

Controlling Johne's Disease in Dairy Herds with the New IDEXX *Mycobacterium Paratuberculosis (M.pt)* Antibody Test Kit

Presenter: Lisa Lemieux



Johne's Disease Impact and Control

Johne's Disease limits milk production

- Studies show that cows that test positive for Johne's disease:
 - produce less milk^{1,2,3}
 - milk produced has lower fat and protein content^{1,2}
 - higher somatic cell scores^{1,2}
- Dairy NAHMS 2002 study showed that infected cows produce 1,000-6,000 fewer pounds of milk during a given lactation and have significantly lower lifetime production.⁴

References:

1. Byrem TM, Norman HD, Wright JR. 2009. Characteristics of milk ELISA results for Johne's disease in US dairy cows. *Journal of Dairy Science* 92(E-Suppl. 1):386-387(abstr. W8).
2. Fus-Szewczyk MM, Szteyn J, Wiszniewska A. Changes in raw milk quality in herds infected with MAP. *Bull Vet Inst Pulawy* 2006. v50: 69-72.
3. Shawn L.B. McKenna, Greg P. Keefe, Ashwani Tiwari, John VanLeeuwen, Herman W. Barkema Johne's disease in Canada Part II: Disease impacts, risk factors, and control programs for dairy producers. *Canadian Veterinary Journal* 2006; v. 47(11):1089-1099.
4. *Hoard's Dairymen* 2006.

Johne's Disease Impact and Control

Costs to the dairy industry:

- Over 68% of U.S. dairy operations are infected with MAP¹
- MAP costs producers up to \$250 per animal in infected herds.²
- Overall loss to the industry is estimated at \$200–\$250 million per year.³

Johne's disease can be controlled:

- In a recent Wisconsin study, regular ELISA testing, followed by control measures based on ELISA results, reduced infection rates from 10% to 3.5%.

References:

1. Johnes' Information Center. Home page. Available at: <http://www.johnesdisease.org>. Accessed June 29, 2009.
2. Wells S. What is the value of Johne's testing? *Hoard's Dairyman*. April 10, 2003.
3. Healthy cows for a healthy industry. *Hoard's Dairyman*. April 10, 2009.

New IDEXX *M.pt.* Antibody Test Kit

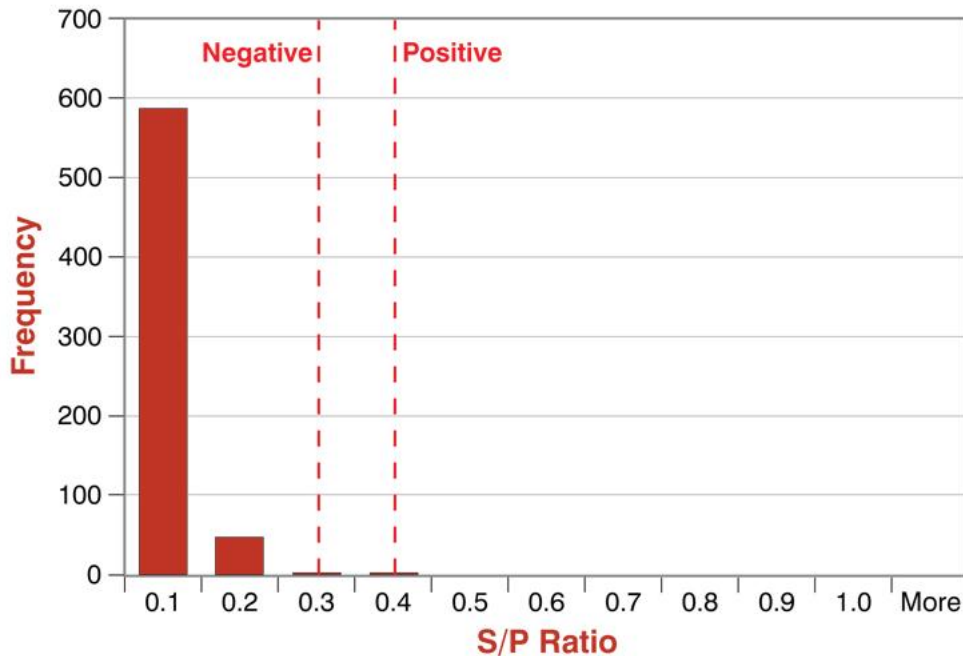
Benefits for labs and producers:

- Proven technology, with a rapid and simple test protocol
 - The flexibility of a single kit that can be run with milk, or serum or plasma samples
- Johne's disease testing on milk samples that are already routinely evaluated for milk quality
 - Eliminates the cost of sample collection
- Superior sensitivity and specificity when compared to other tests on the market
 - Minimizes the need for retesting and ensures quick turnaround time for producers



New IDEXX *M.pt.* Antibody Test Kit Diagnostic Specificity (milk)

Distribution of U.S. and European Negative Populations*



*Presumed negative animals, based on herd history

Performance

- **633 of 634 samples correctly identified as negative**
- **Specificity = 99.8% (95% CI, 99.0–100.0%)**

New IDEXX *M.pt.* Antibody Test Kit Diagnostic Sensitivity Summary (milk)

		Fecal Culture		
		Pos	Neg	Totals
M. pt. ELISA	Pos	92	1	93
	Neg	32	633	665
	Totals	124	634	758

*Expected sensitivity in typical field populations is lower.

