Estimation of sensitivity, specificity and predictive values of two serologic tests for the detection of antibodies against Actinobacillus pleuropneumoniae serotype 2 in the absence of a reference test (gold standard)

Latent-class models were used to determine the sensitivity, specificity and predictive values of a polyclonal blocking enzyme-linked immunosorbent assay (ELISA) and a modified complement-fixation test (CFT) when there was no reference test. The tests were used for detection of antibodies against Actinobacillus pleuropneumoniae serotype 2 in a survey of respiratory diseases in Danish finishing pigs. The estimates were obtained by maximum-likelihood and also by a Bayesian method (implemented with Gibbs sampling). Possible dependence of diagnostic errors was investigated by comparing models where independence was assumed to models allowing for conditional dependence, given the true disease status. No strong evidence of conditional dependence in either test sensitivity or specificity was found. Assuming independence, maximum-likelihood estimates and 95% confidence intervals of the sensitivity and specificity of the ELISA were 100% and 92.8% (90.1-95.5%) and the corresponding values of the CFT were 90.6% (85.8-95.4%) and 98.6% (98.0-99.3%), respectively. Bayesian estimates and posterior 95% credible intervals of the sensitivity and specificity of the ELISA were 99.7% (98.7-100%) and 92.7% (89.9-95.3%) and of the CFT were 90.6% (86.0-95.3%) and 98.7% (98.0-99.3%). The sensitivity and specificity of a combined test, where the CFT is subsequently applied to the pig sera that test positive in the ELISA, are estimated at 90.2% (85.6-95.0%) and 99.9% (99.8-100%), respectively. The cost of the combined test was less than the cost of the use of the CFT alone, at prevalences <54%. Prevalences and predictive values, and their 95% limits were estimated in six sub-samples of data. The estimates of sensitivity and specificity obtained in the present investigation generally validate those reported from other sources.