Assessment of the market of rapid diagnostic tests for influenza

The French National Agency for Medicines and Health Products Safety (ANSM) carried out an assessment of the market of rapid diagnostic tests for influenza after a case was filed with the Directorate General of Health in August 2012. The assessment involved evaluating the performances of the devices present in the market, focusing on their sensitivity, based on the documents provided by their manufacturers.

Twenty rapid diagnostic tests for influenza were determined to be suitable for sale in the French market. The instructions for use of the different devices showed that while the design, sample type, reading time, and storage conditions for all products in the market are comparable, the display of responsiveness to the various known strains, the display of detection limits, and the availability or lack of quality controls differs.

In order to allow the consistency the results from the various rapid diagnostic tests for influenza (current and future), the ANSM is issuing the following recommendations to manufacturers:

ANSM recommendations 2013

- Specify the nature of the antigen(s) targeted by the test's antibodies

- Measure the detection limits using qRT-PCR, expressed in number of equivalent copies/ml

- Compare the rapid diagnostic tests for influenza with the higher-level reference technique, the qRT-PCR

- In each device, apply a sufficient number of positive and negative quality controls

- Confirm the tests with recent seasonal influenza virus strains (i.e. less than 5 years old) that represent the various types and sub-types of influenza virus A and both lineages of virus B (B-Yamagata and B-Victoria). If zoonotic infections arise, especially in the case of a pandemic, performances must be reassessed with the new strain.