

Hepatitis B Viral DNA Quantitative Fluorescence Diagnostic Kit

(PCR-Fluorescence Probing)

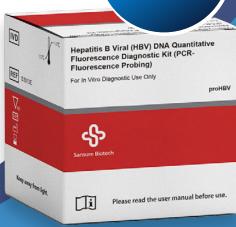




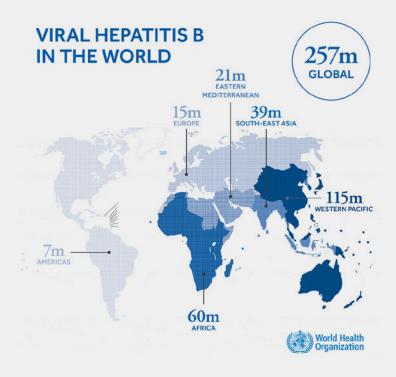
∅ Internal control monitoring

Full automation enabled

Magnetic beads enrich DNA and reveal the truth



WHO estimates that 296 million people were living with chronic hepatitis B infection in 2019, with 1.5 million new infections each year. In 2019, hepatitis B resulted in an estimated 820 000 deaths, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer). [1]



Since 2008, Sansure has developed HBV DNA Quantitative Fluorescence Diagnostic Kit with the foresight which agrees with WHO to provide patients living with HBV infection with an affordable, accessible and sustainable alternative to diagnose HBV, monitor disease progression, and assess the stage of liver disease and eligibility for treatment.

CHRONIC HBV INFECTION CLINIC GUIDELINES FOR HBV DNA TESTING REQUIREMENTS



Virological response during NA is defined as undetectable HBV DNA by a sensitive polymerase chain reaction (PCR) assay with a limit of detection of $10\,\mathrm{IU/mL}$.

— EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection



An undetectable viral load is an HBV DNA level below the level of sensitivity of the laboratory assay. For sensitive polymerase chain reaction assays, this is generally a concentration below 15 IU/ml.

— WHO guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection



ADDR.: No. 680, Lusong Road, Yuelu District, Changsha, Hunan Province, 410205, P.R.China

TEL.: +86-731-88883176-6116 **FAX**: +86-731-89736985

MAIL: info@sansure.com.cn / support@sansure.com.cn

WEB: www.sansureglobal.com



WORKFLOW

1. Upload sample and reagent

2. Select program

3. Detect and analyze



FEATURES



ANTI-CONTAMINATION

UNG enzyme + dUTP anti-contamination system



FULLY AUTOMATED

Matching Natch CS/CS2, which automates nucleic acid extraction for standardised detection



HIGH SENSITIVITY

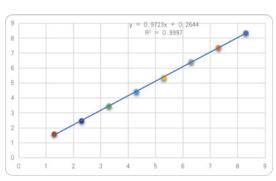
10 IU/mL, meeting chronic HBV infection clinic guidelines



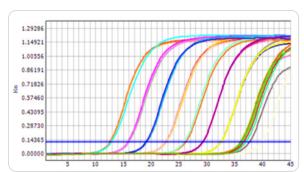
DNA EXTRACTION TECHNOLOGY

Advanced Magnetic Beads Technology, No heating, reduced aerosol contamination

PERFORMANCE



Linear analysis of HBV DNA gradient dilution versus theoretical values $\,$



HBV DNA amplification curve at gradient dilution



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PARAMETERS



Product Features	Parameter
Specimen Type	Serum
Extraction Platform	Advanced Magnetic Beads Technology
Genotype	HBV A-H Genotype
Internal Control	Lentivirus Particles
Anti-contamination	UNG Enzyme + dUTP Anti-contamination System
Sensitivity	10 IU/mL
Linear Range	20 - 2.0E+09 IU/mL

ORDER INFORMATION



No.	Product Name	Spec.
S3011E	Hepatitis B Viral DNA Quantitative Fluorescence Diagnostic Kit (PCR-Fluorescence Probing)	48T/Kit
S1003E	Nucleic Acid (DNA) Extraction or Purification Kit (Magnetic Beads Method)	48T/Kit





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