Influenza Seasonal NA Potency Assay Compatibility with Adjuvanted Vaccines

Overview

The VaxArray Seasonal Neuraminidase Potency Assay (VaxArray NA) is a new tool for Neuraminidase (NA) protein quantification based on a panel of subtype-specific but broadly reactive monoclonal antibodies (mAbs). Multiple antibodies against seasonal A/N1, A/N2, and B-NA strains are printed in an array format on a glass substrate. Signal readout for this multiplexed immunoassay is based on fluorescence from conjugated polyclonal or monoclonal antibody labels.

Many pandemic, dose-sparing, and seasonal vaccines are adjuvanted to increase potency and to reduce the amount of antigen required to elicit a proper immune response. Adjuvants are inherently incompatible with the SRID potency assay. Studies were conducted in order to determine whether the VaxArray Influenza Neuraminidase Potency Assay can successfully be employed to quantify NA in adjuvanted vaccines. The commonly used adjuvants Aluminum hydroxide (Alum) and squalene-based MF59 were tested.

Alum

Mock adjuvanted vaccine samples were formulated by mixing CBER reference reagents with Alum. The resulting mock adjuvanted trivalent mixture was prepared to 15 µg/mL of HA from each subtype and 1.7 mg/mL of elemental aluminum before being analyzed in the VaxArray NA assay. Figure 1 demonstrates the VaxArray NA Assay-determined concentrations for the A/N1, A/N2, and B-NA concentrations compared to the expected NA concentrations based upon the known dilution factor. As shown, the VaxArray Influenza Neuraminidase Assay returned NA concentrations that were within 20% of the expected concentration in a trivalent mixture adjuvanted with Alum.

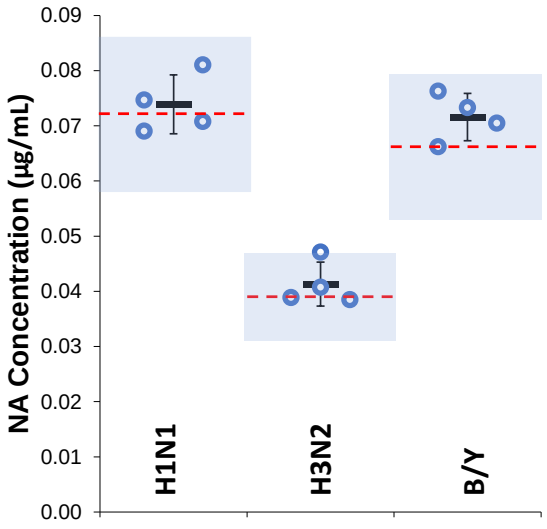

Figure 1 – Quantitative analysis of Alum-adjuvanted trivalent antigen mixture. Blue circles are individual replicates (n=4). Black line is average result. Red dashed line is the expected NA concentration. Blue box is the 20%-of-expected interval.

MF59

The VaxArray NA assay was also tested with MF59, a common squalene-based vaccine adjuvant, as another challenging matrix. The trivalent antigen mixture was prepared to 15 µg/mL of HA from each subtype and

adjuvanted with 19.5 mg/mL of squalene, mimicking a potential adjuvanted vaccine. Quantitative results are shown in Figure 2 for the MF59-adjuvanted trivalent mixture. In all cases, the VaxArray NA Assay demonstrated no effect due to the presence adjuvant. Quantification yielded results consistent with the expected protein content.

Summary

Both Alum and MF59 present analytical challenges for specific protein quantification due to the interference of the adjuvant with other vaccine potency assays. However, the representative studies described here indicate the VaxArray Influenza Seasonal Neuraminidase Assay is a good choice for analyzing NA content in adjuvanted vaccines. The VaxArray Influenza Assay could open up new opportunities for tracking protein content and protein stability, even after the addition of adjuvant to a vaccine, opening the potential for pre-mixing of vaccine and adjuvant.

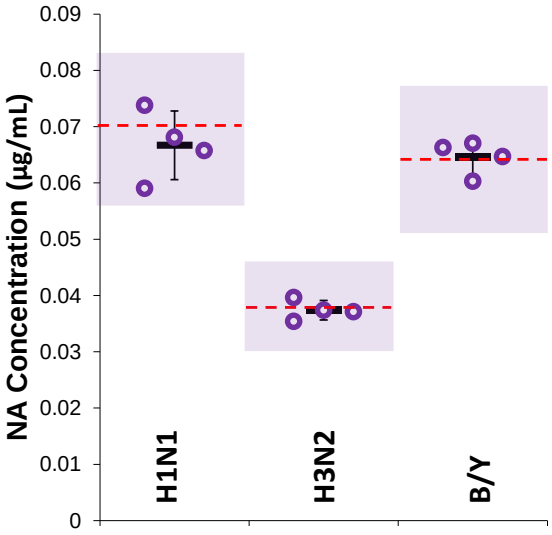

Figure 2 – Quantitative analysis of MF59-adjuvanted trivalent antigen mixture. Purple circles are individual replicates (n=4). Black line is average result. Red dashed line is the expected NA concentration. Blue box is the 20%-of-expected interval.

2100 Central Ave, Suite 106, Boulder, CO 80301
indevr.com | 303.402.9100 | sales@indevr.com