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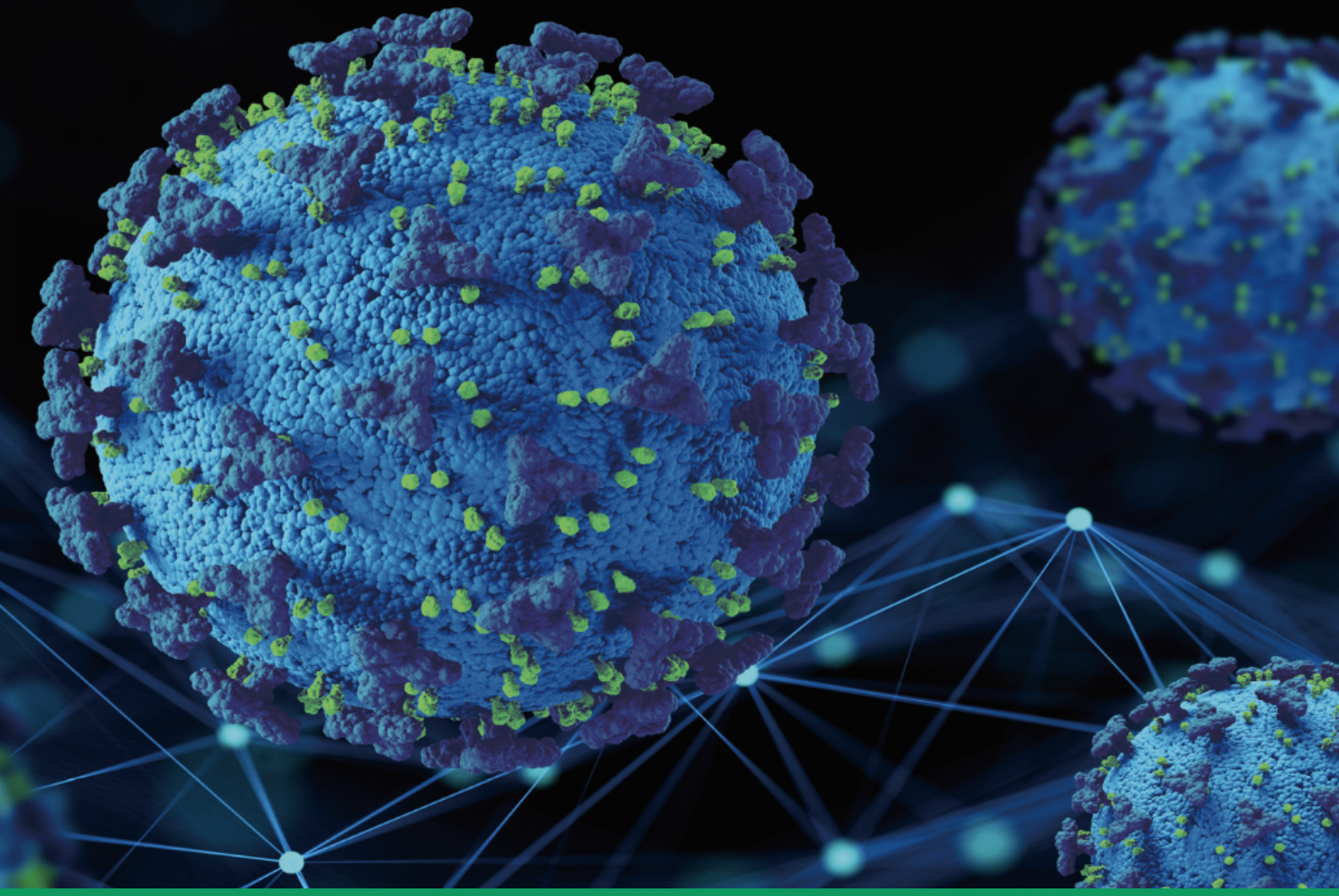

Comprehensive Overview

WHO's Diagnostic Guidelines for Hepatitis B and C Infections

Decode Genetic Life. Assure Human Health.

