



## Technology CTC 18: Bovine TB Test Kit

### Market need

Bovine Tuberculosis (BTB) is a disease which exists, in many countries, at epidemic proportions, and, even in developed countries, causes not only significant financial losses, but also impact to both animal and human populations. To clarify the magnitude of the economic problem, the affected countries, experience losses in meat production (36%), calving (12%), milk production (10%) and an increase in reproductive problems (6-10%). Also, this disease has a strong social impact because of Human Transmission (*zoonosis*). Data extracted from the World Health Organization indicated that 2,000,000,000 people are infected with tuberculosis and 900,000 people contract TB through BTB each year. Thus, the control of BTB is a government concern.

The goal is herd certification free of BTB. The current procedure to certify herds takes 2 months minimum, meanwhile the disease continues spreading, the production of milk and meat goes down and the farmer continues paying for cattle feed. Also, the government restricts meat and milk exports, there is a reduction in production of those products, causing significant impact in the supply for national and international markets. The farmers are exposed for longer period of time to the disease, and infected herds still disseminate it.

The technology was invented because of the need for a fast, specific and sensitive test specific for the pathogen of tuberculosis.

### Benefits

The most important benefit of this technology is the ability to screen in hours for the specific pathogenic BTB instead of months for the standard BTB tests available. The standard method for detection of bovine tuberculosis currently takes 2 months, after detection of positive “suspicious” cattle, which are sent directly to the slaughterhouse to confirm the presence of the pathogen through infected lesion analysis. The real time-based PCR test, BoviMan®, takes only three (3) hours, to confirm the identification of BTB positive cattle, while providing a 87% sensitivity and 97% specificity<sup>1</sup> of quality confirmation results, compared with 100% in both aspects provided by the standard method. This dramatically reduced time frame has significant economic benefits for the farmer and allows public health authorities to act in a timely manner to reduce the spread of the disease.

The cost/benefit to tackle BTB, is more convenient with BoviMan® as a faster and confirmatory procedure to initiate opportune sanitary actions for prevalence reduction and disease control. Culture is more expensive, takes too long to process, and confirmation of the identity of the bacterial growth is still required.

This technology has the potential to make a significant contribution to worldwide BTB eradication, improving both bovine economics and human health.

### Technology description

This technology consists of a diagnostic procedure for the specific identification of *Mycobacterium Bovis*, the pathogen of bovine tuberculosis. The kit consists of a mixture of primers and a probe to amplify a segment of *M Bovis* genome, contained in DNA samples extracted from tuberculosis lesions. BoviMan® confirms the presence of the BTB with 87% sensitivity and 97% specificity, while taking only 3 hours to

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Specificity indicates the proportion of negatives which are correctly identified, whereas sensitivity indicates the proportion of positives correctly identified. Currently, the inventor is able to use only half of the lesion for her testing procedure, as the other part is used for the Gold Standard procedure. Using the whole lesion, the sensitivity and specificity are expected to increase. The exact % will be determined in December 2009, when the results from all samples which have been collected by the SAG between January and September 2009 will be received by the inventor, including the comparison with the Gold Standard, which today requires two months to provide conclusive results.



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confirm the pathogen of bovine tuberculosis, compared with culture procedure that takes 2 months. The testing procedure is easy to learn and can be easily adopted by existing labs.

**Development status**

BoviMan® is a Market Ready Proto-type, with samples ready to ship.

The patent, pending in Chile, Argentina, Uruguay, Colombia, Mexico and United States, covers the set of primers, probes and procedures for the specific identification of the pathogen in biological samples. The manufacturing, processing and sourcing requires no additional special considerations, other than international standards procedures. Samples are dry, easy to mail and are non-hazardous to humans and the environment.

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