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## **DETECTION OF ANTIBODY TO HEPATITIS E VIRUS (HEV) USING TWO NEW RECOMBINANT PROTEINS**

A new enzyme immunoassay (EIA) for the detection of IgG anti-HEV (IgG-EIA) or total anti-HEV activity (t-EIA) in serum specimens was developed using 2 new recombinant proteins. These EIAs were evaluated using 4 panels of serum specimens obtained from (1) acutely HEV infected patients (n=81); (2) patients with non-A, non-C hepatitis (NANCH) (n=84); (3) normal blood donors (BD) from non-endemic regions (n=552); and (4) from experimentally infected chimpanzees (n=32). Both EIAs detected anti-HEV activity in all specimens from acutely HEV infected patients. When BD were tested, more than 15% of specimens were found IgG anti-HEV positive. All BD anti-HEV positive specimens were tested with overlapping synthetic peptides (n=71) spanning the entire HEV open reading frame 2 (ORF2) encoded protein. More than 90% of the anti-HEV positive BD specimens immunoreacted with an average of 15 synthetic peptides derived from different regions of the HEV ORF2 protein. These data suggest that the IgG-EIA is at least 90% specific in detecting remote HEV infections. All panels were additionally tested for IgG anti-HEV activity by 2 commercially available EIAs, EIA-1 and EIA-2. The test results for NANCH and BD panels were concordant for 74.7% and 79%, respectively, between IgG-EIA and EIA-1, for 75% and 79%, respectively, between IgG-EIA and EIA-2, and for 56% and 91.5%, respectively, between both commercial EIAs. In the absence of a gold standard the accuracy of these EIAs was assessed by the computer program based on a maximum likelihood approach using a "latent class" model. This analysis estimated the IgG-EIA sensitivity and specificity to be within the range 93%-100% and 95%-100%, respectively, for different serum specimen collections.

In conclusion, the new IgG-EIA and t-EIA developed in the present study are highly specific diagnostic assays for the detection of anti-HEV activity in serum specimens obtained from different epidemiologic settings.

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