Comprehensive Overview: WHO's Diagnostic Guidelines for Hepatitis B and C Infections

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Hepatitis B virus (HBV) and hepatitis C virus (HCV) infection are major causes of acute and chronic liver disease (e.g. cirrhosis and hepatocellular carcinoma) globally, and cause an estimated 1.4 million deaths annually.Currently, approximately 248 million people are living with chronic HBV infection, and 110 million persons are HCV-antibody positive, with 80 million have active viraemic infection. The burden of chronic HBV and HCV remains disproportionately high in low- and middle-income countries (LMICs), particularly in Asia and Africa. Additionally, even in low-prevalence areas, certain populations have high levels of HCV and HBV infection, such as persons who inject drugs (PWID), men who have sex with men (MSM), people with HIV, as well as those belonging to certain indigenous communities.

WHO surveillance case definitions for viral hepatitis[a]

Clinical criteria AND biomarker or epidemiological criteria		
Serological evidence	hepatitis B	hepatitis C
Acute hepatitis	IgM anti-HBc +	HCV RNA + and anti-HCV -
Chronic HBV infection	HBsAg +[a]	HCV RNA + OR HCV Ag +
Past or present infection	HBsAg + in serum over 6 months and IgM anti-HBc -	Anti-HCV +

anti-HCV: antibody against hepatitis C virus, HBsAg: hepatitis B surface antigen, anti-HBc: antibody against hepatitis B core antigen, RNA: ribonucleic acid

a. Most testing strategies would also test for total anti-HBc. The combination of total anti-HBc and HBsAg is more specific of chronic HBV infection than HBsAg alone.

In the context of hepatitis virus infections, many individuals may not exhibit acute symptoms that go unnoticed by the healthcare system. Consequently, even capturing all diagnosed cases in clinical settings underestimates the actual number of new infections. Chronic infections can remain asymptomatic for decades, necessitating proactive measures like biomarker surveys to assess population prevalence. While research studies estimate the global disease burden of HBV and HCV infections, only a few surveillance systems consistently record the proportion of cirrhosis and/or HCC (hepatocellular carcinoma) attributable to these viruses. Testing and diagnosis serve as crucial gateways to prevention and treatment services, forming an integral part of an effective response to the hepatitis epidemic. Early identification allows individuals with chronic infections to receive necessary care and treatment, preventing or delaying liver disease progression. Testing also facilitates linking individuals to interventions that reduce transmission, including counseling on risk behaviors, provision of prevention commodities (such as sterile needles and syringes), and administering hepatitis B vaccination.

Key characteristics of HBV, HCV and the infections that they cause

Characteristics	HBV	HCV
Incubation period	2–6 months	2–6 months
Estimated number persons with chronic of infection (in millions)	240	130–150
Estimated incidence of clinical acute hepatitis among new infections	Children aged <5 years are asymptomatic; 30–50% among persons aged >5 years	<20%
Estimated number of annual deaths	820,000[a]	542,316[b]
Characteristics of acute hepatitis	Acute hepatitis more common in adults	Acute hepatitis uncommon, almost never fulminant[c]
Chronic infection	Chronic infection leading to sequelae	
Cirrhosis, chronic liver failure and hepatocellular carcinoma	Yes	Yes
Biomarker of recent infection	IgM anti-HBc	RNA or core antigen positive in the absence of anti-HCV
Routes of transmission	○ Perinatal Bloodborne (e.g. health-care setting, PWID) ○ Sexual	○ Bloodborne (e.g. health-care setting, PWID) ○ Perinatal (uncommon) ○ Sexual (uncommon)
Treatment options	Treatment available	Treatment available
Vaccine	Yes	No vaccine
Prevention of new infections	○ Vaccination ○ Safe injection ○ practices Infection control ○ Blood safety ○ Safe sex ○ Harm reduction for PWID	○ Safe injection practices ○ Infection control ○ Blood safety ○ Safe sex ○ Harm reduction for PWID

anti-HBc: antibody against hepatitis B core antigen, anti-HCV: antibody against hepatitis C virus, PWID.: people who inject drugs

a. https://www.medicalnewstoday.com/articles/mortality-rate-of-hepatitis-b

b. WHO; Institute of Health Metrics and Evaluation Progress report on HIV, viral hepatitis and sexually transmitted infections, 2019

