

## Introduction

- Software for HIV-1 genotypic drug resistance testing is routinely used to generate clinical drug resistance interpretations. In this study we compare the differences found in the results obtained with distinct software (Tab. 1).

Tab. 1: Evaluated HIV-1 drug resistance interpretation software systems.

Software	Supplier	Registration	Guidelines
ViroSeq Genotyping Software	Abbott	FDA-approved	ViroSeq v3.0.0.32 (VS)
DPM v1.0	ABL SA	FDA-registered	<ul style="list-style-type: none"> <li>Genotypic-based:                             <ul style="list-style-type: none"> <li>HIVdb v7.0.1 (SD)</li> <li>Others (&gt;7 algorithms)</li> </ul> </li> <li>Virtual-Phenotypic-based:                             <ul style="list-style-type: none"> <li>Geno2pheno v3.3 (G2P)</li> </ul> </li> </ul>
ViroScore-HIV® v3.20	ABL SA	CE-IVD / RUO	Same as DPM v1.0

## Methods

- HIV sequencing data of forty five (45) clinical samples belonging to treatment-experienced patients were analysed using ViroSeq (VS) Genotyping Software v3.0.0.32.
- All (VS) results were compared to the FDA-registered DPM product and to the RUO ViroScore-HIV® system from Advanced Biological Laboratories which include several knowledge databases i.e. Stanford HIVdb v7.0.1 (SD) or the virtual-phenotypic-based algorithm from Geno2Pheno v3.3 (G2P) – Fig. 1.

