## Establishment of in vitro assays for the potency of the influenza vaccines based on the macrophage activations

## Content

Potency of inactivated influenza vaccines have been measured as a content of hemagglutinin (HA) antigen possessing the biological activities by single radial immunodiffusion (SRID) assay based on antigen–antibody interactions. Although this assay is a golden standard for measuring vaccine potency, it takes long time to prepare appropriate strain-specific reagents. Therefore, we developed a new potency assay for inactivated whole virion vaccines, requiring no specific antibody, based on the activation of NF-kB/AP-1 or ISG in vitro culture of human macrophages. Inactivated influenza whole virion vaccines induced macrophage activation in a dose-dependent manner. This activity was also well correlated with the HA antigen content by the standard SRID assay and serum antibody titer and protection from challenge virus infection in vaccinated mice when the vaccine was subject to heat inactivation. These observations demonstrate the newly developed assay is useful for measuring the potency and evaluating the stability of inactivated whole virion vaccines.

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Vaccines and antivirals

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