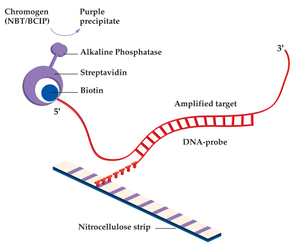
INNO-LiPA™ HBV

Test procedure

Fast, easy and highly specific DNA hybridization tests.

INNO-LiPA™ test principle and main steps

1. Denaturation of amplified biotinylated DNA
2. Hybridization with specific oligonucleotide probes immobilized as parallel lines on membrane-based strips
3. Remove non-specific and unbound DNA
4. Incubation with conjugate and substrate resulting in a purple precipitate



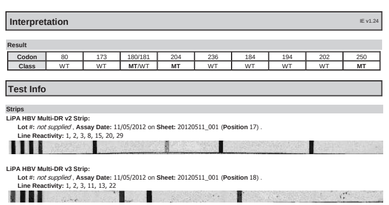
HBV LiPA compatibility

- All LiPA HBV assays
  - use the same program on AutoBlot 3000H or *Auto*-LiPA™ 48
  - have the same manual protocol
  - have identical LiPA reagents
- Amplicon of INNO-LiPA™ HBV Multi-DR can also be used for INNO-LiPA™ HBV Genotyping

LiRAS™ for LiPA HBV:

Easy and objective interpretation software for the developed strips

- Scanning mode with integrated calibration
- Choice between data entry model: scanned or manual entry
- Customized reports: standard or summary report, adjustable to your needs
- Saves electronic image of each strip
- User-friendly and customizable interfaces
- Filter management: e.g. 100 samples with genotype A from January till March
- Patient follow-up*: overview of test performed per patient and follow-up of drug resistance patterns over time



* Only for CE version

INNO-LiPA™ HBV

The complete portfolio for the molecular identification of the Hepatitis B Virus

INNO-LiPA™ HBV Genotyping INNO-LiPA™ HBV Multi-DR INNO-LiPA™ HBV PreCore

Ordering Information

Product		Article no.
Assays		
INNO-LiPA™ HBV Genotyping	CE	80691
INNO-LiPA™ HBV Multi-DR	CE	81383
INNO-LiPA™ HBV Genotyping	RUO	80070
INNO-LiPA™ HBV Multi-DR	RUO	81382
INNO-LiPA™ HBV PreCore	RUO	80883
Software		
LiRAS™ for LiPA™ HBV v1	CE	81387
LiRAS™ for LiPA™ HBV v1	RUO	81386
Automation		
Auto-LiPA™ 48	CE	80628
AutoBlot 3000H	CE	81149

References

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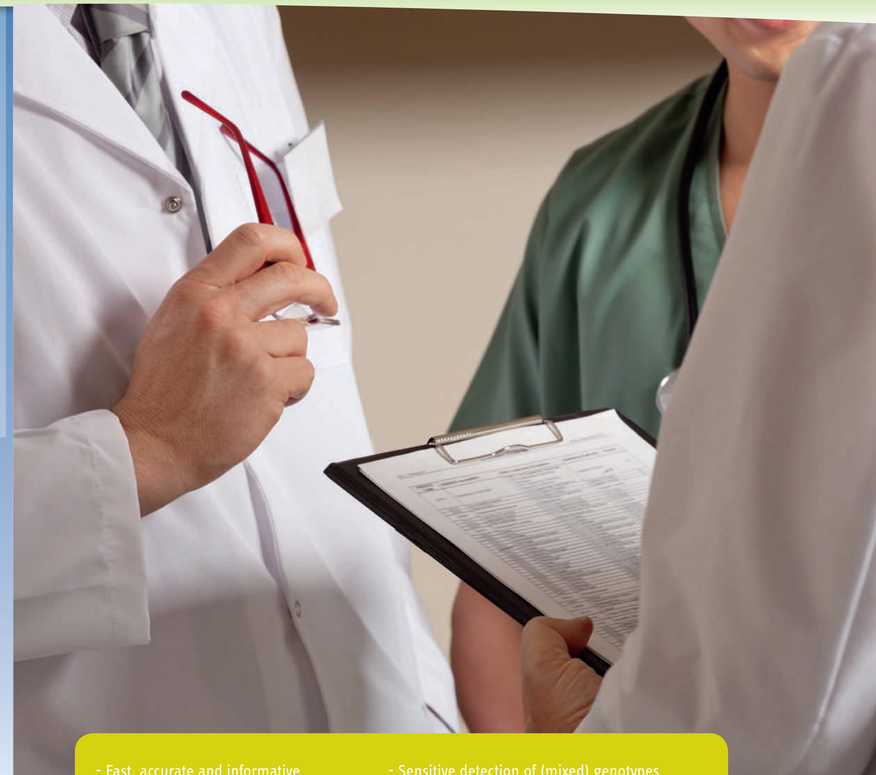

