

AMPLIQUALITY HCV TYPE PLUS

Fast and accurate system for identification of Hepatitis C Virus (HCV) genotypes 1-7

*One-step RT-PCR and Reverse Line Blot of 5'UTR and
CORE region*



AMPLIQUALITY HCV TYPE PLUS is a fast genotyping test based on one-step multiplex RT-PCR and Reverse Line Blot. Simple, fast, reliable and, thanks to the included interpretation software, the test provides univocal results in only a few hours.

Genotyping through analysis of both the 5'UTR and the CORE region of the HCV genome guarantees an efficient discrimination between subtypes 1a and 1b and genotype 6 (subtypes 6c, e-v).

The RT-PCR step employs the dUTP/Cod UNG system in order to prevent carry-over contamination.

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

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.

Hepatitis C infection affects 130-150 million people globally. A significant number of those who are chronically infected will develop liver cirrhosis or liver cancer and approximately 500 000 people die from Hepatitis C-related liver diseases every year. The standard of care for Hepatitis C is changing rapidly. Until recently, Hepatitis C treatment was based only on therapy with interferon and ribavirin, which required weekly injections for 48 weeks (OMS, July 2015). Recently, new antiviral drugs directly targeting the virus have been developed and a new era of Hepatitis C virus treatment is beginning that promises significantly shorter therapy and improved sustained virologic response rates. However, the efficacy of these new therapeutic regimens and the choice of therapy largely depends on the viral strain. Therefore, an accurate method for virus genotyping is required.



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PROTOCOL:

1

RNA EXTRACTION

2

ONE-STEP RT-PCR - 2h 10 min

3

REVERSE LINE BLOT - 1h 30 min

4

INTERPRETATION OF STRIP RESULTS BY SOFTWARE

PRODUCT DESCRIPTION

- One-step procedure for reverse transcription and amplification in a single tube, includes dUTP/Cod UNG system
- Ready-to-use MASTER MIX: only add the Enzyme mix and RNA
- INTERNAL CONTROL: RNA control (IC) for monitoring the complete process of analysis
- POSITIVE CONTROL: plasmid containing a fragment of the HCV 1a genome
- Strips and reagents for visualization of HCV genotypes: analysis of PCR products by Reverse Line Blot in 90 minutes
- Optional automation of strip development using Autoblot 3000H (MedTec) or Profiblot™ T48 (Tecan). Automation minimizes hands-on time and increases accuracy
- CE IVD marked

INTERPRETATION OF RESULTS

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.

ORDERING INFORMATION

Code	Description	Format
03-05-20	AMPLIQUALITY HCV TYPE PLUS	20 tests



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