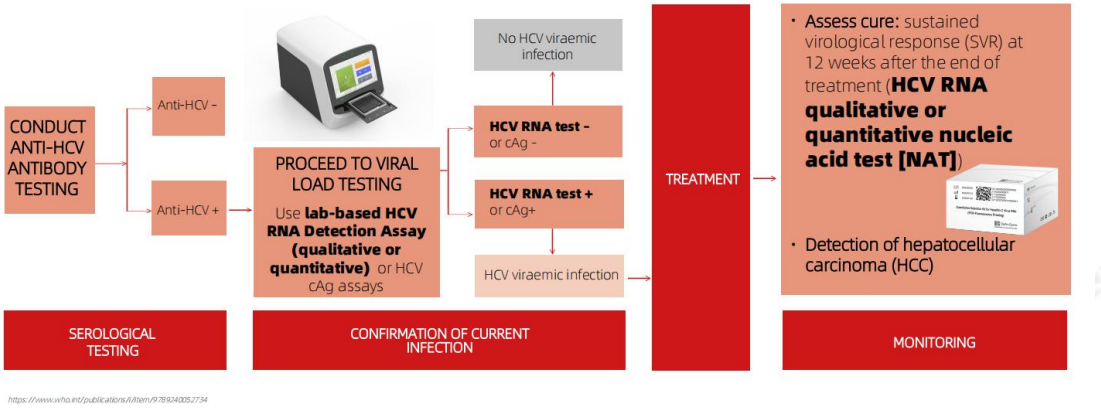
c. Maheshwari A, Ray S, Thuluvath PJ. Acute hepatitis C. Lancet. 2008;372(9635):321–32.

Viral hepatitis surveillance relies on in vitro diagnosis, primarily to identify the specific virus causing acute or chronic hepatitis and distinguish between recent, resolved, and chronic infections. The *Guidelines on Hepatitis B and C Testing* recommends the use of a serological in vitro diagnostic test or rapid diagnostic test to detect HBsAg and HCV antibody followed by NAT (nucleic acid testing) to verify and monitor disease.

HBV detection

The recommendation is to use HBV DNA NAT following a reactive HBsAg serological test result. This aids in guiding treatment decisions, especially in cases without evidence of cirrhosis, and facilitates monitoring for treatment response.

WHO summarized algorithm on HCV testing and managment

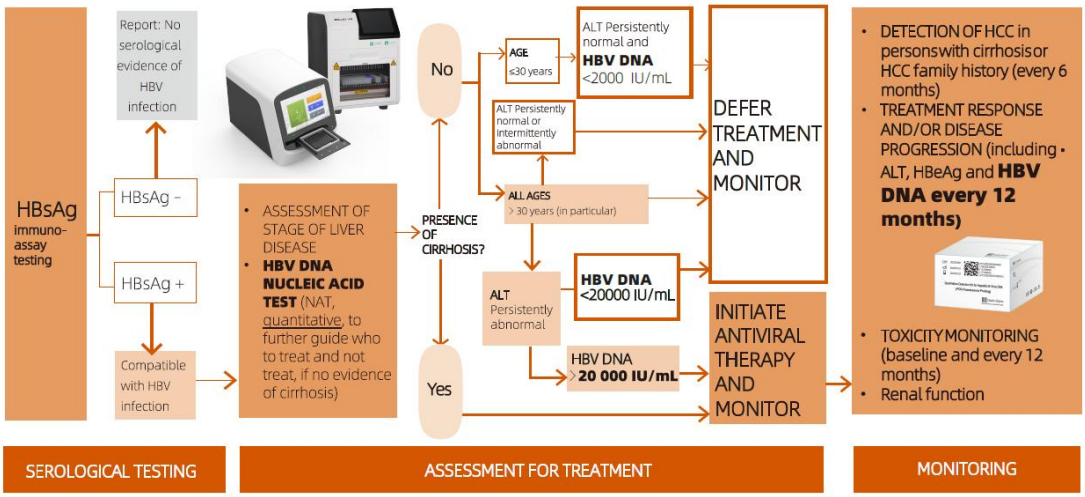


https://www.who.int/publications/i/item/9789240052734

HCV detection

Following a reactive HCV antibody serological test result, a quantitative or qualitative RNA NAT is recommended as the preferred testing strategy to diagnose viraemic infection. Detection of the core HCV antigen may be considered as an alternative irrespective of the critical demands for sensitivity.

Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection



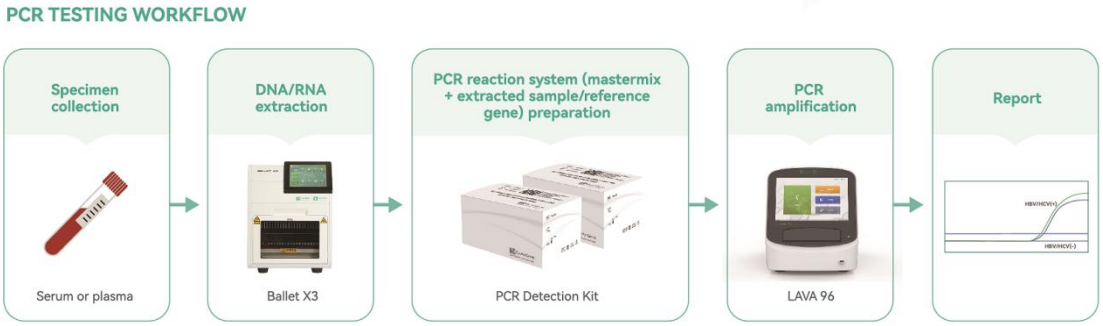
Abbreviations:
HBsAg: hepatitisB surface antigen; ALT: alanine aminotransferase; HCC: hepatocellular carcinoma;

Reference:
Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. Geneva: World Health Organization; 2015
Guidelines on hepatitis B and C testing. World Health Organization; 2017

PCR workflow

For clinical HBV and HCV diagnosis, high-quality sample preparation is the key factor

to get downstream verifiable results. The serological sample (normally serum or plasma) should be purified and nucleic acid enriched before PCR amplification, increased sample volume capacity and enhanced extraction efficiency helps to reduce the burden of virus detection ability from a limited clinical sample.



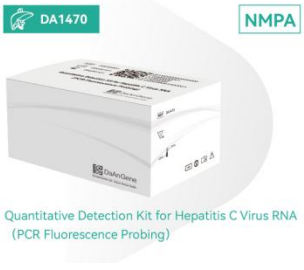
Daan Gene recently launched a pair of ultrahigh sensitivity HBV and HCV PCR detection kit designed for individual testing and disease monitoring in strict compliance with WHO guidelines. This cutting-edge kit, boasting a remarkable limit of detection (LoD) of 2 IU/ml for Hepatitis B Virus and 10 IU/ml for Hepatitis C Virus, utilizes real-time PCR technology. Additionally, it incorporates UNG and dUTP to prevent contamination during experiments. With its superior sensitivity and unrivaled detection capabilities, this kit ensures the precise and accurate identification of hepatitis viruses.

Parameters

Sample Type	Serum or plasma
Specification	Large package, 48 tests/kit
Target Gene	S, C
Analytical Sensitivity (LoD)	2 IU/mL
Linearity Range	20-1E+8 IU/mL
HBV Genotype	A-H
Standards Traceability	WHO International Standard NIBSC 10/266
Anti-contamination	Master Mix contains Uracil-DNA glycosylase (UNG) and dUTP

Parameters

Sample Type	Serum or plasma
Specification	Large package, 48 tests/kit
Target Gene	5'UTR
Analytical Sensitivity (LoD)	10 IU/mL
Linearity Range	20-1E+9 IU/mL
HBV Genotype	Genotypes 1 to 6
Standards Traceability	3th WHO International Standard NIBSC 06/100
Anti-contamination	Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs



If you require our advanced PCR detection kits for Hepatitis B and C viruses, please feel free to reach out to our sales representatives or contact us via email at marketing@daangene.com. We are committed to providing precise and sensitive solutions for individual testing and disease monitoring.

>> Learn More about DaAn Gene Hepatitis Test Kits

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Reference:

1. https://www.who.int/publications/i/item/9789241549981
2. https://www.who.int/publications/i/item/9789241549059

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