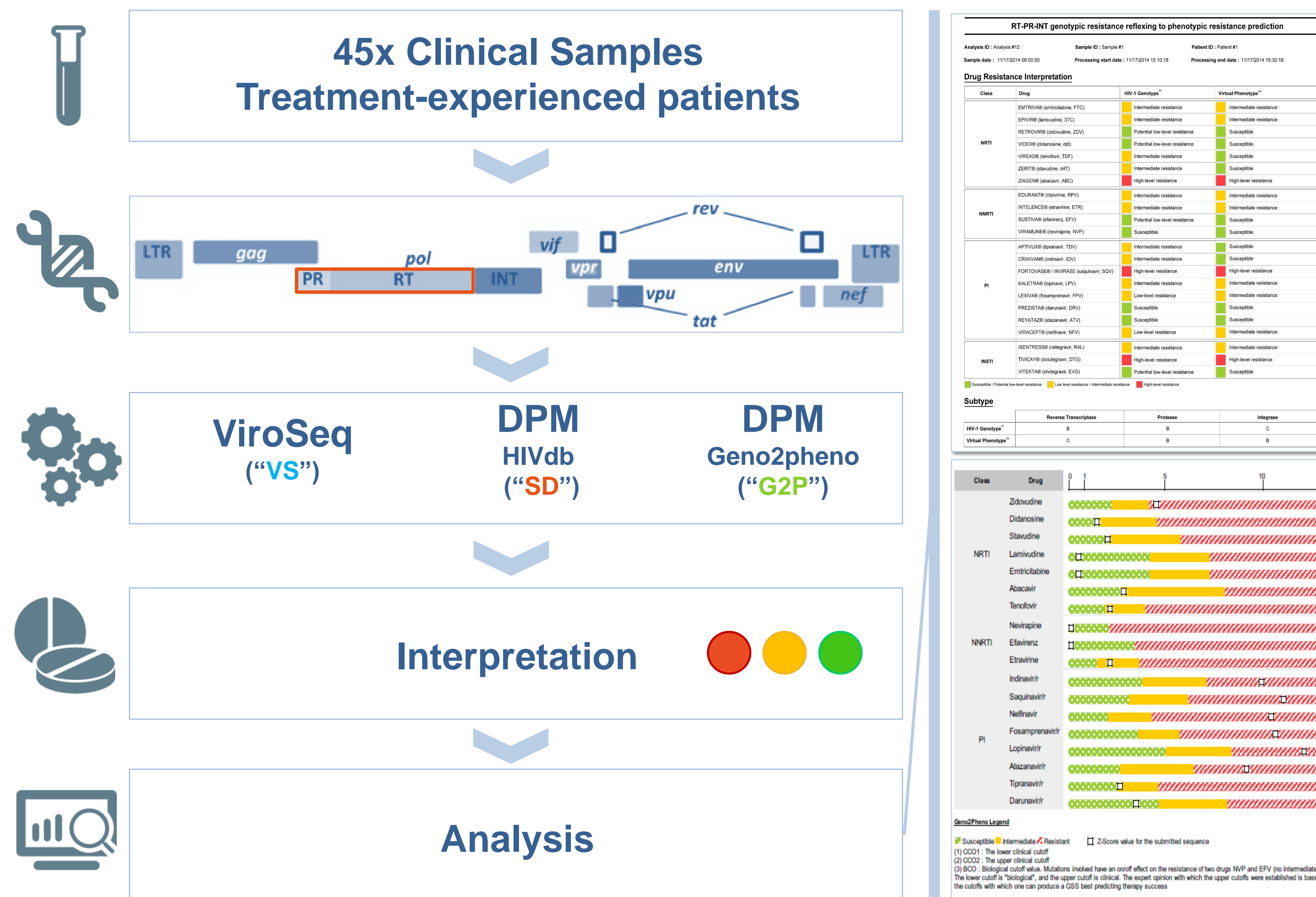


Fig. 1: Samples analysis methodology overview.

## Results

- Overall, G2P was the algorithm showing fewer interpretations classified as “Resistant” (8.9%, compared to 9.4% with SD and 9.2% with VS) and VS was the one showing the highest percentage of “Susceptible” interpretations (86.1%, compared to 75.3% with SD and 78.3% with G2P) – Fig. 2.
- For 41 of the samples we retrieved resistance interpretations for 19 drugs with all three algorithms, allowing us to compare 779 drug resistance results between algorithms. In 34.1% of the samples, VS reported different resistance interpretations for at least one drug when compared to SD, with a 1-level lower resistance value (from Resistant [R] to Intermediate [I] or from I to Susceptible [S]). When considering only the interpretations where SD was in agreement with G2P (714), VS reported 1-level lower resistance values for at least one drug in 12.2% of the samples – Fig. 3.
- At the drug level, differences were observed as shown in Fig. 4.