- Fast, accurate and informative
- Easy to perform
- Highly sensitive
- Full patient profiling with 1 method
- Sensitive detection of (mixed) genotypes
- Earliest detection of drug resistance
- Accurate determination of the true HBeAg status
- HBV treatment management

Fujirebio Europe N.V.
Technologiepark 6- B-9052 Gent - Belgium
T +32 (0)9 329 13 29 - F +32 (0)9 329 17 75
www.fujirebio-europe.com

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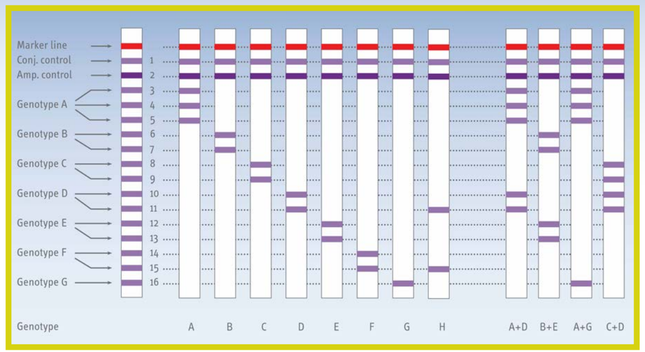
INNO-LiPA™ HBV Genotyping

Line probe assay for the identification of hepatitis B virus genotypes A to H

Strip lay-out



Features and benefits

- Clear identification of mixed infections: LiPA detects up to 16.3 % more mixtures than direct sequencing, confirmed by clonal analysis [1, 2]
- Sensitive detection of genotypes: LiPA is more sensitive than PCR-RFLP (98.8 % vs 65.0 %) [3] and more sensitive than sequencing [2]
- Amplicon of INNO-LiPA™ HBV Multi-DR can also be used for INNO-LiPA™ HBV Genotyping

