

# Novel End-to-end Sequencing Solutions for Sanger and Next Generation Sequencing (NGS) of HIV and Viral Hepatitis C (HCV).



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## Introduction

- The management of patients infected with HIV or Viral Hepatitis C (HCV) relies on an accurate viral genomic profiling.
- Molecular assays combining reagents and powerful data analysis software are on demand by clinical diagnostics labs. We present the **DeepChek® SingleRound RT-PCR and Sequencing HIV & HCV Assays** (Fig. 1).

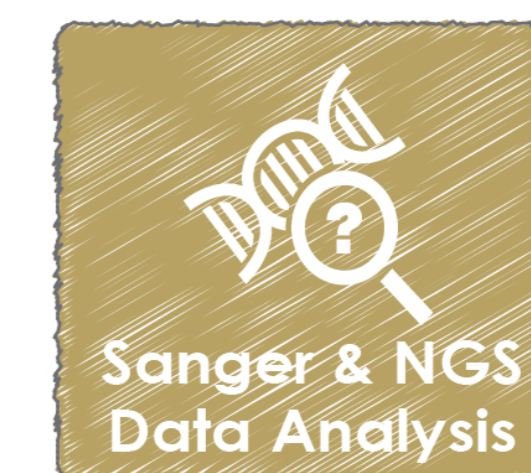


Fig. 1: The DeepChek® SingleRound RT-PCR and Sequencing Assay Technology.

## Methods

- Targeting key HIV and HCV regions (most discriminant subtyping and drug resistance positions are covered - Fig. 2) is the way virology applications are developed.
- The DeepChek® SingleRound RT-PCR and Sequencing Assays are agnostic of the Sanger or NGS platform.
- The ABL's Assays are standardized (GMP manufacturing - Fig. 3)
- They embed all the reagents required for a robust viral sequences amplification.

