A Comparison of Proficiency Testing Methods for *Mycobacterium paratuberculosis* Antibody in the USA

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The goal of proficiency testing for antibodies to *Mycobacterium paratuberculosis* (*M. paratb*) is to assure users that laboratories are able to conduct serology testing in a way that provides quality results. Historically in the United States each laboratory evaluated a panel of 25 sera, including some blind duplicates, and was graded based on qualitative (positive/negative) results reported, such that 90% of the samples must be correctly identified to pass the proficiency test. Qualitative scoring may lead to selection of a panel of sera that give extreme values (positive or negative) to avoid challenges of the interpretation around the qualitative cutoff of the test.

The Z-scoring system can be used to score quantitative outcomes, and has the potential to be adapted for use with many laboratory tests. A combination of positive/negative and Z-scoring is now used by the USA for proficiency testing for *M. paratb* ELISA serology. The Z-scoring system uses the median and inter-quartile range values from the participating laboratories. To pass the test, all qualitative scored samples must be correctly identified and no more than 2 Z-scored samples can have a Z-value ≥ 3 or ≤ -3.

This Z-score can then be used to evaluate inter- and intra-laboratory variation in ELISA readings. Graphical representation of summed Z-scores may assist labs in identifying and resolving laboratory errors. The combination of scoring methods should provide more confidence in the quality of *M. paratb* antibody results in the USA and enhance the value of proficiency testing.

In 2005, Z- scoring was implemented in the USA for ELISA proficiency scoring. Of the 100 labs that submitted results, 57 used the Idexx kit and 43 used the Biocor kit. One of the laboratories using Idexx kits failed, while 5 laboratories using Biocor kits failed. If only a qualitative grading scheme was used, four labs that used Idexx kits and 3 labs that used Biocor kits would have failed the proficiency test.