

# Validation of a New IDEXX Johne's Antibody ELISA for Use on Milk Samples

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## Introduction

Johne's disease (JD), also known as paratuberculosis, is a chronic infectious intestinal disease caused by *Mycobacterium avium* subspecies *paratuberculosis* (MAP). Over 68% of US dairy operations are infected with Johne's disease, causing decreased milk production, diminished fertility and a shortened production life. Johne's disease costs producers \$250 per animal per year in infected herds. Lost productivity from Johne's disease is estimated at \$200-\$250 million per year. Regular ELISA testing, followed by control measures based on ELISA results, reduced infection rates from 10% to 3.5% in a recent Wisconsin study. The new IDEXX *Mycobacterium paratuberculosis* Antibody Test Kit (IDEXX *M. pt.* Ab ELISA), based on proven Institut Pourquier technology, has been validated and USDA licensed for use in bovine milk, serum, and plasma samples. It provides fast and accurate detection of MAP antibodies in dairy and beef cattle.

## Materials and Methods

The IDEXX *M. pt.* Ab Test is performed in a microtiter well coated with inactive *M. paratuberculosis* antigen. After the assay protocol is completed, the absorbance of the generated color is measured using a spectrophotometer. The total assay time is less than two hours. Results are calculated by dividing the absorbance of the samples (corrected by subtraction of the mean negative control absorbance) by the mean absorbance of the positive control (corrected by subtraction of the mean negative control absorbance), which results in an S/P ratio. True animal status was confirmed by culture for samples from positive animals and a combination of herd and culture status for negative samples.

## Results

**Milk:** A set of 124 milk samples from culture positive animals was tested on the new IDEXX *M. pt.* Ab ELISA. The sensitivity for this set of samples was 74.2% ( $92/124 = 74.2\%$ ) with 92 of the samples testing positive. A total of 634 negative milk samples were also evaluated. The specificity for this population was 99.8% ( $633/634 = 99.8\%$ ).

**Serum:** The IDEXX *M. pt.* Ab Test Kit detected 127 positives out of 247 serum samples, from culture positive animal. The resulting sensitivity for this sample set was 51.4% ( $127/247 = 51.4\%$ ). A total of 717 negative serum samples were also tested with a specificity of 99.3% ( $712/717 = 99.3\%$ ).

**Plasma:** The test kit detected 45 of the 82 plasma samples as positive, which resulted in a sensitivity of 54.9% ( $45/82 = 54.9\%$ ). A total of 174 negative plasma samples were also tested. The specificity for this population was 100% ( $174/174 = 100\%$ ).

## Significance

Designed to help veterinarians and producers manage the impact of Johne's disease, the newly licensed IDEXX *M. pt.* Ab ELISA has good sensitivity and excellent specificity, minimizing the need for retesting and ensuring quick turnaround time for producers. The test can be run on milk which means producers can request Johne's testing on milk samples that are already routinely evaluated for milk quality. As with any diagnostic test, the *M. pt.* ELISA should be used under the guidance of a veterinarian as part of the farm's overall health management program.