Duration of viability of desiccated porcine reproductive and respiratory syndrome virus in broken vials of Ingelvac® PRRS modified live vaccine

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Summary

Viable porcine reproductive and respiratory syndrome (PRRS) virus was isolated on Days 0, 1, 2, 3, 7, and 14 from bottles of modified live PRRS vaccine broken on Day 0 and exposed to air. PRRS virus was not isolated from nearby surfaces.

Key words: swine, porcine reproductive and respiratory syndrome virus, modified live virus vaccine, broken vaccine vials, biosecurity

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Resumen – Duración de la viabilidad del virus del síndrome reproductivo y respiratorio porcino desecado en viales rotos de vacuna viva modificada PRRS Ingelvac®

El virus viable del síndrome reproductivo y respiratorio porcino (PRRS) fue aislado los Días 0, 1, 2, 3, 7, y 14 de botellas rotas de vacuna viva modificada de PRRS en el Día 0 y expuestas al aire. El virus de PRRS no fue aislado de superficies cercanas.

Résumé – Durée de la viabilité du virus du syndrome reproducteur et respiratoire porcin lyophilisé dans des fioles brisées du vaccin vivant modifié Ingelvac® PRRS

Du virus du syndrome reproducteur et respiratoire porcin (PRRS) viable fut isolé aux Jours 0, 1, 2, 3, 7, et 14 à partir de bouteilles brisées de vaccin PRRS vivant modifié au Jour 0 et exposées à l'air. Le virus PRRS n'a pas été isolé des surfaces avoisinantes.

This project was performed in response to a concern by a swine veterinarian that broken bottles of Inglevac PRRS MLV vaccine (Boehringer Ingelheim Vetmedica Inc, St Joseph, Missouri) could pose a biosecurity risk by disseminating modified live porcine reproductive and respiratory syndrome virus (PRRSV). Breakage during shipment of Inglevac PRRS MLV vaccine bottles is not uncommon. Clients frequently return broken bottles to the clinic for a refund. Publications regarding viability of the modified live PRRSV in Inglevac PRRS MLV vaccine were not found in a search of the scientific literature. The objective of this study was to test the viability of modified live PRRSV in broken bottles of Inglevac PRRS MLV vaccine following exposure to room air.

Materials and methods

Viability of modified live PRRSV was evaluated over a 2-week period of exposure to room air. Sixty bottles of Inglevac PRRS MLV vaccine containing the desiccated form of modified live PRRSV were each double-bagged in sterile plastic bags (Whirl-Pak; Nasco, Ft Atkinson, Wisconsin). The bottles were then manually broken using a hammer (Day 0) such that at least the bottom quarter of the bottle was broken into pieces of glass ranging in approximate size from 0.1 to 2 cm in the longest dimension. The plastic bags were unrolled and the broken bottles and their contents were then aseptically and carefully poured into open sterile plastic cups, which were placed on a cart in an office. The 60 broken bottles were randomly allocated to six sampling groups of 10 bottles each. Room temperature and relative humidity were recorded on sampling days. Samples were collected from 10 broken bottles on each of Days 0, 1, 2, 3, 7, and 14 by adding 2 mL of sterile vaccine diluent to each cup and manually agitating the cup to reconstitute the vaccine. Sterile syringes and needles were used to recover the reconstituted vaccine samples from each cup. Each sample was placed in a sterile blood collection vial and identified. One positive and one negative control were submitted at each sampling period. The positive control consisted of reconstituted vaccine from an unopened, unbroken, refrigerated bottle of vaccine. The negative control consisted of sterile vaccine diluent only. Additionally, at each sampling period, a sterile swab was used to sample the outside rim of the cart on which the sterile cups containing the broken bottles were placed. The swab was placed in sterile vaccine diluent in a sterile blood collection vial. Samples were placed on ice, immediately hand carried across the street, and submitted to the Purdue University Animal Disease Diagnostic Laboratory (PUADDL) for virus isolation using swine pulmonary alveolar macrophages.[1,2]

Fisher's exact test (GraphPad Instat version 3.00 for Windows 85; GraphPad Software,

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San Diego, California) was used to compare the numbers of samples (broken bottles) from which PRRSV could be isolated among sampling days. A value of $P < .05$ was considered statistically significant.

Results

Room temperature ranged from 22.1°C to 24.2°C and relative humidity ranged from 35% to 53% on sampling days. PRRS virus was isolated from 10 of 10 samples collected on Days 0, 1, 2, and 3; seven of 10 samples collected on Day 7; and eight of 10 samples collected on Day 14. The desiccated vaccine was consolidated and difficult to dilute on Days 7 and 14. Swab samples from the area surrounding the open cups were all negative for PRRSV isolation. All negative controls were negative for PRRSV isolation. All positive controls were positive for PRRSV isolation. The number of broken bottles from which PRRSV could be isolated was not statistically different among sampling days.

Discussion

These results indicate that desiccated Inglevac PRRS MLV vaccine is viable when exposed to room air at temperatures between 22.1°C and 24.2°C for at least 2 weeks. The consistency of the vaccine on Days 7 and 14 might have impaired complete dilution; therefore, negative results might have been obtained because recovery of all viable vaccine virus was prevented. Moreover, virus isolation was performed using swine pulmonary alveolar macrophages because that was the standard operating procedure for PRRS virus isolation at PUADDL at the time of sample submission. Use of another cell line, such as MARC-145 or CL2621, might have enhanced the ability to isolate virus.

The negative results obtained from swab samples of the area surrounding the cups containing broken bottles suggest that under the conditions of this study, the PRRSV in the vaccine did not exit the broken bottle to contaminate surrounding surfaces in the office. However, dissemination of the virus was likely highly dependent on the controlled study conditions and may not reflect real-world situations associated with damaged product.

The positive virus isolates through Day 14 indicate potential biosecurity issues because of viable virus in broken bottles of vaccine; however, the negative surface-swab sample results indicate a probable low risk of virus dissemination from undisturbed broken vaccine vials.

Implications

- Viable MLV PRRSV can be isolated from broken bottles of vaccine exposed to room air for at least 14 days at temperatures of 22.1°C to 24.2°C.
- Under conditions of this study, detectable vaccine virus did not disseminate to surfaces immediately surrounding sterile cups containing the broken bottles of vaccine.

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