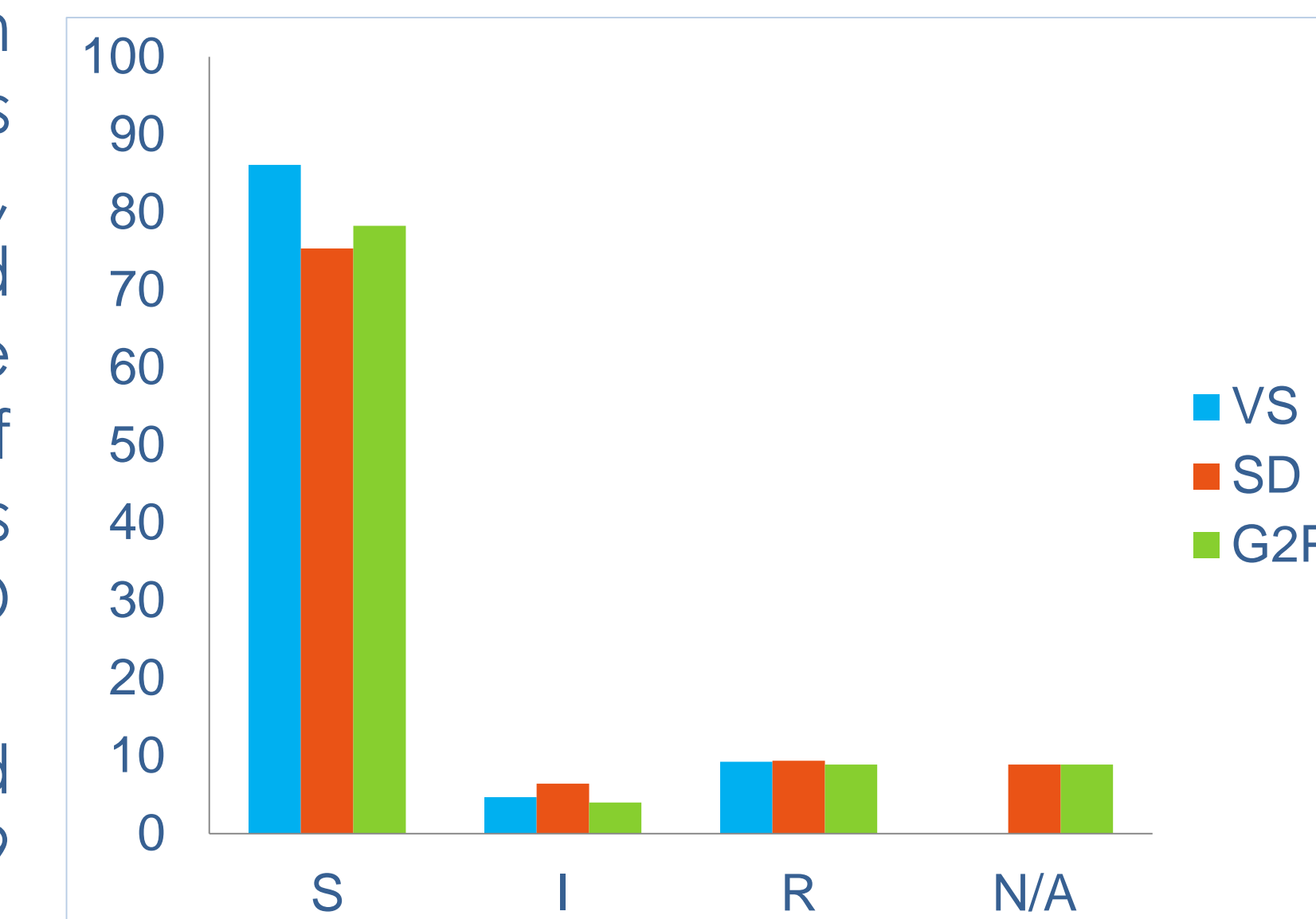


Fig. 2: Comparison of drug resistance interpretations between ViroSeq, HIVdb and geno2pheno.

