

Hepatitis B virus RNA (HBV-RNA) Assay Kit (PCR-fluorescent probe method)

NEW guiding indicator of precision medicine for chronic hepatitis B patients

Hepatitis B virus is a hepatotropic DNA virus that mainly transmits through blood. According to World Health Organization (WHO), there are approximately 296 million chronic hepatitis B (CHB) patients worldwide, and about 820,000 deaths from HBV infection-related diseases every year.

Currently, antiviral drugs (nucleoside (acid) analogs [NAs] and pegylated interferon (PEG-IFN- α)) cannot eradicate covalently closed circular DNA (cccDNA) in the liver. cccDNA in the nucleus can transcribe pregenomic RNA (pgRNA), and subsequently, HBV. HBV RNA in serum is pgRNA, whose level reflects the transcriptional activity of cccDNA.

Clinical Significance of HBV RNA

1. Reflecting the amount and transcriptional activity of cccDNA in the liver of CHB patients

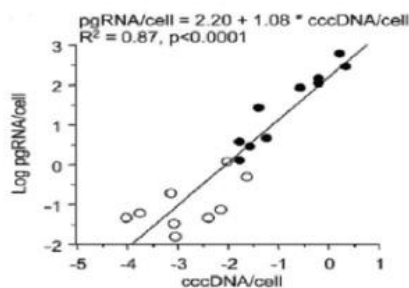


Figure 1. The pgRNA level is positively correlated with that of cccDNA, $R^2=0.87$

3. Predicting the risk of relapse in CHB patients after stopping medication

Research reveals that when NAs are discontinued, the higher the HBV RNA level, the greater the recurrence rate in 6 years' time.

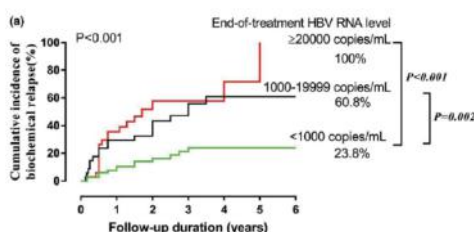


Figure 3. HBV RNA content and cumulative biochemical relapse ratio within 6 years

2. Predicting CHB patients' responses to NAs and PEG-IFN- α treatment (efficacy monitoring)

An international multi-center study reveals that patients who achieved HBV RNA response after treatment have higher HBV DNA sustained virological response rates and HBsAg negative conversion rates than those who did not.

Patients with HBV RNA response are those whose HBV RNA levels either decrease by over $2\log_{10}$ IU/mL, or decrease by over $1\log_{10}$ IU/mL and reach below than the lower detection limit.

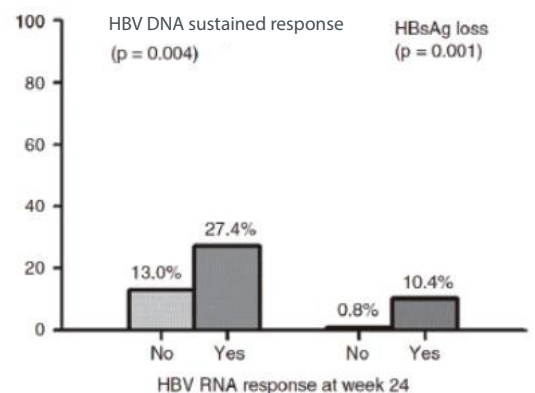


Figure 2. Patients' HBV RNA response and their HBV DNA sustained response and HBsAg negative conversion rates

Product Advantages



Authoritative

Recommended and recognized by various guidelines and consensus worldwide



Compatibility

Compatible with mainstream PCR devices



Accuracy

99.13% consistency with digital PCR results. Directly detects pgRNA

Product Information

Product	Certificate	Sample Type	Packaging	Compatible Devices
Hepatitis B virus RNA (HBV-RNA) Assay Kit (PCR-fluorescent probe method)	NMPA	Serum	48 T/box	ABI Prism 7500, LightCycler480, Agilent Stratagene MX3000, and more



Related Guidelines and Consensus

Guidelines for the Prevention, Diagnosis, Care and Treatment for People with Chronic Hepatitis B Infection, WHO, 2024

Guidelines for Treatment of Chronic Hepatitis B, AASLD, 2015

Clinical Practice Guidelines for Management of Chronic Hepatitis B, KASL, 2022

Expert Consensus on Measurement and Clinical Application of Serum HBV RNA in Patients with Chronic HBV Infection, CMA, 2022

Guidelines for Prevention and Treatment of Chronic Hepatitis B, CMA, 2019