INTRODUCTION AND PURPOSE

The automated VIDAS® system (bioMérieux) using the Enzyme Linked Assays (ELIA) technique is suitable for routine, emergency, specific or complementary testing, notably in infectious diseases diagnostics.

To complete its existing HIV-Hepatitis (HAV & HBV) panel, a VIDAS® Anti-HCV prototype is currently in development allowing qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human serum or plasma. We performed an evaluation of this prototype in terms of sensitivity and specificity compared to 4 already CE-marked tests: Architect® (Abbott), Elecsys® (Roche), Centaur® (Siemens) and Ortho HCV 3.0 ELISA (Ortho-Clinical diagnostics).

METHODS

The VIDAS® Anti-HCV principle combines a two-step enzyme immunoassay indirect sandwich method with a final fluorescent detection (ELFA). Anti-HCV antibodies present in the sample bind with antigens representing the HCV core, NS3 and NS4 proteins (solid phase) and with a monoclonal anti-human IgG antibodies conjugated to alkaline phosphatase (revelation step).

The comparative study performed on 154 tests (132 samples + 22 dilutions) shows that VIDAS® Anti-HCV has a sensitivity equivalent to Elecsys® systems while Ortho HCV and Architect® seem less sensitive for low positive samples.

RESULTS

1. SENSITIVITY:

Performed on 402 positive samples, this analysis demonstrated the correct antibody detection of the VIDAS® Anti-HCV assay independently of the HCV genotype with a large majority of index values (S/CO) higher than 10: 87% versus 74.1% for Architect®.

2. SPECIFICITY:

- The study performed on the 5216 blood bank donor specimens demonstrated a high specificity of 99.71% [99.52%-99.83%].
- In the comparative specificity study performed on 450 negative samples, VIDAS® Anti-HCV showed comparable performances to the 4 other tests with <1% of discrepancy.

CONCLUSION

Evaluation of VIDAS® Anti-HCV sensitivity and specificity showed that this new prototype VIDAS® assay is as performant as other already CE-marked tests, notably Architect® and Elecsys® assays.