

### **Market Control 2004-2006 of Cholesterol-HDL assay devices**

Serum cholesterol-HDL concentration (C-HDL) is a key component of the biological evaluation of the cardiovascular risk. An erroneous C-HDL value can modify the estimate of risk and consequently the therapeutic management of the patient. Taking into account of new methods of direct assay on the market, and of the international and national recommendations regarding diagnosis and of the follow-up of dyslipidemias (Afssaps, NCEP), Afssaps has set up a control of the market for these devices.

The evaluations were carried out on a panel made up to include the limiting values between which analytical quality is essential for correct patient management. Twenty C-HDL assay reagents by direct method were listed on the market, and 38 adaptations were evaluated according to a protocol drawn up by an expert group.

The results of the technical assessment demonstrate appropriate performance in terms of accuracy for concentrations within the decisional target values for 21 adaptations ; the accuracy is compliant for all of the devices. A classification of the reagent - analyzer couples is proposed according to the total error value observed, and the clinical impact likely to result from it.

Concerning the instruction and according to the directive 98/79/CE, some nonconformities and/or remarks were raised, in particular : inaccuracy or lack of indication on the standardization system , risk thresholds and results of analytical performances or interferences.

After the opinion of the DMDIV National Commission, Afssaps recommends the following points, more particularly to the manufacturers, concerning the evaluation of C-HDL assay devices:

- Accuracy : the device, and the reagent - analyzer couples, must be correlated with the available reference measurement, ultracentrifugation coupled with cholesterol quantification using the Abel-Kendall technique in the fraction not precipitated by heparin-MnCl<sub>2</sub> reagent and with recognized and available higher-order reference materials. The concentrations of the samples chosen to make a correlation study must cover the whole measurement range, including in the low values located between 0,20g/L and 0,40g/L ; device bias compared to the reference technique must be indicated in the instruction for use.
- Relevant Interferences : in addition to the interferences generally looked for (haemoglobin, lipids and bilirubin etc.), the following interferences should also be included: dysgammaglobulinaemia, Mg<sup>++</sup> reagents.
- Clinical Reference Values : these must be in agreement with international and national recommendations and correspond to the currently defined risk thresholds: the recommendations of the NCEP updated by ATP III and reviewed by Afssaps in France correspond to risk thresholds.

The information relative to these items must appear clearly, where necessary, in the instruction for use.

The report can be consulted on the site: [www.afssaps.sante.fr](http://www.afssaps.sante.fr)

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