Field and interlaboratory evaluation of four commercial ELISA kits for *M. avium* subsp. *paratuberculosis* antibody detection in bovine serum

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Detection of antibodies by ELISA is an important tool for Johne’s disease control. The goal of this work was to evaluate four commercial ELISA tests. We determined diagnostic sensitivity and specificity on field samples and the robustness of the kits in an interlaboratory trial. To assess diagnostic sensitivity and specificity, 92 sera from fecal culture positive animals at different level of excretion and 32 from negative herds were analysed in one laboratory. All the kits demonstrated a specificity of 100.0%. Merging inconclusive and positive results, test sensitivity was 71.7% for kit A and B and 67.4 for kit C and D. Among infected animals, ELISA sensitivity did not varied significantly with Map excretion levels with all the kit used. For the interlaboratory trial, 30 coded samples composed by eight replicates of one negative sample and two replicates of 11 positive samples were selected and delivered with the kits to 10 laboratories throughout Italy. All the participants tested each sample in duplicates. Decoded results were analysed for reproducibility within and among laboratories and quantitative results were transformed into S/P values to compare analytical results. Kit A gave 100% of the expected results and Kit B gave almost the same outcome: just one laboratory obtained one inconclusive and one negative result in one replicate. Kit C gave the expected results for 9/11 positive samples and Kit D for 5/11 positive samples. Variations among replicates and laboratories were obtained with the remaining positive samples for these two kits. Regarding the replicates on negative sample, 5 incorrect results distributed in three laboratories for kit C and one doubtful replicate in one laboratory for kit D were detected. According to these results, two (A and B) of the four ELISA kits evaluated showed good performances and reproducibility within and among laboratories.