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Field trial of RAPID™ and RAPID™ 2.0 canine heartworm antigen test Kits.

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The primary objective of this study was to check the accuracy, repeatability, reproducibility and precision and to confirm the sensitivity and specificity of a new generation of canine heartworm antigen test kits produced by biotechnology (RAPID™ and RAPID™ 2.0) in a multicentric field study. The RAPID™ test requires only 1 drop of sample followed by 4 drops of assay diluent into the sample well. The RAPID™ 2.0 test requires only 2 drops of sample into the sample well (no assay diluent is needed). The results are read after about 5 minutes for both tests.

Twenty sera were used: The negative group included 5 sera and the positive group included 15 sera. All positive sera were obtained from dogs with confirmed presence of heartworms at necropsy. All negative sera were confirmed by the use of a US Licensed Heartworm Antigen Test Kit. Samples were randomized and the investigators were blinded during the study.

Lot to lot repeatability effect was assessed by using two different lots of product at each study location. Intra-laboratory precision was assessed by performing the test on the same lot at two different days at two locations. The inter-laboratory precision was assessed by comparing the results from all study locations. Observed differences would be analyzed by ANOVA ($p \leq 0.05$).

Both RAPID™ and RAPID™ 2.0 gave the same results. Both the sensitivity and specificity were found to be 100% in both lots of products tested, at each location and at each study day. No lot to lot repeatability effect, Intra-laboratory precision (day effect) and Inter-laboratory precision (lab effect) were found during this study.

Conclusion: The new generation of canine heartworm antigen test kits, RAPID™ and RAPID™ 2.0, appear to be highly sensitive and specific with proven performance under field conditions of use.