

Comparison of three HDV-RNA quantitative commercially available tests in untreated and in myrcludex-B treated patients with hdv related chronic hepatitis in a real-life setting

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Background and Aim. As new anti-hepatitis delta (HDV) therapies are being developed, highly sensitive and reliable quantitative tests are needed. Aim of the study was to compare three commercially available HDV-RNA kits. **Methods.** 92 serum samples from 4 categories of patients were tested for HDV-RNA by 3 assays: RoboGene (HDV-RNA quantification 2.0, Aj-Roboscreen, Germany, LLQ 6 IU/mL), EurobioPlex (HDV qRT-PCR, Eurobio, France, 100 IU/mL) and Dia.Pro (HDV-RNA Quantitation, Dia.Pro Diagnostic Bioprobes, Italy, 50 IU/mL). Total RNA was extracted by EZ1 DSP Virus Kit (Qiagen, Hilden, Germany). **Results.** Group 1: 48 Caucasians with known active HDV-hepatitis [50 years, 56% males, 73% cirrhotics, 64% on tenofovir/entecavir, 80% undetectable HBV-DNA, 50% previously interferon-exposed, ALT 66 (24-304) U/L] had a median HDV-RNA of 5.5 (1.1-7.1), 5.9 (0-8.4), 3.9 (0-6.6) log IU/mL by RoboGene, EurobioPlex and Dia.Pro; viremia tested undetectable in 0 (0%), 3 (6%) and 5 (10%) patients, respectively. Group 2: 15 HBsAg-positive patients [age 42, 27% cirrhotics, 7% HBeAg-positive, 40% on tenofovir/entecavir, 73% undetectable HBV-DNA, 3 with abnormal ALT] had HDV-RNA undetectable with all 3 assays except for one subject who had HDV-RNA 697 IU/mL with Dia.Pro. Group 3 included 9 international quality control sera. The only true-negative sample tested negative by all the 3 assays, while the 8 positive

controls were correctly identified in 100%, 87.5% and 25% of the cases by different assays. Group 4: 21 sera collected during Myrcludex B-treatment. First patient: baseline HDV-RNA was 23,600, 640,006, 12,283 IU/mL; during therapy, RNA progressively declined with both RoboGene and EurobioPlex, till undetectability at week 36; Dia.Pro gave 5 false-negative results. Second patient: baseline HDV-RNA 392,000, 4,248,001, 1,140 IU/mL; RNA declined with the first two assays but not with the last one (2 false-negative results). Overall, the HDV-RNA sensitivity was 100%, 92%, 80%, respectively. **Conclusions.** RoboGene is the most sensitive and reliable test for HDV-RNA quantification.

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