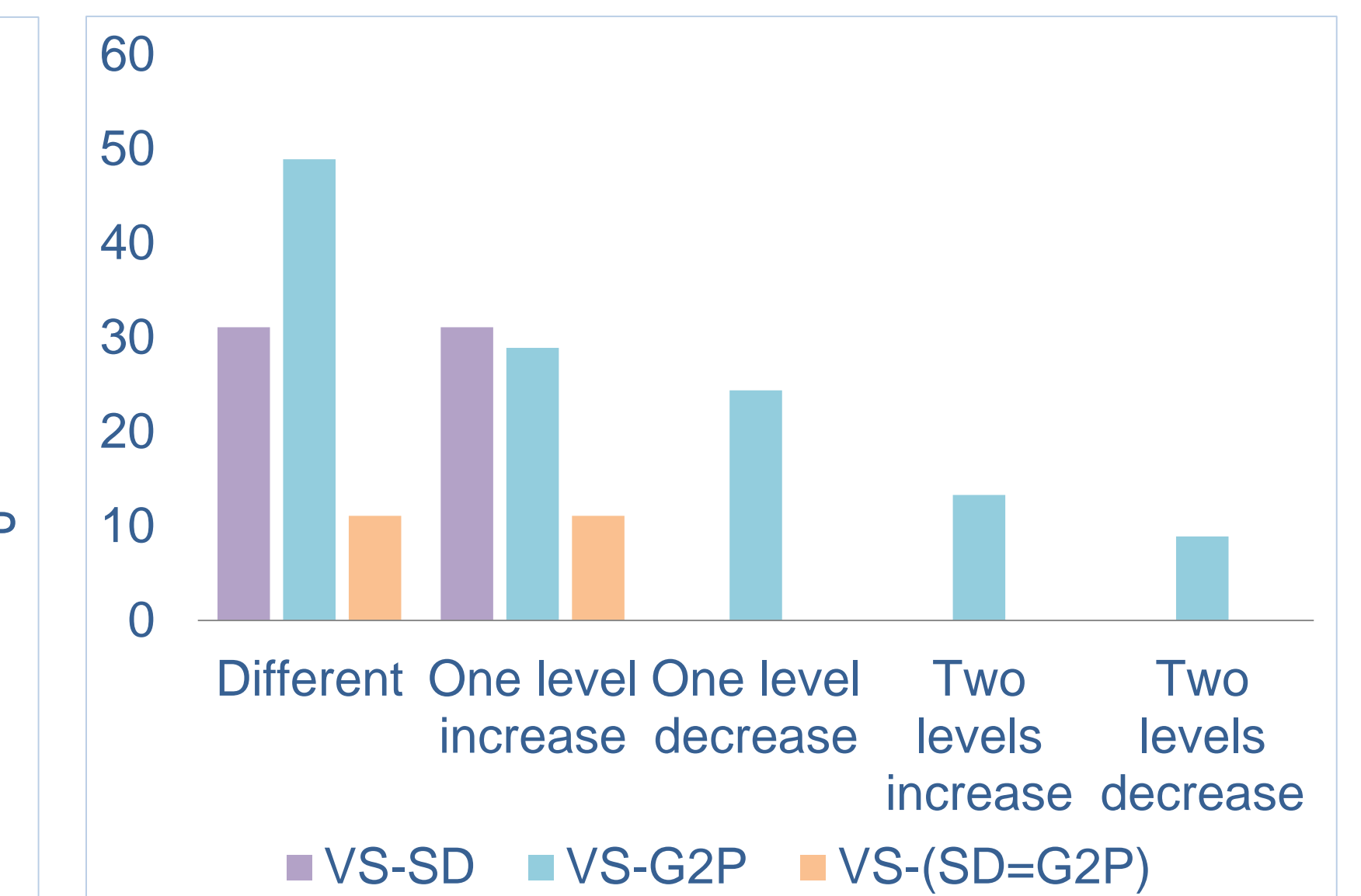


Fig. 3: Percentage of samples showing different drug resistance interpretations.

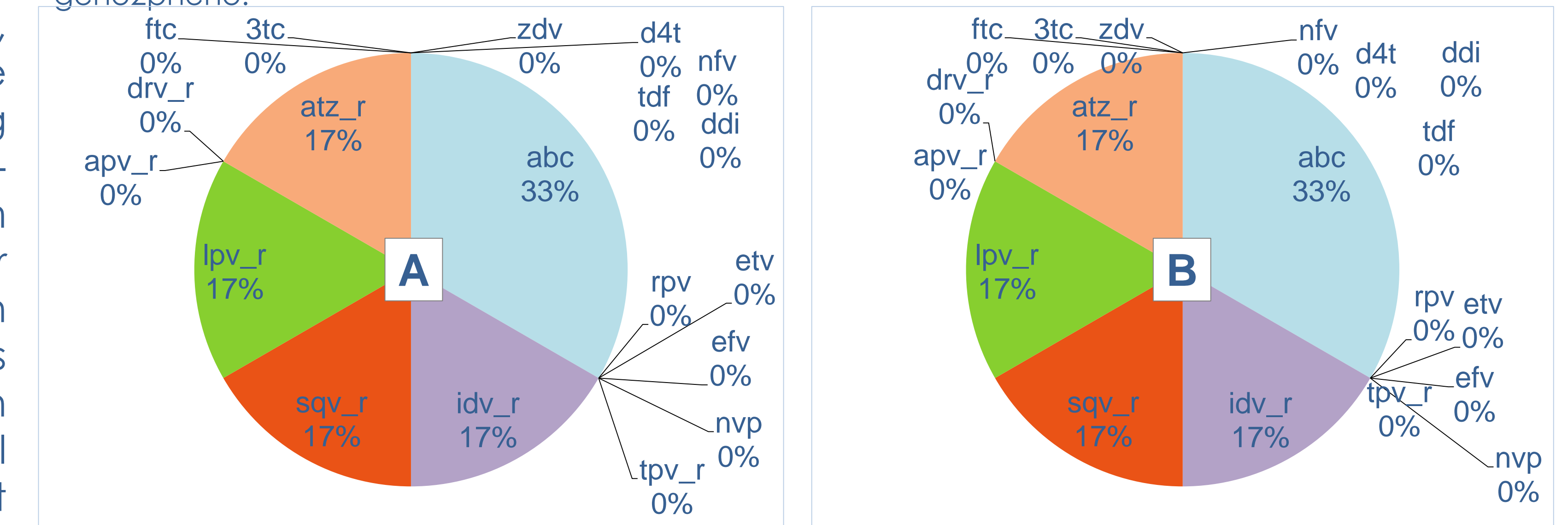


Fig. 4: Repartition per drug of results showing a different interpretation (A) or a one-level increase (B) for VS among specimens showing same interpretation results between SD and G2P.

## Conclusions

- Laboratories performing DR testing should be aware of alternative interpretive systems which could be used to supplement their existing DR reports.