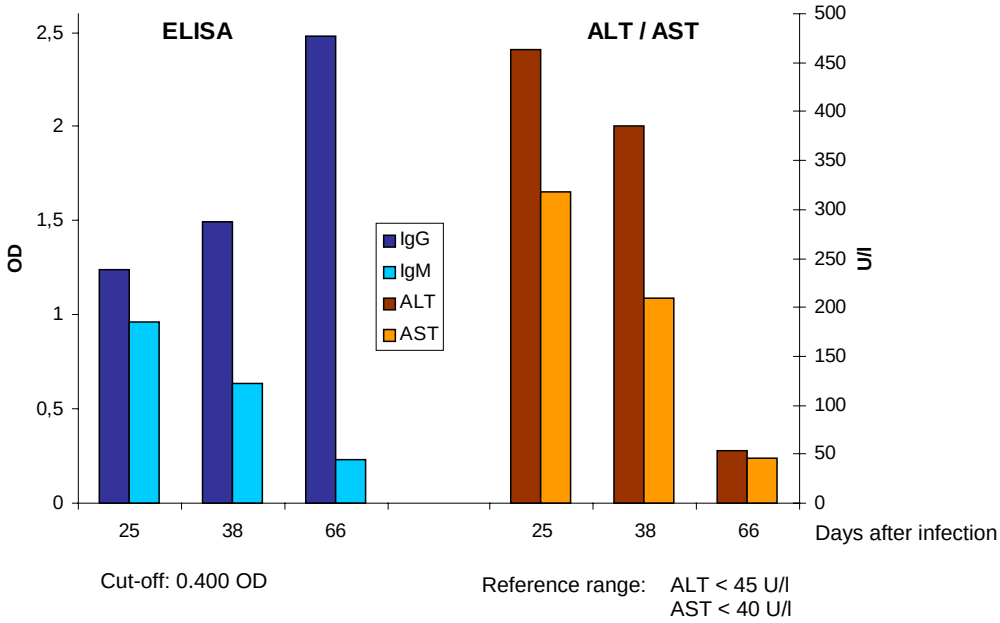
Improvement of viral hepatitis screening (Non A-C) by sensitive Hepatitis E virus serology

Despite successful hepatitis A and hepatitis B vaccination viral hepatitis infections (hepatitis A-E) belong to the most important infections worldwide. Hepatitis B (hepatitis D) and Hepatitis C infections are caused parenterally, while hepatitis A and hepatitis E infections are usually transmitted by fecal-oral route. Hepatitis E infections occur especially in developing countries of Africa, the Middle East, Southeast and central Asia, Middle America (especially Mexico) and South-America. But nevertheless HEV infections have also been reported in industrialised countries among individuals without any travel history to endemic areas. Increasing evidence indicates that HEV is a zoonotic disease. Reports of autochthonous HEV infections in non-endemic regions suggest swine and other animals as possible source of infection. The importance of HEV infections is reflected by a mortality rate of approx. 20.0% in pregnant women and 0.5-4.0% in males and non-pregnant females.

Correlation of *recom*Well HEV results (IgG, IgM) and transaminase (ALT, AST) values



*recom*Well HEV results show good correlation to the data of clinical chemistry (transaminases). IgM and IgG quantification allows to distinguish the acute phase from the convalescent phase of HEV infection

Sensitivity

RT-PCR positive samples[1]	***recom*Well HEV**		**ELISA B**	
(n=14)	IgG	IgM	IgG (n=13)	IgM
negative	0	0	0	3
borderline	1	0	0	0
positive	13	14	13	11
sensitivity (%)	100.0	100.0	100.0	78.6

[1]Universitätsklinikum Charité, Berlin

In comparison to ELISA B recomWell HEV shows a higher sensitivity (IgM results). Sensitive IgM detection reduces the diagnostic window, therefore PCR positive samples are likely to be also positive in *recom*Well HEV IgM.

Specificity

Hepatitis A, B, C positive samples[2]	***recom*Well HEV**		**ELISA B**	
(n=66)	IgG	IgM	IgG	IgM
negative	58	65	60	63
borderline	0	0	0	0
positive	8	1	6	3
reactivity rate (%)	12.1	1.5	9.1	4.6
reactivity rate in blood donors (%) (n=200)	12.0	1.0	4,0 %	3,5 %
[2]positive for (each and/or) HBs, HBe antigen, anti HBs IgM, anti HBs, anti HBc, anti HCV, anti HAV IgM, anti HAV IgG antibodies				

In comparison to ELISA B the *recom*Well HEV shows a higher specificity (IgM results). Reactivity rates are comparable to examinations of blood donors. Especially *recom*Well HEV IgM reduces unspecific IgM results.

HEV-Genotypes

Geographical distribution of Hepatitis E genotypes 1-4 of Human and Pig (according to Frösner et. al, 2004 (lecture), Ling Lu et al, Rev. Med. Virol., 16, 5-36, 2006)				
Genotype	**Human**	**Pig**	***recom*Blot HEV**	***recom*Well HEV**
1	Algeria, Bangladesh, Burma, Chad, China, Egypt, Europe/Germany, India, Japan, Kyrgyzstan, Morocco, Namibia, Nepal, Pakistan, Spain, Sudan, Uzbekistan, Vietnam, Central Africa	no isolates	positive	positive
2	Chad, Mexico, Nigeria, Namibia	no isolates	positive	positive
3	Austria, Canada, Europe/Germany, Greece, Great Britain, Italy, Japan, Korea, Netherlands, Spain, USA	Argentina, Australia, Canada, Great Britain, Japan, Korea, Mexico, Netherlands, Spain, Taiwan, USA	positive	positive
4	China, Japan, Taiwan, Vietnam	Bali, China, Japan (seldom), India, Taiwan	positive	positive

*recom*Well HEV as well as *recom*Blot HEV are capable to detect all four HEV genotypes world-wide.

Summary

- **Recombinant antigens assure a high sensitivity and specificity**
- ***recom*Well HEV identifies all world-wide existing HEV genotypes 1, 2, 3, 4**
- **IgM and IgG quantification reflects the phases of HEV infection**
- **Sensitive IgM detection reduces the diagnostic window**
- **Clarification of unclear PCR results**