

# Robust Viral Hepatitis C Subtyping through DeepChek HCV NS5B Assay.

**ABL**Advanced  
Biological  
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## Introduction

- Even if direct-acting antivirals (DAAs) used to treat viral hepatitis C (HCV) infection are very potent, a correct and sensitive stratification of patients, based on infecting viral strains profiling is required to optimize patient management.
- We present the DeepChek® SingleRound RT-PCR and Sequencing **HCV NS5B/5'UTR** Assay.

## Discussion

- Developed through several scientific collaboration and partnerships with external pathology laboratories together with Advanced Biological Laboratories (ABL), the DeepChek® SingleRound RT-PCR and Sequencing **HCV NS5B/5'UTR** Assay is a product combining all reagents suited for the amplification of the NS5B region, the related Sanger sequencing primers and the data analysis software (Fig. 1).
- Suited to any kind of Sanger or Next Generation Sequencing (NGS) platform, the assay has been tested, used and improved through continuous efforts and for 17 years (1998-2015) in France.
- On average, around 5280 clinical samples were tested, analyzed; sequencing was possible on a heterogeneous panel of HCV strains comprising subtypes (1-6).
- The test is sensitive: viral load ranging from 1250 to 150 000 000 IU/ml were successfully amplified.
- The data analysis component is included in the Assay and carried-out through the DeepChek®-HCV software application (Fig. 2) which summarizes in a clinical diagnostics report format, key information including genotype(s), subtype(s), co-infections assessment with quantification of related quasi-species.

### SingleRound RT-PCR and Sequencing HCV NS5B/5'UTR Assay

- ✓ Manufactured through ISO-certified process
- ✓ From 150uL to 1mL plasma (fitted to low viral load samples - 100 copies/mL targeted in routine use)
- ✓ Generating amplicons ready-to-go to Sanger and Next Generation Sequencing
- ✓ 24x NS5B tests/kit
- ✓ Reagents for 8x 5'UTR tests included to achieve 100% efficiency (on clinical samples tested so far)
- ✓ Fitted to many lab workflow (extraction methods, thermocyclers, sequencers...)

