Elecsys® HBsAg II immunoassay

Reliable and consistent results for patient oriented decision making

HBV infection accounts annually for 1 million deaths worldwide from cirrhosis, liver failure, and hepatocellular carcinoma. After infection, HBsAg is the first immunological marker detectable in serum and is usually present weeks to months before the onset of clinical symptoms and the appearance of other biochemical markers.[1] Screening tests require high levels of sensitivity to detect HBsAg early during the course of disease as well as the ability to recognize HBsAg mutants.[2]

High specificity in clinical routine and blood donors for less retesting

A literature review on the specificity of the Elecsys HBsAg II revealed equal or superior performance as compared to competitors in the majority of study sites worldwide.[3-5]

Excellent seroconversion sensitivity for early detection of infection

Elecsys HBsAg II showed statistically significant better sensitivity in seroconversion panels to the compared tests.

Seroconversion panel	Total number of days	Mean number of days
Elecsys HBsAg II	51	3.19*
AxSYM HBsAg (V2)	85	5.31*
ADVIA Centaur HBsAg	71	4.44*
HBV-DNA PCR	0	0*

*Table 1: Seroconversion sensitivity: comparison of Elecsys HBsAg II, ADVIA Centaur HBsAg and AxSYM HBsAg (V2) using the PEI calculation model. * Differences between Elecsys HBsAg II and all other immunoassays were statistically significant (Wilcoxon matched pairs test; P < 0.05).[4]*

Excellent clinical sensitivity and reliable detection of relevant HBV mutants and genotypes

The Elecsys HBsAg II shows a high sensitivity for the detection of all stages of HBV infection and HBsAg mutants and can therefore be recommended for clinical diagnostic laboratories and for blood donor screening.

Clinical Sensitivity

Elecsys	Architect	Elecsys	AxSYM
Beijing, China [5] n=32		**Guangzhou, China [5]** n=182	
100% (32/32)	100% (32/32)	100% (182/182)	98.9% (180/182)
Shanghai, China [5] n=83		**Guangzhou, China [5]** n=153	
100% (83/83)	98.9% (82/83)	100% (153/153)	100% (153/153)
Beijing, China [5] n=59		**Shanghai, China [5]** n=228	
100% (59/59)	93.2% (55/59)	100% (228/228)	98.3% (224/228)
Bangkok, Thailand [3] n=114			
100% (114/114)	99.1% (113/114)*		

*Table 2: Clinical sensitivity of HBsAg assays. The Elecsys HBsAg II assay was compared to the routinely used assays in the respective study sites. Positivity of the samples was confirmed by the confirmatory assay (neutralization assay). * Further investigation of the Architect negative sample revealed several mutations (L94S, L97V, 98V, L98V, T123A), of which T123A lay within the 'a' loop potentially affecting recognition by the Architect.[3]*

Recombinant HBV mutants

Mutation		Elecsys	Architect	AxSYM	Centaur
R1	(F8L/R24K/N40R/G43R/L94S/M103I/113A114/M133T/P142L/D144G)	Y	Y	Y	N
R2	(I110L/S113T/T114S/T126I/N131T/F134Y/T143S/G145R)	Y	Y	Y	N
R3	(S132Y/P142S/G145R)	Y	Y	Y	N
R4	(Q129P/F134R/P142L/D144E/G145K/S171F/L175S)	Y	Y	Y	N
R5	(R122I)	Y	Y	Y	N
R6	(R122T)	Y	Y	Y	Y
R7	(C124R)	Y	Y	N	N
R8	(E122I)	Y	Y	Y	Y
R9	(T123N)	Y	Y	N	Y
R10	(G145K)	Y	Y	Y	N
R11	(122RA123)	Y	Y	N	Y
R12	(P142L/G145R)	Y	Y	Y	N
R13	(D144G)	Y	Y	Y	N

Table 3: Recombinant HBV mutants.[3-5] Mutations are located in the highly variable 'a' loop of the HBsAg and reflect the clinically most relevant native mutants found in patient collectives from all over the world described in the literature. Y = positive test result, N = negative test result.

Roche Diagnostics Ltd.
CH-6343 Rotkreuz
Switzerland
www.cobas.com

References

1 Shiels, M.T., Taswell, H.F., Czaja, A.J., Nelson, C., Swenke, P. (1987). *Gastroenterology. Oct;93*(4), 675-80.
2 Weber, B. (2005). *J Clin Virol. Feb;32*(2), 102-12.
3 Louisirirotchanakul, S., Khulpulsup, K., Akraekthalin, S., Chan, K.P., Saw, S., Aw, T.C., Cho, D.H., Shin, M.G., Linn, F. (2010). *J Med Virol. May; 82(5),* 755-762.
4 Mühlbacher, A., Weber, B., Burgisser, P., Eiras, A., Cabrera, J., Louisirirotchanakul, S., Tiller, F. W., Kim, H.S., v. Holden, J., Bossi, V., Echevarria, J.M. (2008). *Med Microbiol Immunol. Mar;197*(1), 55-64.
5 Jia, Y.D., Ma, H., Wei, L., Zhang, X.X., Mao, Y.L., Wang, L.L., Gao, Z.L., Hou, J.L., Zhang, J. (2009). *Med Microbiol Immunol. Oct; 198,* 263-269.