEASE  
MANAGEMENT**

**CONTACT**

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