



Mycobacterium avium spp paratuberculosis Antibody Test Kit, ELISA
Bovichek® M. avium spp paratuberculosis (Johne's)

The test is using an original antigen providing great specificity and sensitivity

Paratuberculosis (Johne's disease) is a contagious disease caused by *Mycobacterium avium ssp paratuberculosis* (Map). Although this mycobacteria has been identified in several species (eg hare, crow, etc.) and even humans, the disease is affecting mainly wild and domestic ruminants. Paratuberculosis is a long lasting disease characterized by a progressive inflammation of the small intestine resulting in chronic diarrhea, slow wasting, reduction of fertility and milk production.

The diagnosis of Map infections is based on the detection of Map by culture or PCR and/or the demonstration of a humoral or a cellular immunological response. The most popular immunological assays consist in detecting anti-Map antibodies in the blood or milk. Among the assays the most sensitive are ELISA. Most commercial ELISA use as antigen aqueous extract of Map. They also include an absorption step of the samples using an environmental mycobacteria, *Mycobacterium phlei* in order to remove cross-reacting non-specific antibodies.

The diagnostic sensitivity of the Map ELISA greatly varies depending on the stage of the disease. In the early stages the test sensitivity is very low (eg <30%). While the disease is progressing the test sensitivity also increases and may reach up to 80%. In the final stage of the disease some animals have no more detectable antibodies (anergy phase).

Recently Biovet has developed an ELISA based on a Map antigen (ethanol extract) and an absorbant (proprietary environmental *Mycobacterium*) different from those used in other assays. The combination of these components provide original properties to the test. Moreover the use of antigen-coated and uncoated wells (two-well test) also contributes to the test specificity.

Serum samples from 350 and 150 cattle expected to be free or infected with Map were examined with the Biovet ELISA test, and two commercial tests approved for use in the USA and Canada. Results are presented in table 1. They suggest that the Biovet assay has diagnostic sensitivity and specificity similar to those of the two other commercial kits. Interestingly some samples from infected cattle were positive in only one of the tests.

Major advantages

• Excellent sensitivity	sensitivity = 86.67%
• High specificity	specificity = 98.86%
• High throughput	up to 92 samples/plate
• Convenient	12 strips of 8 wells by plate
• Very fast	results in less than two hours
• Similar if not better	analytical sensitivity than another commercial kit

Bovichek® *M. avium* spp *paratuberculosis* (Johne's)

Results of testing serum samples with the Bovichek *Map* ELISA kit and two commercial *Map* ELISA kits

	Samples from expected <i>Map</i> free animals (n = 350)	Test specificity	Samples from confirmed <i>Map</i> infected animals (n =150)	Test sensitivity
Biovet positive	4	98.86%	130	86.67%
Test A positive	5	98.57%	132	88.00%
Test B positive	3	99.14%	128	85.33%

Materials provided with the kit

Components	Quantity
• Strips of 8 wells coated with <i>Map</i> antigen	12
• Strips of 8 wells without <i>Map</i> antigen used as control	12
• Positive control serum	200 µL
• Negative control serum	200 µL
• Ready-to-use sample dilution buffer	40 mL
• Concentrated wash solution (10X)	2 X 125 mL
• Concentrated conjugate	125 µL
• Ready-to-use substrate	30 mL
• Ready-to-use stop solution	30 mL

The materials provided are sufficient for testing up to 92 samples.

Materials Required but not Provided

- Purified water
- Adjustable single- and multi-channel micropipettes
- Single use micropipettes tips
- ELISA microplate washer (facultative)
- Test tubes for sample dilution
- ELISA 96-well microplate reader equipped with 450 nm filter
- Containers for preparation of solutions

REFERENCES

1. **Anonymous.** Paratuberculosis (Johne's disease). OIE Terrestrial Manual 2014. Chapter 2.1.11.
2. **Collins MT.** Diagnosis of paratuberculosis. Vet Clin North Am Food Anim Pract. 2011;27(3):581-91
3. **Collins MT, Gardner IA, Garry FB, Roussel AJ, Wells SJ.** Consensus recommendations on diagnostic testing for the detection of paratuberculosis in cattle in the United States. J Am Vet Med Assoc. 2006; 229(12):1912-9.
4. **Nielsen SS, Toft N.** Ante mortem diagnosis of paratuberculosis: a review of accuracies of ELISA, interferon-gamma assay and faecal culture techniques. Vet Microbiol. 2008; 129(3-4):217-35.
5. **Scott MC, Bannantine JP, Kaneko Y, Branscum AJ, Whitlock RH, Mori Y, Speer CA, Eda S.** Absorbed EVELISA: a diagnostic test with improved specificity for Johne's disease in cattle. Foodborne Pathog Dis. 2010; 7(11):1291-6
6. **Speer CA, Scott MC, Bannantine JP, Waters WR, Mori Y, Whitlock RH, Eda S.** A novel enzyme-linked immunosorbent assay for diagnosis of *Mycobacterium avium* subsp. *paratuberculosis* infections (Johne's Disease) in cattle. Clin Vaccine Immunol. 2006; 13(5):535
7. **Wadhwa A, Bannantine JP, Byrem TM, Stein TL, Saxton AM, Speer CA, Eda S.** Optimization of serum EVELISA for milk testing of Johne's disease. Foodborne Pathog Dis. 2012 Aug;9(8):749-54.

IMPORTANT:

- Requires a permit to release veterinary biologics from CFIA in Canada. This product is not licensed by CFIA and any claims made have not been substantiated by CFIA.
- Requires a Research and Evaluation import permit from the USDA in the US. This product is not licensed by the USDA and any claims made have not been substantiated by the USDA.

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