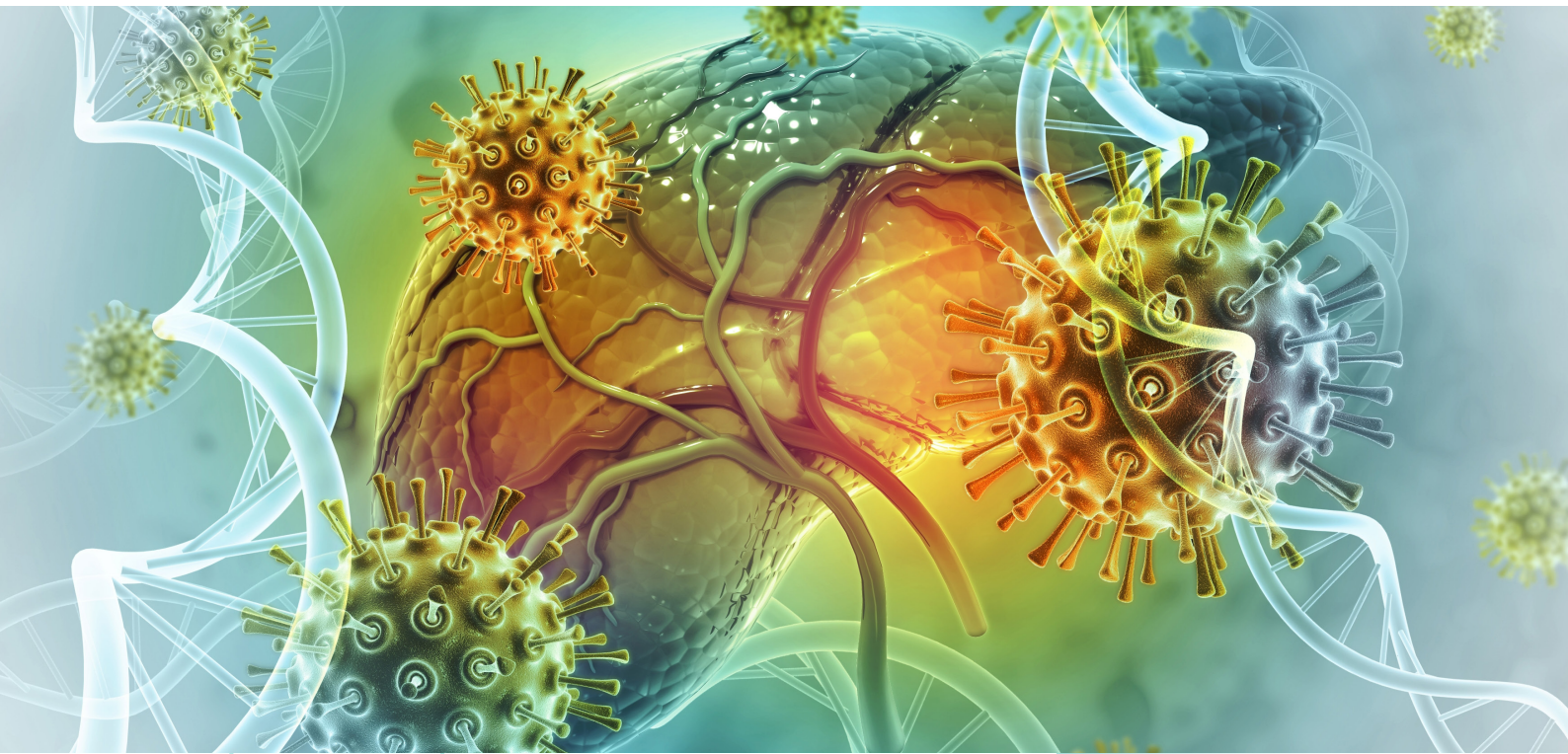


AMPLIQUALITY HCV TYPE PLUS

**Sensitive and accurate system for identification of Hepatitis C Virus (HCV) genotypes 1-7 and subtypes 1a and 1b.
Single-Step RT-PCR and Reverse Line Blot of 5'UTR and CORE region**



AMPLIQUALITY HCV TYPE PLUS is a genotyping test based on single-step multiplex RT-PCR and Reverse Line Blot.

The system can identify HCV genotypes 1 to 7, and subtypes 1a and 1b. Additionally it can identify subtypes: 2a/2c, 2c, 2b, 3a, 3b/g/i, 3c, 3f/k, 3h, 4a, 4a/b/c/d/f, 4d, 4e, 4h/k, 4m, 4n, 4q, 4r, 4v, 5a, 6a/b, 7a/b.

The test has been validated in accordance with the European CTS for *in vitro* diagnostic medical devices on serum and plasma samples, using NS5b sequencing as reference genotyping method.


For *in vitro* diagnostic use



AMPLIQUALITY HCV TYPE PLUS

Globally, approximately 50 million people have chronic hepatitis C virus (HCV) infection, with around 1 million new infections annually. In 2022, the WHO estimated 242,000 deaths from hepatitis C, primarily due to cirrhosis and hepatocellular carcinoma. Direct-acting antiviral medicines (DAAs) can cure over 95% of those infected, but diagnosis and treatment access remain limited. New HCV infections are often asymptomatic, leading to few diagnoses during the early stages. Chronic HCV also remains undiagnosed for years due to its asymptomatic nature until serious liver damage occurs. The diagnosis requires a first test for anti-HCV antibodies to identify people who have been infected with the virus, and a second nucleic acid test for HCV RNA to confirm chronic infection and the need for treatment.

WHO's new global health sector strategy sets new actions and targets to eliminate viral hepatitis by 2030.

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- 1 RNA Extraction
 - 2 Single-Step RT-PCR 2 h 40 min
 - 3 Reverse Line Blot 1 h 30 min
 - 4 Interpretation of strip results by software

PRODUCT CHARACTERISTICS:

- **One-step procedure**, for reverse transcription and amplification in a single tube
- **RNA Internal control (IC)** that permit assessment of the quality of the RNA extract.
- **Positive control** based on plasmid containing a fragment of the HCV 1a genome.
- Includes **dUTP/Cod UNG** system to prevent carry over contamination.
- Optional automation of strip development by using:
 - Autoblott 3000H (MedTec)
 - ProfiBlot™ T48 (Tecan Diagnostics)
 - DYNABLOT Heat (DYNEX TECHNOLOGIES)
- Continuously monitored with the following EQA schemes:
 - INSTAND Virus Genome Detection - Hepatitis C virus geno/subtyping
 - QCMD - Hepatitis C virus genotype
- The kit includes the interpretation software **HCV TYPE PLUS Strip Reader**, which allows fast and reliable interpretation of the assay results. The software identifies the genotype on the basis of the band pattern on the strip and provides a report.

SPECIMENS:

- Validated on:
- **Plasma**
 - **Serum**

Reverse
Line Blot

* EU-IVDR

ORDERING INFORMATION:

PRODUCT	CODE	N° TESTS	FORMAT
AMPLIQUALITY HCV TYPE PLUS	03-05-20 M	20	Manual
	03-05-20 A	20	Automated