

Multi-level Interpretation of the New IDEXX *M. paratuberculosis* ELISA on Serum and Milk Based on Likelihood Ratio Analysis

M.T. Collins¹, DVM, PhD, DACPVM; N. Djuranovic²; Lisa Estey², PhD; Valerie Leathers², PhD
¹Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin, Madison, WI 53706
²IDEXX Laboratories, Westbrook, ME 04092

Introduction

The new IDEXX ELISA for paratuberculosis measures the concentration of antibody in clinical samples, serum, plasma or milk. ELISA reader results, measured as optical density (OD) units, are transformed to S/P (sample/positive) ratios. Conventional ELISA interpretations employ a single cutoff for interpretation of S/P values as either negative (below the cutoff) or positive (above the cutoff). Prior studies demonstrated a strong correlation of S/P values with the probability animals are shedding *Mycobacterium avium* subsp *paratuberculosis* (MAP) in fecal samples collected at the same time as serum samples by likelihood ratio (LR) analysis, highlighting the clinical value of knowing the magnitude of S/P or equivalent transformed ELISA OD values (Collins *et al*, 2005).

Materials and Methods

LR analysis was performed for data generated using the new IDEXX ELISA kit for paratuberculosis on both bovine serum or plasma samples and milk samples. Bovine serum/plasma samples originated from 221 non-infected and 331 fecal culture-positive dairy cattle. Bovine milk samples came from 649 non-infected and 248 fecal culture-positive dairy cattle. Roughly half of all samples originated from cattle in Europe, and the others from cattle in the US.

Results

ELISA results on serum or plasma samples expressed as S/P values were divided into the following five

ranges: 0.00 to 0.099; 0.10 to 0.199; 0.20 to 0.499; 0.50 to 0.999; and ≥ 1.00 . The percentage of ELISA results in each range for the 321 MAP-infected cows was divided by the percentage of ELISA results in each range for the 221 non-infected cows to derive LRs. The resulting LRs for the IDEXX ELISA on serum/plasma were 0.3, 1.6, 2.4, 16.6, and 101.4, respectively. ELISA results on milk samples expressed as S/P values were divided into the same five S/P ranges: 0.00 to 0.099; 0.10 to 0.199; 0.20 to 0.499; 0.50 to 0.999; and ≥ 1.00 . The percentage of ELISA results in each range for 248 MAP-infected cows was divided by the percentage of ELISA results in each range for the 649 non-infected cows to derive LRs. The resulting LRs for the IDEXX ELISA on milk were 0.2, 0.4, 31.4, 89.0, and 361, respectively.

Significance

The magnitude of IDEXX ELISA S/P results were directly related to the LR. At the highest, so-called "high positive" range, i.e. $S/P \geq 1.00$, the odds such samples originated from MAP-infected dairy cattle was $>100:1$. These LR values can be used in combination with estimates of within-herd prevalence of MAP infection (pre-test probability of infection) to significantly improve decision making based on ELISA results.