Performance

- 124 U.S. and European fecal-culture-positive samples
- Correctly identified 92 of 124 samples as positive
- Sensitivity = 74.2%* (95% CI, 65.8 - 81.1%)

New IDEXX *M.pt.* Antibody Test Kit Reproducibility

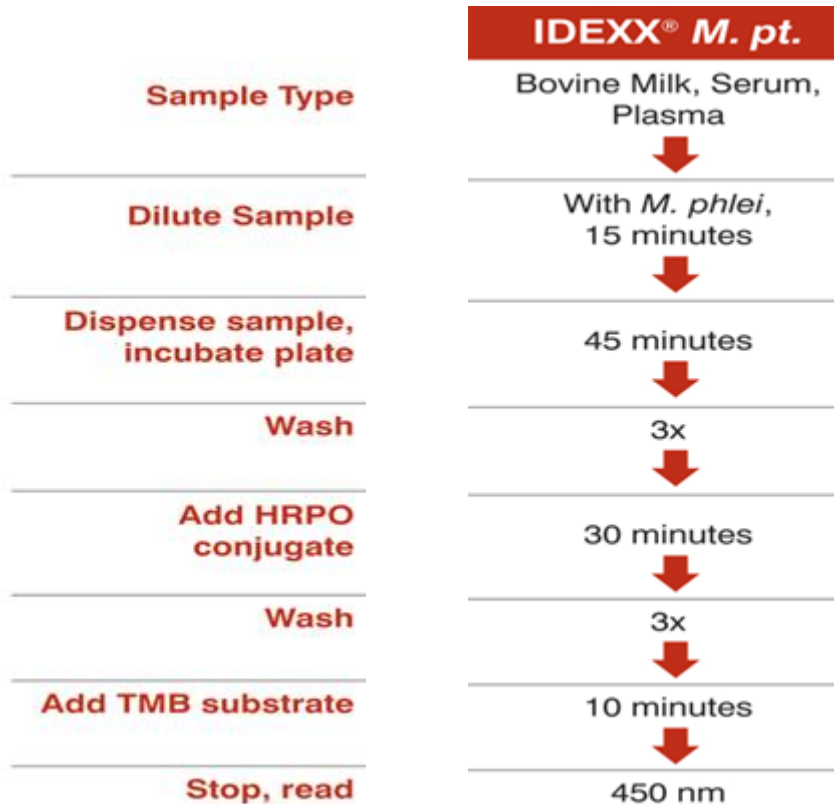
Intra-batch reproducibility:

- Two plates of same batch tested with positive (CV = 7.35%) and negative samples (CV = 3.61%)
- Very uniform row-to-row and column-to-column trends due to excellent uniformity of plate coating procedure

Lot- to- lot reproducibility:

- Seven positive samples tested on 3 different batches. CV ranged between 2.5% - 5.3%
- Very uniform lot-to-lot performance due to excellent optimization process

New IDEXX *M.pt.* Antibody Test Kit Easy to Use, Streamlined Protocol



Key Points

- Results in approximately 100 minutes
- Easy to automate
- Fixed stopping time
- Stable, ready-to-use reagents

New IDEXX *M.pt.* Antibody Test Kit Performance vs. Another *M.pt.* Ab ELISA (Internal Study)

Study Details—Milk

IDEXX <i>M. pt.</i> Antibody Test Kit Sensitivity = 52%; specificity = 98%		
	Known Status*†	
	Pos	Neg
Pos	64	9
Neg	60	550
Totals	124	559

Competitor A Sensitivity = 44%; specificity = 99%		
	Known Status*†	
	Pos	Neg
Pos	55	3
Neg	69	556
Totals	124	559

Study Details—Serum

IDEXX <i>M. pt.</i> Antibody Test Kit Sensitivity = 68%; specificity = 99%		
	Known Status*†	
	Pos	Neg
Pos	84	8
Neg	39	693
Totals	123	701

Competitor A Sensitivity = 67%; specificity = 99%		
	Known Status*†	
	Pos	Neg
Pos	83	9
Neg	40	692
Totals	123	701

- The IDEXX test has a better sensitivity in milk samples as compared to competitor A.

Test With Confidence™



New IDEXX *M.pt.* Antibody Test Kit

Milk Performance Study at an Independent Laboratory

MILK - Independent Study		Fecal Culture		
		Pos	Neg	Totals
IDEXX	Pos	15	0	15
ELISA	Neg	16	102	118
	Totals	31	102	133
95% Confidence Limits				
Low CL High CL				
Sensitivity	48.4 %	32.0	65.1	
Specificity	100.0 %	95.5	100.7	

The IDEXX test has a better sensitivity in milk samples as compared to competitor A.

MILK - Independent Study		Fecal Culture		
		Pos	Neg	Totals
Competitor A	Pos	13	0	13
ELISA	Neg	18	102	120
	Totals	31	102	133
95% Confidence Limits				
Low CL High CL				
Sensitivity	41.9 %	26.5	59.3	
Specificity	100.0 %	95.5	100.7	

Test With Confidence™



New IDEXX *M.pt.* Antibody Test Kit IDEXX *M.pt.* Kit Features and Benefits

- New milk and plasma claims, in addition to serum claim using proven Insitut Pourquier technology
- Excellent specificity and sensitivity; outperforms other ELISA tests on sensitivity in milk
- Consistent lot-to-lot performance
- Familiar ELISA format; no retraining needed
- Suitable for manual, semi-automated or fully automated work flows
- Use with xChek® software for rapid result interpretation. Results in < 2 hrs.
- Reliable and steady supply from IDEXX



Test With Confidence™

IDEXX

Questions?

Please contact Lisa Lemieux at IDEXX for further information:

**Lisa Lemieux
Livestock Sales Manager, North America
IDEXX Laboratories, Inc.
Direct Tel: 207-556-4376
Email: Lisa-Lemieux@idexx.com**

Thank you!