



Coccivac® Vaccines are ALV-J Negative: Production Methods are Proven to Destroy the ALV-J Virus

A study was conducted in conjunction with Dr. Jack Rosenberger, University of Delaware, to test the ability of the processing steps used to prepare Coccivac-B vaccine and Coccivac-D vaccine for their ability to inactivate ALV-J virus. Test samples of typical production material were intentionally inoculated with ALV-J at sequential stages of a mock production of a serial of vaccine. Four replicates of samples were inoculated at 4 points during the production process (16 samples) and tested for ALV-J at the University of Delaware using DNA extraction and PCR. (See materials and methods)

Materials and methods:

Infected feces from a standard production harvest provided the starting material for the study. The feces were excreted from straight-run broiler chickens inoculated with *Eimeria maxima* sporulated oocysts. Post-inoculation, the feces were

collected and blended with water. Eighty ml of the resulting suspension was taken and separated into 4 equal preparations of 20 ml each.

The first preparation (A) was not inoculated and served as a control. The second preparation (B) was inoculated with approximately 10^4 TCID₅₀ per ml of ALV-J virus and the remaining two preparations (C) and (D) were inoculated with the same amount of virus at steps later in the mock production process. All preparations were separately washed with the same volume of water, and concentrated by centrifugation.

The resulting pellets were resuspended to the original volume with water, and the supernatant was collected. The supernatant was treated by centrifugation, resuspension, collection and centrifugation for a total of 3 treatments.

Preparation C was spiked with ALV-J at this stage. All preparations continued in the normal vaccine manufacturing process. Just before the last step (inactivation with beta propriolactone), preparation D was spiked with ALV-J (see diagram).

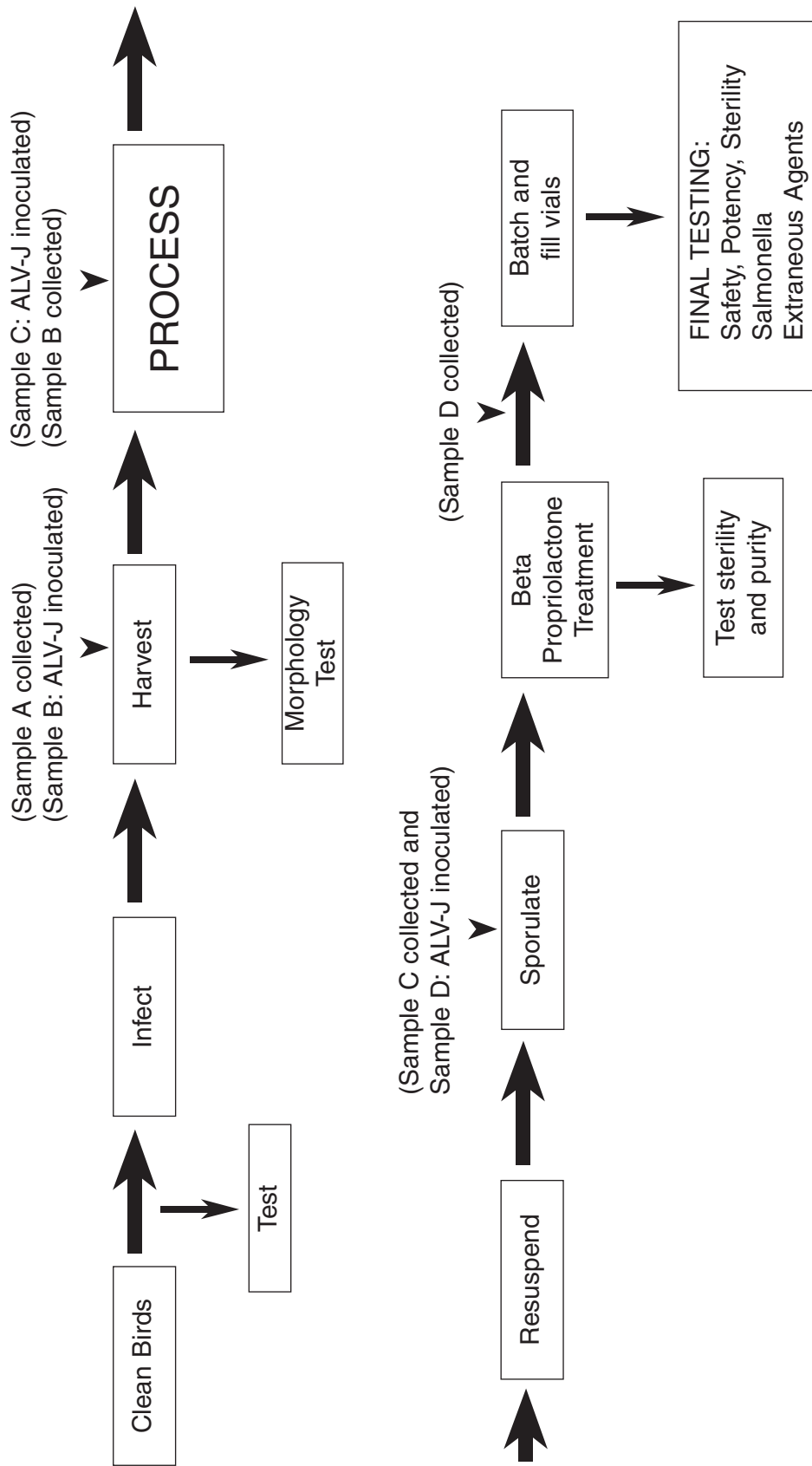
Samples were inoculated at 4 points during the production process (4 groups X 4 sampling points = 16 samples) and collected after the subsequent processing step. The samples were frozen immediately and sent to the University of Delaware to determine the presence of ALV-J using PCR. PCR testing was conducted by Dr. Jack Rosenberger's laboratory according to their established laboratory procedure.

Results:

All 16 samples were found to be negative for ALV-J via DMA extraction and PCR testing.

Key Points

- All samples were negative for ALV-J when tested by the University of Delaware using PCR.
- The Coccivac production process involves several stages designed to eliminate contaminating organisms. Each individual stage eliminated the intentionally inoculated ALV-J.
- The cumulative effect of all of the processes will assure that no Coccivac vaccines have any potential for contamination with ALV-J.



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