Validation of several commercial tests for detecting bovine leukemia virus (BLV) infection under Chilean conditions without gold standard

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In Chile, there is a high proportion of BLV infected farms and the within-herd prevalence is approximately from 40 to 50%. For planning a sustainable and effective control strategy quantitative epidemiological information is needed for the Chilean dairy production systems, which is currently insufficient.

The aim of this study was to assess diagnostic performance, without gold standard, of the main commercial tests available in Chile and a PCR protocol, applied on individuals.

During 2007, 274 randomly selected samples from 72 herds were tested by PCR, Agar gel immunodiffusion (AGID-Bommelli), two serum ELISA - one indirect (CHEKIT-Leucose-Serum ® IDEXX-BOMMELI) and one blocking (INGEZIM BLV) - and one milk ELISA (CHEKIT Leukotest ® IDEXX-POURQUIER). ELISA cut-off points were estimated according to manufacturer's instructions and results were expressed as positive, negative or doubtful. DNA was obtained from frozen blood and primers corresponding to the *env* region were selected. Known positive and negative control DNA samples were included in each test run and samples showing a band migrating at 444 base pairs were considered as positive.

Diagnostic performance was estimated by Bayesian inference considering no-gold standard. The unknown infection status (D) can be introduced in the model as a latent variable. This latent class model comprises a mixture of separate multinomial distributions for truly positive (D = 1) and negative (D = 0) animals. Joint probabilities for combinations of test results for D = 0 and D = 1 were expressed analogous to log-linear and multi-logistic models and were assumed to be the same across herds. Consequently, Sensitivity (Se) and Specificity (SP) were assumed constant across herds. Conditional dependence was represented by additional interaction terms between tests.

The results are presented in the following table:

	TEST				
	PCR	INGEZIM BLV	AGID	Pourquier	Bommeli
Sensitivity	0.80	1.00	1.00	0.90	1.00
	(0.73;0.86)	(0.98;1.00)	(0.99;1.00)	(0.84;0.94)	(0.99;1.00)
Specificity	0.64	1.00	0.75	0.92	0.92
	(0.54;0.73)	(0.99;1.00)	(0.66;0.83)	(0.86;0.97)	(0.85;0.96)

The confidence intervals for the interaction parameters for dependence (not shown), both for the gamma priors (non-negative dependence) and normal priors (negative or positive dependence), are fairly wide, indicating that the data do not offer a great deal of information with respect to conditional dependence between tests. Estimated SE's of the serum ELISA tests are higher than AGID. However, specificity AGID performed worse than expected and it was below to any ELISA test. PCR performed poorly with respect to SE and SP (74.0 and 64.0 respectively) compared with the other tests.

In conclusion, some ELISA tests have comparable SE and SP to the official test AGID, INGEZIM BLV could be preferred for routine screening of infected animals due to the operational advantages and performance. However, milk test performed acceptable well too. Therefore, they should be incorporated as an alternative test in monitoring and control programs in Chile.