

Market control based on package leaflets of serology
reagents for the Lyme borreliosis
(molecular biology techniques excluded)

November 2016

The french Ministry of health referred to the High Council of the Public Health (HCSP) in 2012 to assess the knowledge on the epidemiology, the diagnosis and the treatments of the Lyme borreliosis. The report of the HCSP, dated March 28th 2014, is on it's website since December 2014. (<http://www.hcsp.fr/explore.cgi/avisrapportsdomaine>).

For this report, the ANSM had established a current situation of biological diagnosis reagents by collecting the data in the IFU supplied by the manufacturers. The report of the HCSP picks out certain inadequacies in these data, which concern in particular defects of information relative to the composition of reagents and to the assessment of the performances. To prevent these inadequacies, the report of the HCSP states recommendations to the manufacturers of reagents serodiagnosis of Lyme borreliosis. These recommendations take into account the essential requirements of the European directive 98/79/CE and the European recommendations stemming from the scientific consensus of the European Union Concerted Action on Lyme borreliosis (EUCALB). These give, among others, guidelines for the performances expected from reagents. On the basis of the recommendations of the HCSP, a market control was set up by the ANSM. It consisted in sending in 2015 and in 2016, to every manufacturer and for each reagent, non-compliances or remarks raised in their IFU.

The present report, dated January 2017, at the end of the various exchanges of the ANSM with the manufacturers, integrates the modifications or the information relative to the IFU or to the performances supplied by the manufacturers. The report was developed with the support of the National Reference center (CNR) of Borrelia.

61 reagents are put on the market in France by 17 manufacturers. It can be distinguished :

- 40 ELISA and IFI. For these reagents, the majority presents performances corresponding to the recommendations of the HCSP. Without 2 exceptions, their composition consist of antigens of various pathogenic species in Europe or common to these various species.
- 17 d'immuno-dot. The reagents of immuno imprint also present performances corresponding to the recommendations of the HCSP, except one of them as regards the cerebrospinal fluid. The composition of the antigens of immuno imprint consists of antigens belonging to the various pathogenic species in Europe or common to these various species.

Commitments on new versions of IFU or the complements to study are in progress for 10 manufacturers to improve the concordance with the recommendations of the HCSP. One manufacturer stops to put reagents on the market.

- 3 rapid tests and 1 self-testing device. Their methods of evaluation still require follow-up studies to allow the validation of their sensibility and their specificity. Furthermore, the use of an autodiagnosis device is difficult to justify considering the clinical peculiarities of the Lyme borreliosis, besides the insufficiency of its performances and the non-compliance observed. ANSM has already committed actions against the manufacturers of these tests, which could lead to administrative measures in case of no compliance.

In this report, the ANSM maintained the recommendations intended for the manufacturers and completed them by recommendations intended for the users.