

# A Rapid Serologic Test for the Detection of Antibodies to *Mycobacterium paratuberculosis* with Applications for Bovine Practitioners

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## Introduction

A prototype enzyme linked immunoabsorbent assay (ELISA) test has been developed on the IDEXX SNAP™ device to detect antibodies to *Mycobacterium avium* subspecies *paratuberculosis* (MAP), the causative organism of Johne's disease in ruminants. Initial validation studies have been completed utilizing bovine serum as the specimen type. This SNAP test format has potential applications as an animal-side or in-clinic assay for large animal veterinarians who require a rapid test result on symptomatic or suspicious animals. Total assay time is 22 minutes. The purpose of this study was to evaluate the performance of this new MAP ELISA by testing populations of dairy cattle (n = 1276). A comparison of results obtained with the prototype SNAP assay and a USDA-licensed, microtiter-plate antibody test kit was made.

## Materials and Methods

Bovine serum specimens (n = 1276) were collected from 11 different dairy herds and two sire service facilities of varying geographic origin. Herd status was investigated with regard to previous diagnostic test histories (serology and culture), differential observations of herd veterinarians (evidence of symptomatic animals), and with regard to the introduction of replacement cattle into the herds (open vs. closed herd). Sera were tested with the prototype test system and with a USDA-licensed microtiter plate antibody test kit. Quantitative data were recorded for the SNAP test platform by taking densitometric readings of the diagnostic spot at the completion of the test protocol. These values were compared to the sample-to-positive S/P ratios yielded

by the microtiter-plate technique. Regression analyses of these data were performed. SNAP test results recorded by visual observation were also compared to plate test results. This comparison yielded relative agreement levels in final specimen dispositions between these two tests.

## Results

Eleven of the thirteen herds studied were presented with known test histories for paratuberculosis. The percent agreement in test results between the two assay methods utilized for herd groups defined by test histories were as follows: known infected herds - 94.4%; presumed negative herds - 99.1%; herds of unknown status - 96.8%. Regression analysis of quantitative data recorded shows a significant correlation between test results for the two techniques utilized, ( $R^2 = 0.73$ ;  $p < 0.0001$ ; 95% CI). Of the sera tested, 96.6% (1232 of 1276) yielded an agreement in serologic status as determined by the two test methods evaluated.

## Conclusions

The relative sensitivity and specificity of a new lateral flow ELISA test was measured against an established USDA-approved diagnostic product. These data provide evidence of a significant correlation in the performance of the new SNAP test to that of the IDEXX MAP Antibody Test Kit which is manufactured in a microtiter-plate format. Further, the prototype SNAP test yields specimen dispositions which are consistent with the known source-herd histories for the bovine populations studied.