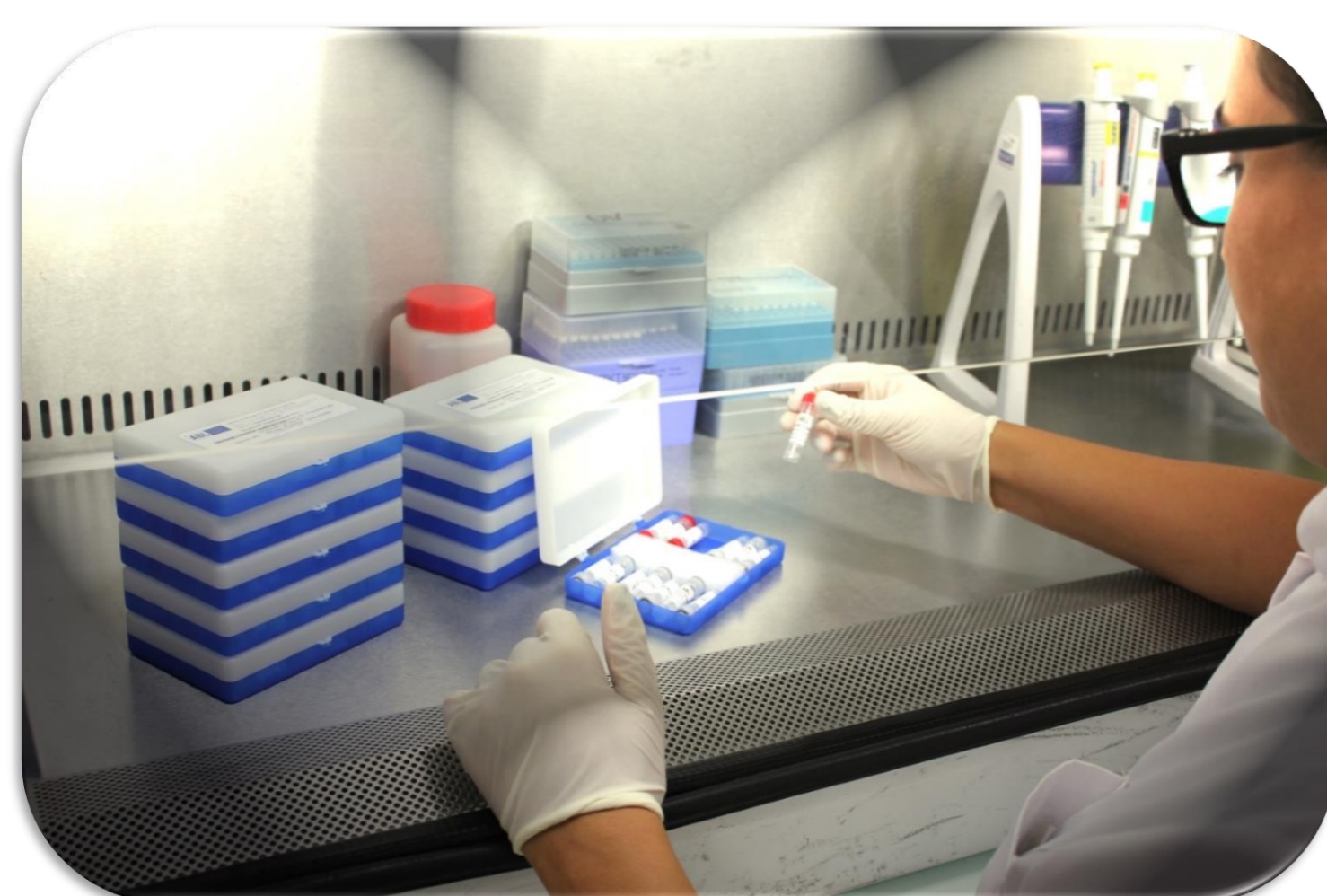


Fig. 3: Assays manufacturing illustration.

- HIV-1 reverse transcriptase, protease and integrase amplicons, and NS5B amplicons have been generated (Fig. 4) from a panel of hundreds of well-characterized frozen clinical plasma samples from the Caribbean region, Brazil and Europe.

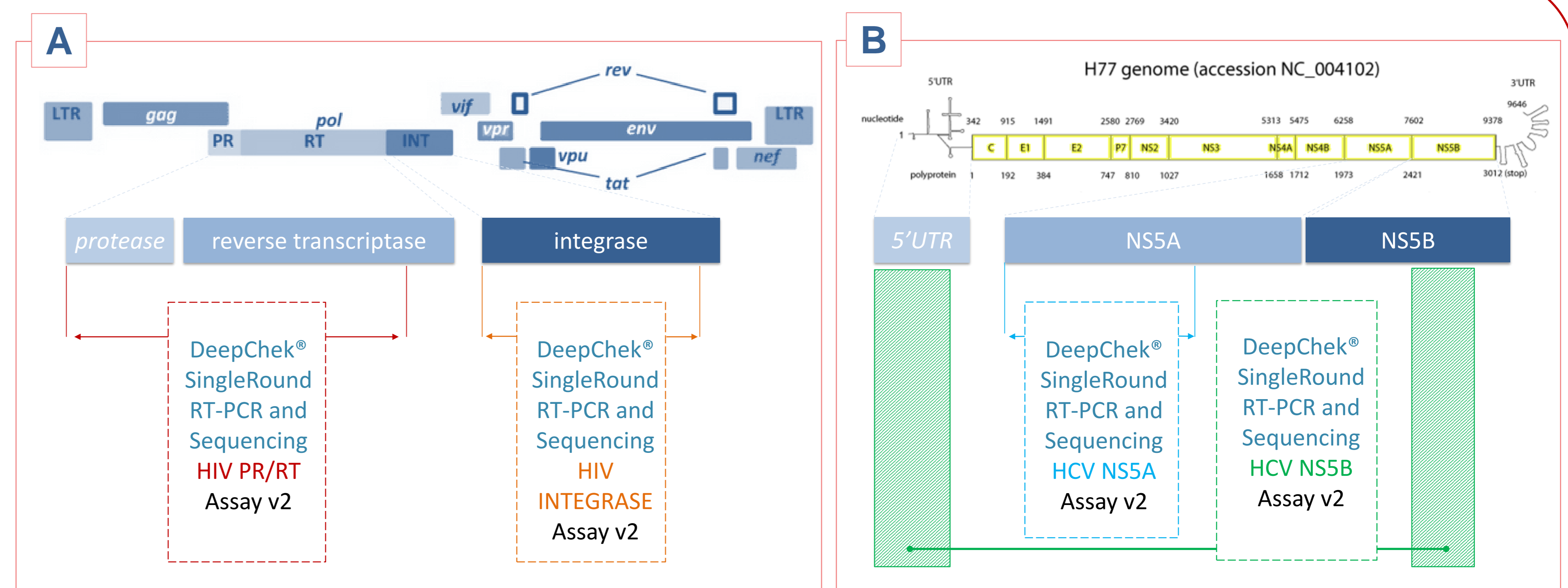


Fig. 2: The DeepChek® SingleRound RT-PCR and Sequencing Assays – Regions of interest for HIV (A) and HCV (B).

