Monitoring Johne's ELISA Test Results Across Laboratories

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Abstract

When the same serum sample is repeatedly tested using an ELISA for *Mycobacterium avium* subsp. *paratuberculosis* in different laboratories the overall variation in results can be attributed to various sources. In this study the largest amount of variability was attributed to kit lot. The sources of variability should be considered to assure the delivery of high quality results to clients and decision makers.

Introduction

Johne's disease, caused by *Mycobacterium avium* subsp. *paratuberculosis* (MAP), has been estimated to cost the U.S. dairy industry more than $200 million annually. Serological tests for antibodies play a significant role in control programs for MAP. The objectives of this study were to document the expected variability and identify sources of variability that could be minimized by adoption of standardized techniques a study was designed.

Materials and Methods

Five laboratories using the IDEXX ELISA for MAP were recruited to participate in the pilot. Three serum samples, one negative (NC), one positive (P), and one high positive (HP), were aliquoted and lyophilized. Each laboratory received the three samples. After reconstitution the 3 serum samples were included on all plates when client samples were being tested. Each plate or each run was treated as a separate observation.

Results

Overall 868 plates were run representing 5 kit lots. The data were analyzed graphically to observe variation over time and among kit lots. In addition, a random effects model was used to estimate the contribution of each of the factors (lab, kit lot, well, day-to-day) to the overall variability in S/P ratios. Modeling the S/P ratio for the P sample showed that the largest amount of variation was attributed to kit lot followed by random error and inter-laboratory variation. Variation among the S/P values for the HP sample showed a different pattern with random variation accounting for most of the variation followed by test date and laboratory.

Discussion

These data should be compared to other ELISA based tests to determine comparability in terms of overall amount of variation in the outcome and the proportional distribution of variation attributed to specific factors. Routine monitoring of variation in ELISA results using a standard panel of sera on a national or international basis would help discover sources of error and improve the overall quality control for paratuberculosis serology.

The full text of this work has been submitted to the Journal of Veterinary Diagnostic Investigation for review and publication.