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Preliminary validation of an indirect ELISA for diagnosis of Johne's disease in goats

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Introduction

Johne's disease, caused by *Mycobacterium avium* ssp. *paratuberculosis* (MAP), affects a wide range of livestock species, causing chronic and severe enteritis. In the United States, there are currently no serologic tests licensed by the USDA for diagnosis of this disease in small ruminants, although several are marketed for cattle. An accurate test that was legal for diagnostic use domestically would be a valuable tool for goat and sheep producers and veterinarians in the management of Johne's disease. This study provides preliminary validation of a new indirect ELISA for the detection of anti-MAP antibodies in goats.

Materials and Methods

An indirect ELISA was developed based on antigen processed from whole MAP, with an anti-ruminant secondary antibody to target detection of cattle, sheep, and goat anti-MAP antibodies. For preliminary assay validation in goats, the negative cohort consisted of 76 negative serum samples collected from a Johne's-free herd and 10 other confirmed negative samples from the sham vaccinated group of a Johne's vaccination study. From this same vaccination study, 71 test positive samples were obtained for the positive cohort. Based on the resulting data, a cutoff was chosen to maximize the balance of sensitivity and specificity. For comparison, sensitivity was also calculated at the cutoff where maximum specificity of 100% was achieved.

Results

Based on the balanced cutoff determined in this preliminary evaluation, sensitivity of this assay for detection of anti-MAP antibodies in goat serum samples was 76.1% and specificity was 89.5%. If the cutoff was increased to achieve a specificity of 100%, the sensitivity correspondingly decreased to 64.8%. Additional optimization and validation of this assay is ongoing and will allow a better determination of optimal cutoff.

Significance

Diagnosis of Johne's disease in any species poses unique challenges due to the nature of the bacterium and its interactions with the immune system as well as the prolonged course of disease. Currently available technology limits the sensitivity of serology in all species. Depending on the chosen cutoff, sensitivity of this ELISA for goats was 76.1% with specificity at 89.5% and 64.8% with a specificity of 100%, consistent with published data for other assays evaluated for Johne's diagnosis in small ruminants. This assay shows significant promise for use as a herd health management tool in the control of Johne's disease in goats, and will be further evaluated for possible USDA licensure for domestic use in small ruminant species.