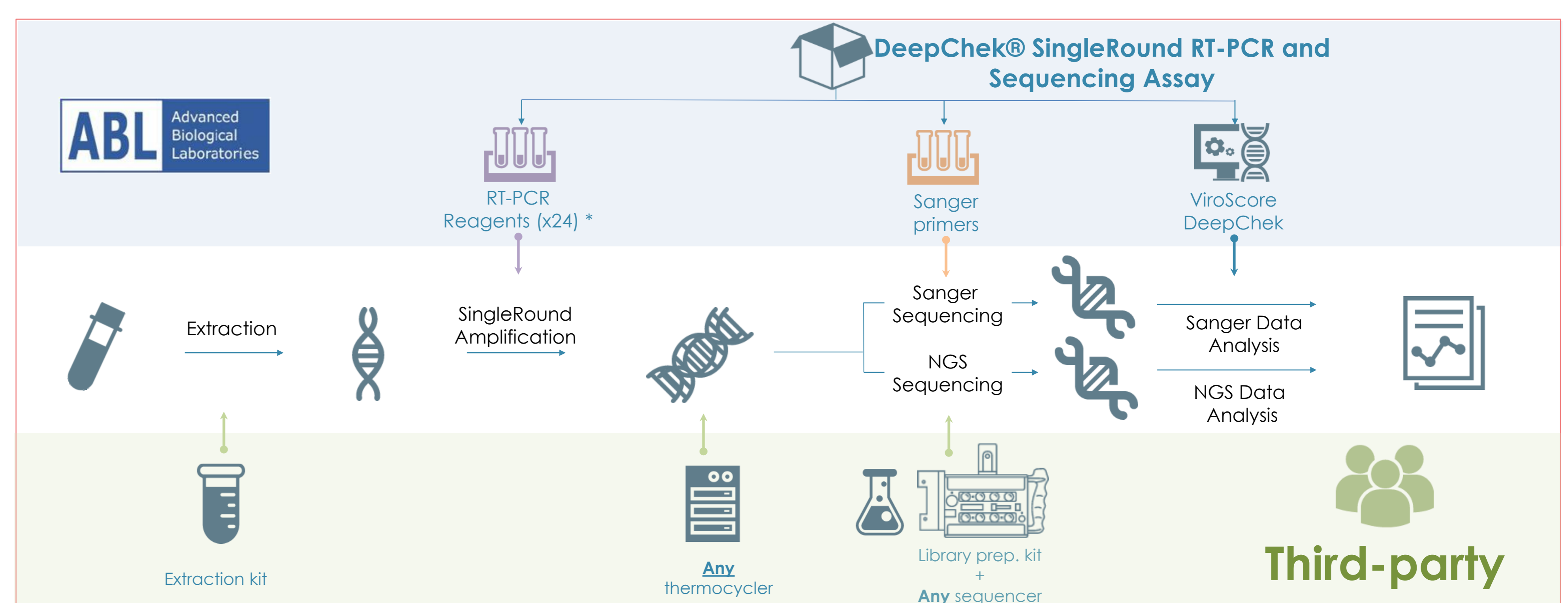


Fig. 4: The DeepChek® SingleRound RT-PCR and Sequencing Assays – Workflow overview.

## Results

- Overall performance of the assays are shown in Figure 5.
- Amplicons were sequenced using two methodologies (Sanger sequencing with Big Dye kits on one hand and NGS with Illumina Nextera XT and MiSeq® on the other hand).
- Sequences were analyzed with ViroScore® and DeepChek® technology respectively (Fig. 5 A & B): clinical genotyping reports (combining genotypes, mutations, and drug resistance assessment) were automatically generated.
- All results were in agreement with previous samples characterization.