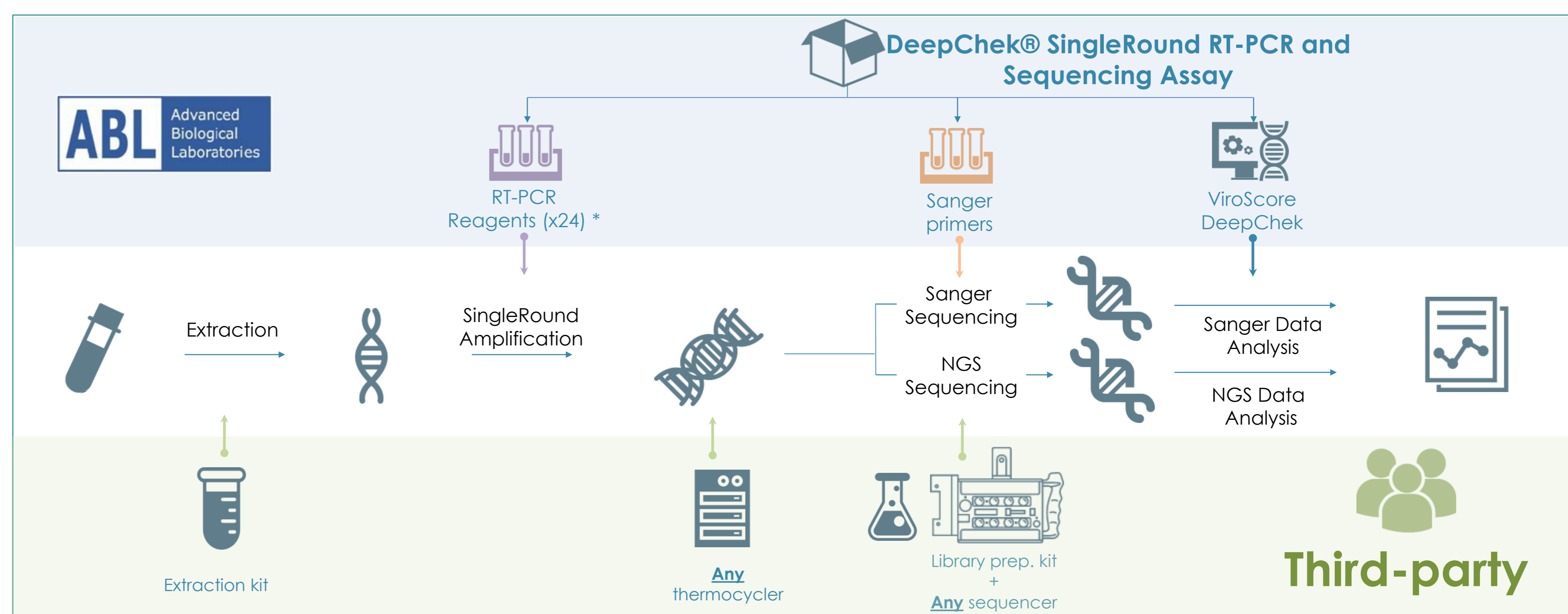
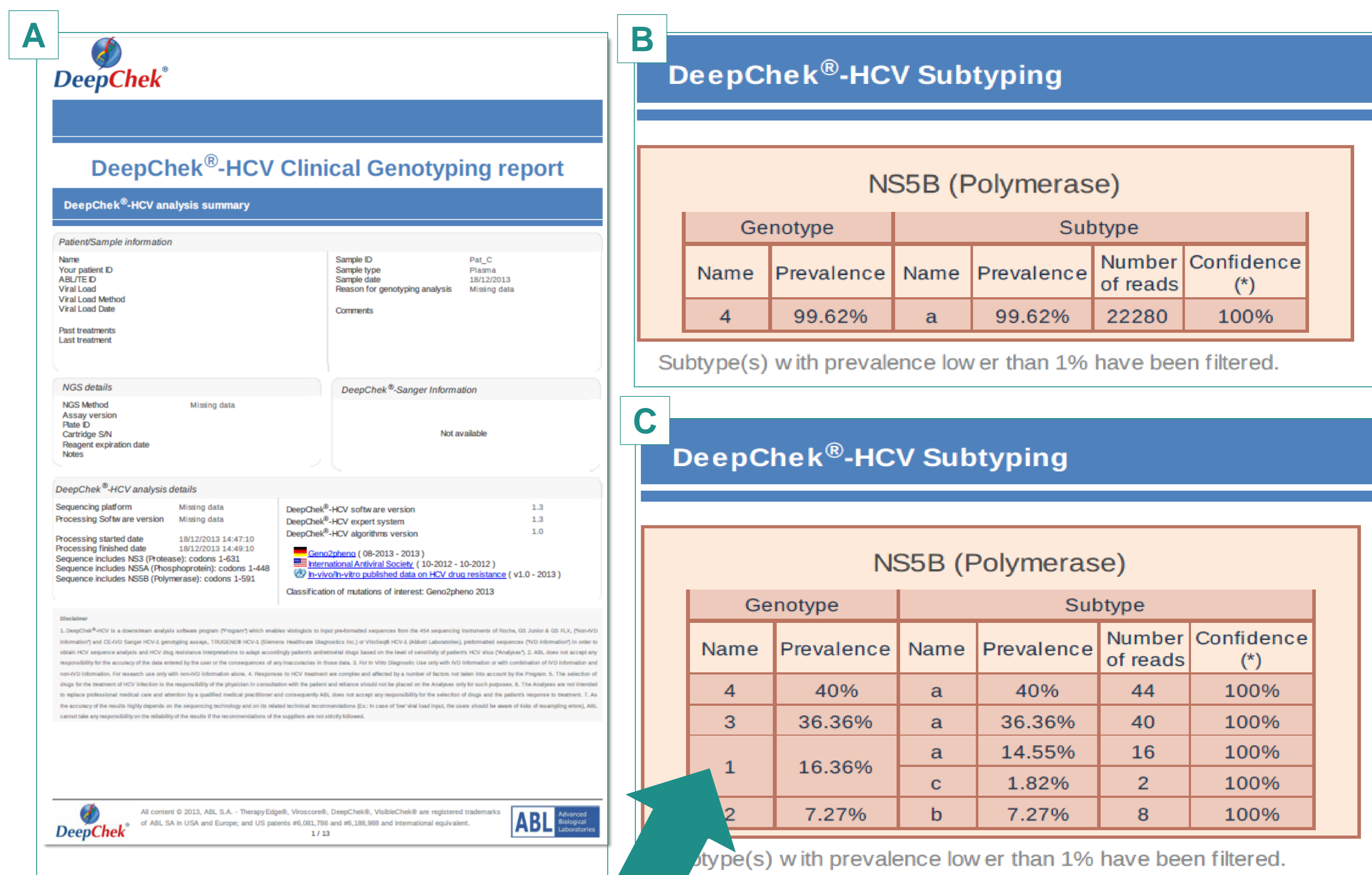


Fig. 1: The DeepChek® SingleRound RT-PCR and Sequencing Assays – Workflow overview.



### Collaboration with Vall d'Hebron Research Institute

Researchers from Vall d'Hebron Research Institute (VHIR) have developed a new deep sequencing methodology that accurately classifies the 7 confirmed genotypes and 67 confirmed subtypes of the hepatitis C (HCV) virus, and the different subtypes.

Fig. 2: The DeepChek® HCV genotyping report. Examples: a mono-infected sample (B); and a sample showing co-infection with several quasi-species (C).

## Conclusions

- DeepChek® SingleRound RT-PCR and Sequencing HCV **NS5B/5'UTR** Assay is a product which can be used in routine and surveillance. It is in the process of CE marking for IVD use. Already, it efficiently contributes to a sensitive profiling of HCV infection. It should lead to a better personalized HCV care compared to standard genotyping and subtyping methods.

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