Detection of acute Hepatitis E and seroprevalences in Germany with new recomWell HEV in comparison to Wantai HEV
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Abstract
Being underdiagnosed for a long time, the Hepatitis E virus (HEV) is now known to be endemic in western countries due to zoonotic transmission, e.g. by raw meat. Seroprevalences in Europe can vary between 0.5% and 52%. Apart from geographic region and study cohort; the sensitivity of the used serological assay has a major impact on the seroprevalence data.
In several European countries HEV was described as the most frequent viral cause for acute hepatitis. Furthermore, HEV is associated with several extrahepatic manifestations, like e.g. with neurological diseases. Besides viral RNA detection via PCR, the detection of specific IgM antibodies confirms an acute HEV infection.
Mikrogen offers its improved versions of recomWell HEV IgG, IgM ELISA assays since 2015 as avenues for epidemiological studies and for acute hepatitis diagnostics. In this study the performance of the new recomWell HEV kits has been compared to Wantai HEV IgG, IgM, which is known for its high sensitivity. Both brands represent the two most commonly used commercial HEV ELISA assays in Europe.

Results

![Graph showing seroprevalences and diagnostic sensitivity](image)

**Figure 1**: Seroprevalences in Germany (200 sera from healthy German blood donors), **Figure 2**: Diagnostic sensitivity using 89 well-defined samples from patients with confirmed acute HEV infection (clinical signs, IgM and IgG positive reactivity confirmed with different ELISA assays)

Conclusion
The new recomWell HEV IgG and IgM assays show an excellent and improved performance. The diagnostic sensitivity for IgG antibodies is similar to Wantai HEV IgG. The finding is also reflected by the determination of comparable seroprevalences (32/33%) for German blood donors. This diagnostic performance needs to be considered when looking at published comparative studies, where mainly the previous version of recomWell HEV IgG has been used (blood donor seroprevalence of around 18%).
Yielding a diagnostic sensitivity of 98.9% recomWell HEV IgM performs better compared to Wantai HEV IgM with 93.3%. Therefore, recomWell HEV IgM is highly suitable for the detection of acute Hepatitis E.