

HEPATITIS DELTA

An underdiagnosed disease that requires action

Hepatitis D virus (HDV) is a hepatotropic, defective virus that requires **hepatitis B virus (HBV)** to complete its life cycle and can cause acute and **chronic liver disease**. HDV has recently been classified as **carcinogenic¹** to humans (Group 1), just like hepatitis B and C viruses.

Why HDV matters

The most severe form of viral hepatitis

- An estimated 12-60 million people worldwide are infected with HDV¹
- HDV causes accelerated progression of liver disease, leading rapidly to cirrhosis and hepatocellular carcinoma.^{1,2}
- Compared with HBV alone, HDV co-infection significantly worsens clinical outcomes, increasing the risk of liver failure, transplantation, and death.³

Gaps in HDV diagnostics



No systematic HDV screening in HBV patients, despite guidelines recommendations



Anti-HDV IgG can be unreliable early on. Confirm diagnosis with quantitative HDV RNA



Standardized HDV RNA testing is limited. Viral load monitoring remains essential for care



Low disease awareness among healthcare providers

HDV diagnosis remains **challenging**, and standardized **quantitative HDV RNA testing** is essential to close the diagnostic gap and support informed clinical decisions.

HEPATITIS DELTA REALTIME PCR KIT

VIRCELL HEPATITIS DELTA REALTIME PCR KIT

Your reliable molecular solution for HDV diagnosis

Quantitative RT-qPCR assay that allows accurate detection and quantitation of HDV RNA (covering genotypes 1 to 8) in human serum and plasma, standardized against **1st WHO International Standard (7657/12)**.⁵

Confirms active HDV infection and **supports treatment monitoring** through viral load quantification in IU/mL.



PRODUCT FEATURES

- Quantitative HDV RNA detection with results in IU/mL.
- Traceable quantification using 4 Quantification Standards (QS) aligned with **1st WHO International Standard 7657/12**.⁵
- **Broad genotype coverage:** detects all 8 known HDV genotypes.
- **Internal control** for monitoring the carry-over of amplification inhibitors and the correct amplification set-up.
- Only 5 µL of eluate needed for accurate quantitation.
- Minimized hands-on time and errors using a pre-saved standard curve valid for the entire lot.
- **Pre-dispensed lyophilized master mix** to ensure stability and reduce transportation costs.
- Convenient pack size of 24 tests, adapted to routine testing needs.
- Compatible with most common RT-qPCR thermocyclers.
- **VIRCOM software** for curve visualization and easy calculation of sample concentration.

APPLICATIONS⁴

Human serum and plasma samples.

PERFORMANCE⁴

	Sensitivity	Specificity	No. of samples
HDV	97%	100%	245
HDV			
LoD (IU/µL)	0.09		
LoD (IU/mL)	23		

TARGETS⁴

	Target	Channel
HDV (1-8)	HDAG-L gene	FAM
Internal Control (IC)	Exogenous	HEX/VIC

1. World Health Organization (WHO). Hepatitis D – Fact sheet.

2. Stockdale AJ, et al. The global prevalence of hepatitis D virus infection: systematic review and meta-analysis. J Hepatol. 2020;73:523–532.

3. Da BL, Heller T, Koh C. Hepatitis D infection: from initial discovery to current investigational therapies. Gastroenterol Rep (Oxf). 2019; 7(4):231-245.

4. Vircell, S.L. Hepatitis Delta RealTime PCR Kit (RTPCR017-LP): Instructions for Use (IFU). Document No.: F-POC-00021-14-01. Granada (Spain): Vircell; 2026

5. Paul-Ehrlich-Institut. WHO International Standard for Hepatitis D Virus RNA (7657/12) – Instructions for Use.

Description	Reference	Class	Content
HEPATITIS DELTA REALTIME PCR KIT	RTPCR017-LP	CE ₀₁₂₃ IVDR - Class D	24 tests

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