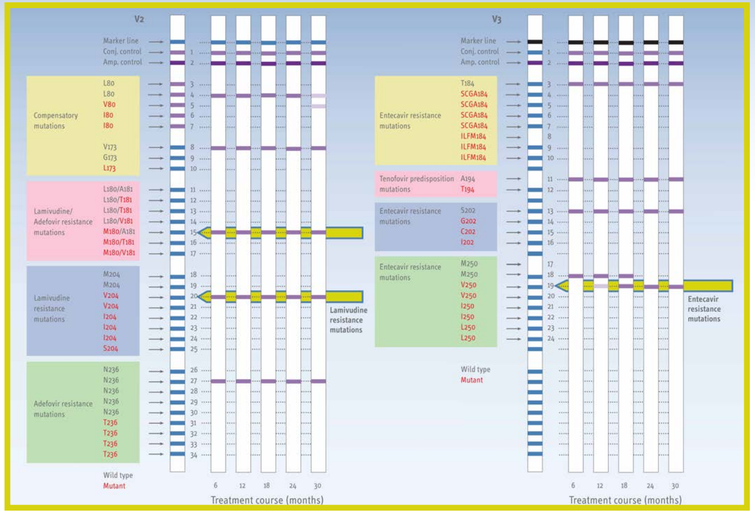
Clinical relevance of HBV Genotyping

- Genotyping linked with treatment response and part of clinical guidelines [4]: HBV genotypes A and B are associated with a better response to pegylated IFN-α than genotypes C and D.[5] The mutational pattern of lamivudine drug resistance differs between genotypes A and D.[6]
- The correlation between levels of Hepatitis B surface antigen (HBsAg) and the HBV genotype makes both markers valuable tools for prognosis and management of chronic hepatitis B: HBsAg levels differ according to HBV genotype prior to treatment [7-12], during treatment with pegylated IFN-α [8, 12] and nucleos(t)ide analogues [13] and during the natural course of HBV infection. [14]

INNO-LiPA™ HBV Multi-DR

Line probe assay for the simultaneous detection
of hepatitis B virus wild-type motif and resistance associated mutations

Strip lay-out



Features and benefits

- Relevant, accurate and up-to-date detection of drug resistance associated mutations as well as known compensatory mutations
- LiPA is highly sensitive and specific and offers the earliest timepoints for detection of mutants:
  - 2,8 times greater chance for LiPA to detect a given mutation than direct sequencing at any moment in time [15]
  - early detection of genotypic resistance allows rapid and effective HBV suppression [16]
- HBV drug resistance testing: part of clinical guidelines [17-19]

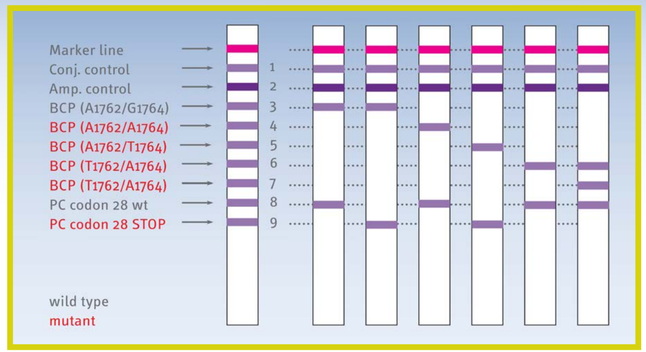
Clinical relevance of HBV drug resistance testing

- Antiviral drug resistance in patients with chronic hepatitis B leads to antiviral treatment failure.[20]
- Resistance should be identified as early as possible before viral load rebound and before rise of ALT (alanine aminotransferase) levels.[21]
- As soon as drug resistance is identified, an appropriate therapy can be initiated with the most effective antivirals now available.[16]

INNO-LiPA™ HBV PreCore

Line probe assay for the simultaneous detection of HBV wild-type motif and mutations
in the basal core promotor (BCP) and PreCore regions

Strip lay-out



Features and benefits

- More sensitive than direct sequencing for the detection of mixed sequences in precore (PC) and basal core promotor (BCP) region [22]
- Prediction of increased risk for hepatocellular carcinoma and progression of liver disease [23-27]
- Determine cause of HBeAg negativity: treatment response or PC/BCP mutations? [28-29]

Relevance of HBV PreCore in clinical practice

- Indication on treatment response and duration:
  - Pegylated IFN-α therapy response: patients without PC/BCP mutations are good candidates for interferon treatment, independent of the HBV genotype [28]
  - Nucleos(t)ide analogues treatment + PC/BCP mutations + drug resistance mutations might lead to a higher or lower replication fitness of the resistant virus [29]
- Risk of fulminant hepatitis and hepatocellular carcinoma: chronic hepatitis B patients infected with PC/BCP mutant viruses are more susceptible to severe hepatitis and acute-on-chronic liver failure (ACLF) [23-27]