Market control 2004-2005 Syphilis (anti-*Treponema pallidum* serology)-Afssaps

Afssaps (French Health Products Safety Agency) has managed a Market control of 11 in vitro diagnostic medical devices (5 ELISA , 5 rapid tests, 1 similar product) marketed in France used to detect anti -*Treponema pallidum* antibodies. The aim of this comparative evaluation was : ① to control the sensitivity and specificity of the devices with the help of a panel of 100 sera (50 negatives and 50 positives, validated clinically and biologically), ② To evaluate the limit of detection with the use of dilutions of the WHO serum ③To evaluate the profile of the devices with ten positives samples of Lyme disease serology ④To study the conformity of the instruction for use to the essential agreement of the European directive 98/79/EC. Within the 11 devices which have been controlled, 4 devices which are rapid tests have given a lot of false negatives results on the 50 positives sera tested. In another way, the study of the instructions for use leads to inform some manufacturers that they weren't in conformity with the in vitro medical devices directive 98/79/EC. After several consultations of the manufacturers, the 4 devices with the worst performances in comparison to the other tested devices have been withdrawn of the market by the manufacturers in charge of the device and the instructions for use have been modified and put in conformity.