

Market Control 2004-2006
of screening and quantification devices for anti-HBs antibodies

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Detection of anti-HBs antibodies is indicated to control vaccine immunization and to specify the serologic status of an Ag negative HBs/anti HBc positive subject. In 2002, the results of the CNQ showed a wrongly negative result for one reagent and in 2001 a reagent vigilance report described the lack of sensitivity of one reagent.

As one of its missions, Afssaps has set up a market control of reagents for screening and quantification of anti-HBs antibodies. This control consisted on the one hand, in studying the behaviour of the reagents in terms of the recognition of a panel of 177 native samples with as reference the European Common Technical Specifications (CTS; at least 98% sensitivity and specificity) and on the other hand, testing the accuracy of the reagents and the compliance of the stated detection limit using series of dilutions to the international standard (in serum and plasmatic medium) taking into account the existence of CTS (the analytical sensitivity must be at least 10 UI/l). The instruction for use were studied regarding the essential requirements of 98/79/CE Directive 98/79/CE.

The results show that out of the 15 reagents tested:

- Two reagents give non-compliant results in terms of recognition of the panel samples as well as an underestimation of the OMS range.
- Two reagents underestimate the OMS range.
- One reagent give "reactive" samples between 0 and 10 UI/l but the instruction for use instructs for them to be considered as negative for vaccinations.

With regard to the instruction for use, 5 are compliant with the essential requirements of Directive 98/79/CE.

Correspondence with details of the results for each reagent was addressed to the manufacturers. On examining these, two manufacturers chose to stop marketing their product and two manufacturers decided to restandardize their reagent. Concerning the instruction for use, certain manufacturers modified these in order to be compliant with the essential requirements of the Directive. For two manufacturers, the discussions are still ongoing.

Thus, because of the actions carried out by the manufacturers after the publication of the results of this market control, it can be concluded that currently the screening and quantification devices for anti-HBs antibodies studied are calibrated in an acceptable way compared to the international standard.

Lastly, the expert group wishes to draw the biologists' attention to the ANAES recommendations on the "Diagnosis and follow-up of viral hepatitis (other than blood, organ or tissue donations)":

- In the event of negative anti-HBs serology following a vaccination control against hepatitis B, before concluding that there is no response to vaccination, Ag HBs and anti-HBc should be looked for so as not to fail to recognize an infection by HBV.
- In the event of anti-HB serology near threshold, a similar attitude should be adopted before concluding the existence of low level immunization.