

# Pre-clinical evaluation of the safety and performance of VAX-ID<sup>®</sup> for intradermal delivery of vaccines

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## INTRODUCTION

Intradermal (ID) vaccination has gained renewed interest due to its dose-sparing potential. This route of administration, which targets the dermal layer of skin can save up to 10 times the vaccine dose, decrease volumes kept in the cold chain, and can increase acceptability. ID vaccination is thus particularly attractive for use in mass vaccination campaigns, or for vaccines that are expensive or in short supply. The aim of this in vivo study was to evaluate injectability and suitability of VAX-ID<sup>®</sup> (Figure 1), an ID injection device by Idevax.



Figure 1: VAX-ID<sup>®</sup> intradermal injection device.

## MATERIALS & METHODS

Two 12kg piglets received 19 injections using VAX-ID<sup>®</sup> containing a 32G needle. An injection mixture of NaCl 0.9% and Chinese ink 1:0.15 ratio was injected in 3 sites: neck, back, and abdomen. The injection sites were immediately visually inspected for bleb formation, leakage, and local adverse effects. Next, the piglets were euthanized. A total of 19 tissue samples were collected and immediately fixed in 4% buffered formalin. The samples were stained with hematoxylin and eosin (H&E) for histological analysis.

## RESULTS & DISCUSSION

Visual inspection showed bleb formation (Figure 2) in 95.24% of the samples evaluated, and the average bleb diameter was 0.61cm. The bleb formation is a sign of successful intradermal injection. With VAX-ID<sup>®</sup> the bleb is less pronounced than with standard of care and presents a unique donut-like shape due to the device design.

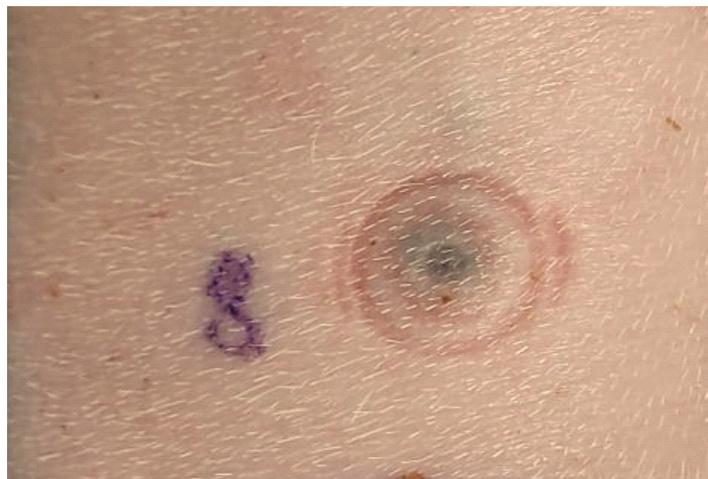
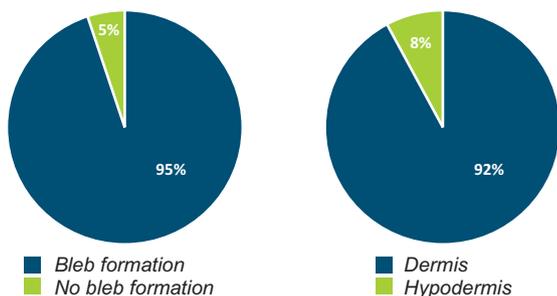


Figure 2: Bleb formation post injection with VAX-ID<sup>®</sup> 32G.

ID injection using VAX-ID<sup>®</sup> showed dye deposition mainly in the dermis 91.67%, reaching both the papillary and reticular dermis (Figure 3). Transient erythema was observed in the injection site, micro bleeding was only noticed in two samples, while macro bleeding was not observed in any of the samples.

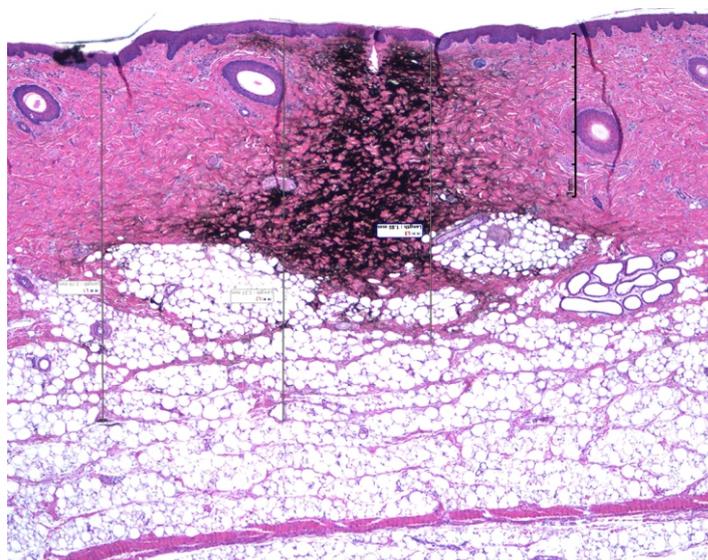


Figure 3: Piglet skin dye deposition post injection with VAX-ID<sup>®</sup> 32G.

## CONCLUSION

VAX-ID<sup>®</sup> containing a 32G needle was able to successfully inject the dye in the dermal layer of the skin in 12kg piglets, as confirmed by the histological evaluation. The device induced bleb formation after injection, indicating a successful intradermal injection. No serious adverse events were observed.