## Efficacy of an Inactivated Monovalent AIV-H5 Vaccine against early challenge with HPAI-H5N8 clade 2.3.4.4b

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Avian influenza type A viruses, members of the family Orthomyxoviridae, are negative-sense, single-stranded, segmented RNA viruses, that are associated with the rapid emergence of new variants compromising poultry health and food security worldwide. Along with biosecurity and systematic surveillance, vaccination can play a major role in controlling HPAI outbreaks by mitigating viral shedding, preventing transmission, and reducing mortality rates in those affected flocks. The objective of this study was to assess the efficacy of a monovalent oil-emulsion vaccine containing an inactivated reassortant AIV with the HA gene of strain Chicken/ME-2018/H5N8, that is closely related to clade 2.3.4.4b of H5N8 viruses currently circulating across Middle East, Europe, Asia and the Americas. To evaluate the efficacy of a single-dose regimen, two-week-old SPF chickens were subcutaneously immunized with 0.5 mL of a vaccine formula containing 10<sup>8</sup>/EID<sub>50</sub> /dose. Three weeks post-vaccination experimental birds were challenged with a wild-type HPAI-H5N8 2.3.4.4b virus having 96.1% homology with the vaccine strain (nucleotide identity). Results demonstrated that the vaccine induced protective hemagglutination-inhibition (HI) antibody titers as early as 2 weeks PV (≥5.0 log2). Vaccinated birds were protected against clinical signs and mortality (100 % survival rate) and viral shedding was not detected in both tracheal and cloacal swabs as from 3 days post-infection. In this context, the monovalent vaccine has demonstrated to be an effective tool to control HPAI challenges in chickens infected with current circulating clade 2.3.4.4b AIV. Results in vaccinated birds concisely show that i) protective HI antibody titers are triggered as early as 2 weeks post-vaccination; ii) birds were protected against clinical signs and mortality, and iii) viral shedding was consistently reduced.

## **KEYWORDS:**

HPAI, H5N8, Clade, Challenge, Outbreak, Vaccine.

