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Quantification of the haemagglutinin in monovalent influenza vaccines by a latex agglutination assay (LAA) as an alternative to the single radial immunodiffusion (SRID) assay

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To formulate inactivated influenza vaccines, the concentration of haemagglutinin (HA) must be accurately determined. The standard test currently used to measure HA in influenza vaccines is the single radial immunodiffusion (SRID) assay. The SRID assay is a cumbersome technique presenting a number of drawbacks such as low sensitivity and interference by some adjuvants. We developed a very simple, sensitive and rapid alternative HA assay using latex agglutination. The LAA uses the Spherotest® technology, which is based on the agglutination of HA-specific immunoglobulin-coated latex beads, which bind to the HA. The amount of HA in a sample can then be calculated from the level of bead agglutination by a simple absorbance measurement. A standard curve is generated using serially diluted HA reference protein. The results show that for monovalent A/H5N1 and A/H1N1 vaccines, the LAA demonstrated equivalent linearity, accuracy and precision as compared to the SRID assay. Moreover, unlike the SRID assay, LAA enables HA quantification in AlOOH-adjuvanted vaccines and in emulsion-based adjuvanted vaccines without interference. In addition, LAA was found to be more simple, rapid and sensitive than SRID. In conclusion, LAA may be useful to rapidly and accurately quantify the influenza HA protein in monovalent vaccines, especially in those formulated with low amounts of HA in the presence of an adjuvant.

Biography

Sophie Buffin joined the Research department of Sanofi Pasteur in 2005 with a Master's degree. She is currently a Ph.D. student at the University of Lyon.

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