### PERFORMANCES

- From 150uL to 1mL plasma
- 24 samples/kits
- Specificity:** validated with most subtypes
- Sensitivity:** detection of low viral load using ultracentrifugation
- 12 months expiration date on an average
- No need for gel confirmation (soon)

### SINGLEROUND RT-PCR

- Reduce risks of contamination
- No need for Nested-PCR (systematically)
- No Nested-PCR used with high viral load samples
- Not targeting the genes used for viral load determination (HIV & HCV)
- Better and shorter workflow (cost-effectiveness)
- Use of high fidelity enzymes
- Include more samples per run

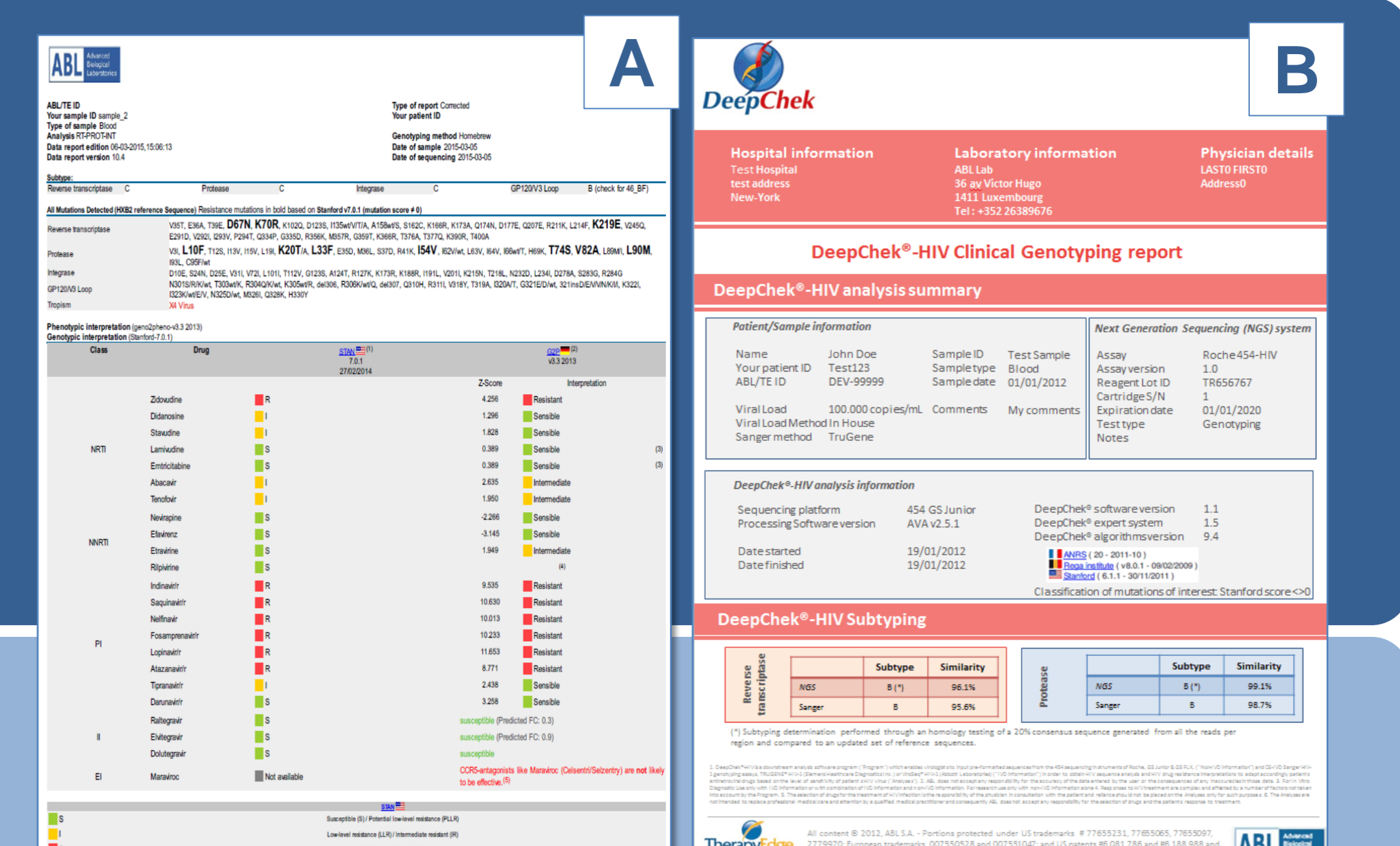


Fig. 5: Performances and reporting for Sanger (A) and Next Generation Sequencing (B) overview.

## Conclusions

- We developed an innovative and robust end-to-end solution which combines reagents and analysis software systems, directly compatible with diagnostics actionable interpretations for HIV and HCV infection disease management.