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## Detection of acute hepatitis E and seroprevalences in Germany with new recomWell HEV in comparison to Wantai HEV

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**Introduction:** Being underdiagnosed for a long time, the hepatitis E virus (HEV) is now known to be endemic in Europe and often described as the most frequent viral cause for acute hepatitis. HEV ELISA test systems are used routinely as screening assays in serological diagnostics and for epidemiological studies. In this evaluation, the performance of the improved versions of *recomWell* HEV IgG, IgM, distributed since 06/2015, was compared to Wantai HEV IgG, IgM. Both brands represent the two most commonly used commercial HEV ELISA assays in Europe.

**Material & Methods:** In order to detect seroprevalences in Germany, 200 sera from healthy blood donors (Bavarian Red Cross) have been analyzed with *recomWell* HEV IgG (new & previous version) and Wantai IgG. Diagnostic sensitivity of *recomWell* HEV IgM (new) and Wantai IgM was evaluated using 89 well-defined samples from patients with confirmed acute HEV infection. Subsequent follow-up samples from one PCR positive patient have been analyzed with both ELISA IgM assays. Diagnostic specificity of *recomWell* HEV IgM (new) and Wantai IgM was determined with a HEV panel consisting of 359 samples (200 sera from blood donors and 159 sera from patients with clinical suspicion of non-E-hepatitis confirmed as HIV, HCV, HAV, Parvovirus B19, EBV, or CMV positive).

**Results:** Analysis of 200 German blood donors results in similar HEV seroprevalences for *recomWell* IgG (33%) and Wantai IgG (32%). The clear improvement in sensitivity is demonstrated by the comparison of the new (33%) and previous version (18.5%) of *recomWell* HEV IgG. With respect to diagnostic specificity, both *recomWell* IgG and Wantai IgG demonstrated a very good and comparable performance (data not shown). With 98.9% *recomWell* HEV IgM shows excellent diagnostic sensitivity. Only one serum from a total of 89 was not found positive, whereas Wantai HEV IgM missed 6 sera, reaching a sensitivity of 93.3%. Analysis of paired samples demonstrates that *recomWell* HEV IgM detects IgM specific antibodies over a long period starting at the end of the viremic phase. Interestingly, Wantai HEV IgM is not able to detect specific antibodies in any sample of this PCR positive individual. IgG seroconversion was confirmed (data not shown). Both test systems, *recomWell* HEV IgM and Wantai HEV IgM, show a convincing specificity. Only 5 from 359 sera were found positive by each assay, resulting in a diagnostic specificity of 98.6%.

**Conclusion:** The new *recomWell* HEV IgG, IgM assays show an excellent performance. Diagnostic sensitivity for IgG antibodies is similar to Wantai HEV IgG, reflected by the determination of comparable seroprevalences for German blood donors. Achieving a diagnostic sensitivity of 98.9% *recomWell*, HEV IgM performs better compared to Wantai HEV IgM with 93.3% and is highly suitable for the detection of acute hepatitis E.

### Biography

F Struck has an expertise in Serodiagnostics of Infectious Diseases for 20 years, and is employed as a Project Manager of Infections and Autoimmune Diseases at Mikrogen GmbH since 2008.

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