

VaxArray: Eliminating the Need for Animals for Vaccine Potency Testing

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The VaxArray platform is based on a multiplexed immunoassay and is designed to replace animal testing of vaccine potency. The first application of this technology focused on influenza vaccines. Specifically, the performance of rapid (2 hr) VaxArray assays for influenza hemagglutinin (HA) and neuraminidase (NA) was investigated. We evaluated the use of these assays to assess the potency of HA and NA of an A/H3N2 subunit vaccine by determining the correlation between the amounts measured by VaxArray and the immunogenicity in mice (all animal use was carried out in accordance with all applicable animal care and use laws, regulations, and guidelines, and that the study was approved by the appropriate Institutional Animal Care and Use Committee). The antibody response after one and two doses of five formulations of the vaccine ranging from 5 mg/mL to 80 mg/mL of HA, was measured by hemagglutination inhibition (HAI) and neuraminidase inhibition (NAI) assays. For hemagglutinin, vaccine potency determined by VaxArray was equivalent to potency measured single radial immunodiffusion and these amounts were predictive of immunogenicity, with excellent correlation between potency measured by VaxArray and the HAI geometric mean titers (GMT). Likewise, the amount of NA measured by VaxArray was predictive of the NAI GMT. The VaxArray NA assay reported non-detectable levels of intact NA for a sample that had been heat degraded at 56 C for 20 h, demonstrating that the assay measures the native, active form of NA. Importantly, the force degraded sample induced low HAI titers and the NAI titers were not measurable, supporting the conclusion that the VaxArray HA and NA assays measure the immunogenic forms of these A/H3N2 antigens. This study indicates that VaxArray assays can be used to assess the potency of HA and NA components in influenza vaccines as a proxy for immunogenicity.

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