

GGAGGAATATG
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GTCCATGTAGT
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AAATTATCATAGTAGCAGTCCATGTAGCAGT
GGACCAG
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ATCCAGAGAGGACCAGGGAGAGCATTGTT
AGAGBACCAGGGAGAGCATTGTTACAATA
TTTGTTACA

RUO

HBV

Solution

Rev. 01/2023

HBV SOLUTION

Background

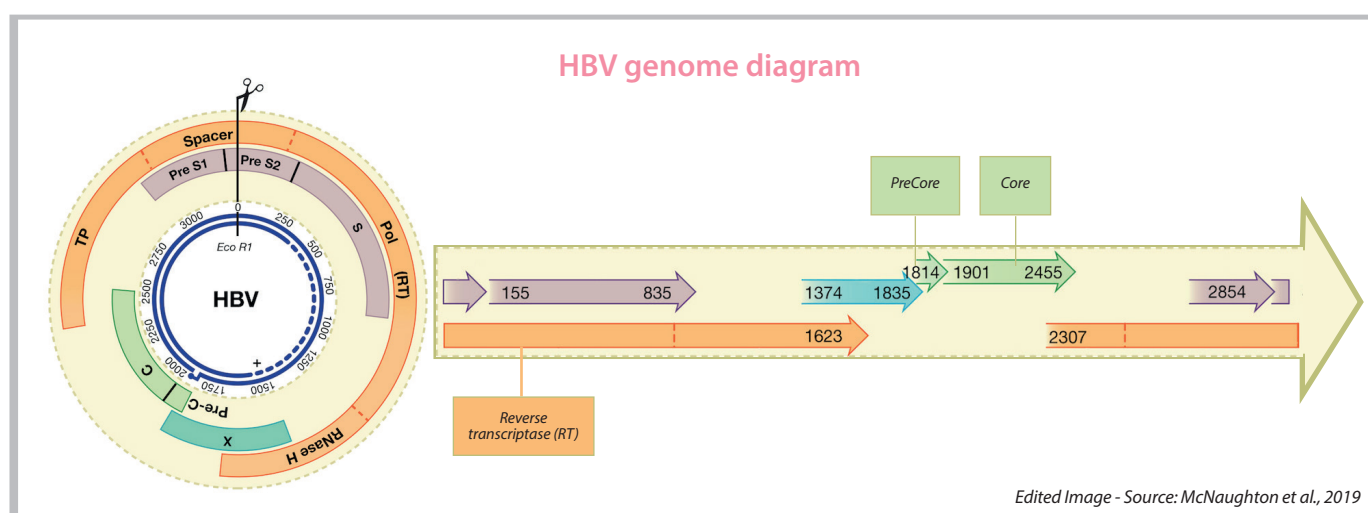
HBV virus belongs to the Hepadnaviridae family. Ten genotypes (A to J) have been described, five of which are causing 96% of chronic HBV infections (C 26%, D 22%, E 18%, A 17%, B 14%) (Velkov *et al.*, 2018).

This virus can rapidly mutate in the host under the pressure of the immune system, even during antiviral therapy treatments. The onset of HBV drug-resistances can be attributed to the combination of several factors, such as rapid replicative mechanisms, the existence of previous mutations, the immune system response in presence of chronic infection and the antiviral agent characteristics (Deng *et al.*, 2011).

Next Generation Sequencing (NGS) is an appropriate technique for HBV genotyping and an effective method in identifying drug-resistance mutations (Barbosa *et al.*, 2020).

Intended Use

The AD4SEQ HBV Solution kit is an *in vitro* qualitative method based on PCR amplification of two DNA viral regions (Reverse transcriptase and preCore) followed by NGS sequencing; the kit is useful for the determination of viral genotype and for the identification of drug-resistance mutations from plasma and serum samples positive for HBV. A dedicated software allows visualization and analysis of data from sequencing.



Sample Type

- ✓ Plasma
- ✓ Serum
- ...Positive for HBV virus

NGS Instruments

- ✓ Illumina® MiSeq™
- ✓ Illumina® iSeq™ 100
- ✓ Illumina® MiniSeq™

Performance Features

- ✓ Sequencing library preparation in ~ 8 hrs
- ✓ Input: ≥ 500 IU/ml
- ✓ Drug-resistance identification
- ✓ HBV genotyping
- Data analysis by dedicated software (developed by SmartSeq S.r.l.)

DNA Extraction – Validated Methods

- ✓ QIAamp® UltraSens Virus Kit (Qiagen)
- ✓ EZ1® Virus Mini Kit 2.0 (Qiagen)
- ✓ Any other extraction method available in the laboratory may be used upon users' validation

Workflow Overview



Performance features

- ✓ Target regions sequencing (Reverse Transcriptase, preCore) in a single amplification reaction
- ✓ Sequencing library preparation in ~ 8 hrs
- ✓ Input: ≥ 500 IU/ml
- ✓ Drug-resistance identification
- ✓ HBV genotyping
- ✓ Data analysis by dedicated software (developed by SmartSeq S.r.l)

Sequencing Information

Instrument	Illumina® Kit	Number of Samples	Sequencing Time <small>(Illumina® Official Data)</small>
Illumina MiSeq™	MiSeq™ Reagent Nano Kit v2 (300 cycles)	30	~ 20 h
Illumina MiSeq™	MiSeq™ Reagent Nano Kit v2 (500 cycles)	30	~ 24 h
Illumina MiSeq™	MiSeq™ Reagent Micro Kit v2 (500 cycles)	96	~ 39 h
Illumina MiniSeq™	MiniSeq™ Mid Output (300 cycles)	up to 384	~ 28 h
Illumina iSeq™ 100	iSeq™ 100 i1 Reagent (300 cycles)	up to 96	~ 20 h

Ordering Information

Cat. No.

AD4SEQ

HBV Solution

30 rxns

AD-004.030